

**PB 22 of 2021**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021   
(No. 3)**

*National Health Act 1953*

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I, THEA CONNOLLY, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health, 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 31 March 2021

**THEA CONNOLLY**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Department of Health

1. **Name of Instrument**
2. This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021 (No. 3)*.
3. This Instrument may also be cited as PB 22 of 2021.
4. **Commencement**

This Instrument commences on 1 April 2021.

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

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

1. Subsection 10A(3)
   1. omit: **1 April 2021** substitute: **1 January 2022**
2. 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 C9717 C9798 C11509 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11591 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11591 | P9715 P11509 P11531 P11555 P11571 P11576 P11577 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11591 | P9717 P11518 P11547 P11548 P11591 | 2 | 5 | 2 |  |  |
|  | Injection 20 mg in 0.4 mL pre-filled syringe | Injection |  | Amgevita | AN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | C(100) |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11516 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11579 C11591 | P9798 | 2 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11516 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11579 C11591 | P9715 P11509 P11531 P11555 P11571 P11576 P11577 | 2 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11516 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11579 C11591 | P9717 P11516 P11518 P11547 P11548 P11579 P11591 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 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) |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11518 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11587 P11591 P11593 P11594 P11602 P11603 P11609 P11618 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6946 | 4 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6946 | 4 | 2 | 4 |  |  |
|  |  |  |  |  | VE | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P11534 P11624 | 4 | 5 | 2 |  |  |
|  |  |  |  |  | VE | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P11534 P11624 | 4 | 5 | 4 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 6 |  |  |
|  | 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) |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11518 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11587 P11591 P11593 P11594 P11602 P11603 P11609 P11618 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 6 |  |  |
|  | Injection 40 mg in 0.8 mL pre-filled pen | Injection |  | Amgevita | AN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Hadlima | OQ | 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 | AN | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6946 | 4 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11529 P11534 P11624 | 4 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hadlima | OQ | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6946 | 4 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11529 P11534 P11624 | 4 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6946 | 4 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11529 P11534 P11624 | 4 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6946 | 4 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P11529 P11534 P11624 | 4 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11529 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11624 C11631 C11634 C11635 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  | Injection 40 mg in 0.8 mL pre-filled syringe | Injection |  | Amgevita | AN | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  | Hadlima | OQ | 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 | AN | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hadlima | OQ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  | OQ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  | OQ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  | OQ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  | OQ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  | OQ | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  | OQ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  | Hyrimoz | SZ | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  | Idacio | PK | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11516 P11518 P11523 P11524 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11579 P11587 P11591 P11593 P11594 P11602 P11603 P11604 P11605 P11606 P11609 P11618 P11631 P11634 P11635 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C11526 |  | 2 | 5 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11516 C11518 C11523 C11524 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11579 C11587 C11591 C11593 C11594 C11602 C11603 C11604 C11605 C11606 C11609 C11618 C11631 C11634 C11635 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  | Injection 80 mg in 0.8 mL pre-filled pen | Injection |  | Humira | VE | MP | C6946 C6963 C10838 C10892 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P11089 P11096 P11113 P11122 P11138 P11154 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6946 C6963 C10838 C10892 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P6946 | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C6946 C6963 C10838 C10892 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P10838 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6946 C6963 C10838 C10892 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P6963 P10892 P11558 P11559 P11595 P11613 P11615 P11622 P11623 P11636 P11638 P11640 P11641 | 3 | 0 | 1 |  |  |
|  | Injection 80 mg in 0.8 mL pre-filled syringe | Injection |  | Humira | VE | MP | C6946 C10838 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P11089 P11096 P11113 P11122 P11138 P11154 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6946 C10838 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P6946 | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C6946 C10838 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P10838 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6946 C10838 C11089 C11096 C11113 C11122 C11138 C11154 C11558 C11559 C11595 C11613 C11615 C11622 C11623 C11636 C11638 C11640 C11641 | P11558 P11559 P11595 P11613 P11615 P11622 P11623 P11636 P11638 P11640 P11641 | 3 | 0 | 1 |  |  |

1. Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan in each of the forms: Sachets containing oral powder 24 g, 30 (GA gel); and Sachets containing oral powder 25 g, 30 (GA express 15)
   1. insert in numerical order in the column headed “Circumstances”: C11482
2. Schedule 1, Part 1, entry for Apomorphine in the form Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Apomorphine | Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL | Injection |  | Movapo | TD | MP NP | C10844 |  | 360 | 5 | 5 |  |  |
|  |  |  |  | MP | C11385 C11445 |  | 360 | 5 | 5 |  | C(100) |

1. Schedule 1, Part 1, entry for Apomorphine in the form Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL | Injection |  | Movapo | TD | MP NP | C10844 |  | 180 | 5 | 5 |  |  |
|  |  |  |  |  | MP | C11385 C11445 |  | 180 | 5 | 5 |  | C(100) |

1. Schedule 1, Part 1, entry for Apomorphine in the form Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe | Injection |  | Movapo PFS | TD | MP NP | C10844 |  | 180 | 5 | 5 |  |  |
|  |  |  |  |  | MP | C11385 C11445 |  | 180 | 5 | 5 |  | C(100) |

1. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 3]*
2. *omit from the column headed “Circumstances”:* **C8680**
3. *omit from the column headed “Circumstances”:* **C8727**
4. *insert in numerical order in the column headed “Circumstances”:* **C11488**
5. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
6. *omit from the column headed “Circumstances”:* **C8680**
7. *omit from the column headed “Circumstances”:* **C8727**
8. *insert in numerical order in the column headed “Circumstances”:* **C11488**
9. *omit from the column headed “Purposes”:* **P8680**
10. *omit from the column headed “Purposes”:* **P8727**
11. *insert in numerical order in the column headed “Purposes”:* **P11488**
12. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 4 mg *[Maximum Quantity: 28; Number of Repeats: 3]*
13. *omit from the column headed “Circumstances”:* **C8680**
14. *omit from the column headed “Circumstances”:* **C8727**
15. *insert in numerical order in the column headed “Circumstances”:* **C11488**
16. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 4 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
17. *omit from the column headed “Circumstances”:* **C8680**
18. *omit from the column headed “Circumstances”:* **C8727**
19. *insert in numerical order in the column headed “Circumstances”:* **C11488**
20. *omit from the column headed “Purposes”:* **P8680**
21. *omit from the column headed “Purposes”:* **P8727**
22. *insert in numerical order in the column headed “Purposes”:* **P11488**
23. Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 25 mg *[Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C6151 C10748 C10752 C10755 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |

1. Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 25 mg *[Maximum Quantity: 4; Number of Repeats: 2]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C6151 C10748 C10752 C10755 | P6151 | 4 | 2 | 2 |  |  |

1. Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 30 mg *[Maximum Quantity: 2; Number of Repeats: 0]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C6151 C10748 C10752 C10755 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |

1. Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 30 mg *[Maximum Quantity: 4; Number of Repeats: 2]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C6151 C10748 C10752 C10755 | P6151 | 4 | 2 | 2 |  |  |

1. Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 40 mg *[Maximum Quantity: 2; Number of Repeats: 0]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C6151 C10748 C10752 C10755 | P10748 P10752 P10755 | 2 | 0 | 2 |  |  |

1. Schedule 1, Part 1, entry for Buprenorphine in the form Transdermal patch 40 mg *[Maximum Quantity: 4; Number of Repeats: 2]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Buprenorphine Sandoz | SZ | MP NP | C6151 C10748 C10752 C10755 | P6151 | 4 | 2 | 2 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Cabazitaxel Juno | JU | MP | C4662 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Captopril in each of the forms: Tablet 25 mg; and Tablet 50 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Zedace | AF | MP NP |  |  | 90 | 5 | 90 |  |  |

1. Schedule 1, Part 1, entry for Cefuroxime
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL | Oral |  | Zinnat | AS | PDP |  |  | 1 | 0 | 1 |  |  |
|  |  |  |  |  | MP |  |  | 1 | 1 | 1 |  |  |

1. Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2;   
   Number of Repeats: 0]*
2. *omit from the column headed “Circumstances”:* **C10468**
3. *omit from the column headed “Circumstances”:* **C10507**
4. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
5. Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2;   
   Number of Repeats: 2]*
6. *omit from the column headed “Circumstances”:* **C10468**
7. *omit from the column headed “Circumstances”:* **C10507**
8. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
9. Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2;   
   Number of Repeats: 5]*
10. *omit from the column headed “Circumstances”:* **C10468**
11. *omit from the column headed “Circumstances”:* **C10507**
12. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
13. Schedule 1, Part 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 6;   
    Number of Repeats: 0]*
14. *omit from the column headed “Circumstances”:* **C10468**
15. *omit from the column headed “Circumstances”:* **C10507**
16. *insert in numerical order in the column headed “Circumstances”:***C11386 C11430**
17. *omit from the column headed “Purposes”:* **P10468 P10507**
18. *insert in numerical order in the column headed “Purposes”:* **P11386 P11430**
19. Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2;   
    Number of Repeats: 0]*
20. *omit from the column headed “Circumstances”:* **C10468**
21. *omit from the column headed “Circumstances”:* **C10507**
22. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
23. Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2;   
    Number of Repeats: 2]*
24. *omit from the column headed “Circumstances”:* **C10468**
25. *omit from the column headed “Circumstances”:* **C10507**
26. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
27. Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2;   
    Number of Repeats: 5]*
28. *omit from the column headed “Circumstances”:* **C10468**
29. *omit from the column headed “Circumstances”:* **C10507**
30. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
31. Schedule 1, Part 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 6;   
    Number of Repeats: 0]*
32. *omit from the column headed “Circumstances”:* **C10468**
33. *omit from the column headed “Circumstances”:* **C10507**
34. *insert in numerical order in the column headed “Circumstances”:* **C11386 C11430**
35. *omit from the column headed “Purposes”:* **P10468 P10507**
36. *insert in numerical order in the column headed “Purposes”:* **P11386 P11430**
37. Schedule 1, Part 1, entry for Cinacalcet
    1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cinacalcet | Tablet 30 mg (as hydrochloride) | Oral | a | Cinacalcet Mylan | AF | MP NP | C10068 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Pharmacor Cinacalcet | CR | MP NP | C10068 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Cinacalcet Mylan | AF | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |
|  |  |  | a | Pharmacor Cinacalcet | CR | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |
|  | Tablet 60 mg (as hydrochloride) | Oral | a | Cinacalcet Mylan | AF | MP NP | C10068 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Pharmacor Cinacalcet | CR | MP NP | C10068 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Cinacalcet Mylan | AF | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |
|  |  |  | a | Pharmacor Cinacalcet | CR | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |
|  | Tablet 90 mg (as hydrochloride) | Oral | a | Cinacalcet Mylan | AF | MP NP | C10068 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Pharmacor Cinacalcet | CR | MP NP | C10068 |  | 28 | 5 | 28 |  |  |
|  |  |  | a | Cinacalcet Mylan | AF | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |
|  |  |  | a | Pharmacor Cinacalcet | CR | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |

1. Schedule 1, Part 1, entry for Dupilumab
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dupilumab | Injection 200 mg in 1.14 mL single dose pre-filled syringe | Injection |  | Dupixent | SW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C11374 C11377 C11425 C11443 C11479 C11480 |  | 2 | 5 | 2 |  |  |
|  | Injection 300 mg in 2 mL single dose pre-filled syringe | Injection |  | Dupixent | SW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C11374 C11377 C11425 C11443 C11479 C11480 |  | 2 | 5 | 2 |  |  |

1. Schedule 1, Part 1, entry for Erlotinib in each of the forms: Tablet 25 mg (as hydrochloride); Tablet 100 mg (as hydrochloride); and Tablet 150 mg (as hydrochloride)
2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Erlotinib Sandoz | SZ | MP | C4473 C4600 C7446 |  | 30 | 3 | 30 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Tarceva | RO | MP | C4473 C4600 C7446 |  | 30 | 3 | 30 |  |  |

1. Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Maximum Quantity: 30;   
   Number of Repeats: 1]*
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Esomeprazole | TY | MP | C8774 C8775 C8776 C8780 C8827 C11310 | P8774 P8775 | 30 | 1 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8827 | P8774 P8775 | 30 | 1 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Esopreze | BG | MP | C8774 C8775 C8776 C8780 C8827 C11310 | P8774 P8775 | 30 | 1 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8827 | P8774 P8775 | 30 | 1 | 30 |  |  |

1. Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Maximum Quantity: 30;   
   Number of Repeats: 5]*
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Esomeprazole | TY | MP | C8774 C8775 C8776 C8780 C8827 C11310 | P8776 P8780 P8827 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8827 | P8776 P8780 P8827 | 30 | 5 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Esopreze | BG | MP | C8774 C8775 C8776 C8780 C8827 C11310 | P8776 P8780 P8827 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8827 | P8776 P8780 P8827 | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Maximum Quantity: 60;   
   Number of Repeats: 5]*
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Esomeprazole | TY | MP | C8774 C8775 C8776 C8780 C8827 C11310 | P11310 | 60 | 5 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Esopreze | BG | MP | C8774 C8775 C8776 C8780 C8827 C11310 | P11310 | 60 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Maximum Quantity: 30;   
   Number of Repeats: 1]*
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Esomeprazole | TY | MP | C8777 C8778 C8902 C11370 | P8902 | 30 | 1 | 30 |  |  |
|  |  |  |  |  |  | NP | C8777 C8778 C8902 | P8902 | 30 | 1 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Esopreze | BG | MP | C8777 C8778 C8902 C11370 | P8902 | 30 | 1 | 30 |  |  |
|  |  |  |  |  |  | NP | C8777 C8778 C8902 | P8902 | 30 | 1 | 30 |  |  |

1. Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Maximum Quantity: 30;   
   Number of Repeats: 5]*
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Esomeprazole | TY | MP | C8777 C8778 C8902 C11370 | P8777 P8778 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8777 C8778 C8902 | P8777 P8778 | 30 | 5 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Esopreze | BG | MP | C8777 C8778 C8902 C11370 | P8777 P8778 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8777 C8778 C8902 | P8777 P8778 | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Maximum Quantity: 60;   
   Number of Repeats: 5]*
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Esomeprazole | TY | MP | C8777 C8778 C8902 C11370 | P11370 | 60 | 5 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Esopreze | BG | MP | C8777 C8778 C8902 C11370 | P11370 | 60 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Fluticasone propionate
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fluticasone propionate | Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) | Inhalation by mouth | a | Axotide Junior | GC | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  | a | Flixotide Junior | GK | MP NP |  |  | 1 | 5 | 1 |  |  |
|  | Pressurised inhalation containing fluticasone propionate 125 micrograms per dose, 120 doses (CFC-free formulation) | Inhalation by mouth | a | Axotide | GC | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  | a | Flixotide | GK | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  | a | Fluticasone Cipla Inhaler | LR | MP NP |  |  | 1 | 5 | 1 |  |  |
|  | Pressurised inhalation containing fluticasone propionate 250 micrograms per dose, 120 doses (CFC-free formulation) | Inhalation by mouth | a | Axotide | GC | MP NP |  |  | 1 | 1 | 1 |  |  |
|  |  | a | Flixotide | GK | MP NP |  |  | 1 | 1 | 1 |  |  |
|  |  | a | Fluticasone Cipla Inhaler | LR | MP NP |  |  | 1 | 1 | 1 |  |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses | Inhalation by mouth | a | Axotide Junior Accuhaler | GC | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  | a | Flixotide Junior Accuhaler | GK | MP NP |  |  | 1 | 5 | 1 |  |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses | Inhalation by mouth | a | Axotide Accuhaler | GC | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  | a | Flixotide Accuhaler | GK | MP NP |  |  | 1 | 5 | 1 |  |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms per dose, 60 doses | Inhalation by mouth |  | Flixotide Accuhaler | GK | MP NP |  |  | 1 | 1 | 1 |  |  |

1. Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Pressurised inhalation containing fluticasone propionate   
   50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | PAVTIDE MDI 50/25 | GC | MP NP | C4930 |  | 1 | 5 | 1 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Seretide MDI 50/25”:* **a**
2. Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses
3. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | PAVTIDE ACCUHALER 100/50 | GC | MP NP | C4930 |  | 1 | 5 | 1 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Seretide Accuhaler 100/50”:* **a**
2. Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses
3. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | PAVTIDE ACCUHALER 250/50 | GC | MP NP | C4930 |  | 1 | 5 | 1 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Seretide Accuhaler 250/50”:* **a**
2. Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses
3. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | PAVTIDE ACCUHALER 500/50 | GC | MP NP | C4930 C10121 |  | 1 | 5 | 1 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Seretide Accuhaler 500/50”:* **a**
2. Schedule 1, Part 1, after entry for Framycetin
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fulvestrant | Injection 250 mg in 5 mL pre-filled syringe | Injection |  | Fulvestrant Sandoz | SZ | MP | C11473 |  | 2 | 5 | 2 |  |  |

1. Schedule 1, Part 1, entry for Gabapentin in each of the forms: Capsule 100 mg; Capsule 300 mg; and Capsule 400 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | APX-Gabapentin | GX | MP NP | C4928 |  | 100 | 5 | 100 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | GANIRELIX SUN | RA | MP | C5046 |  | 10 | 0 | 1 |  | D(100) |
|  |  |  |  |  |  | MP | C5046 |  | 10 | 0 | 5 |  | D(100) |

1. *insert in the column headed “Schedule Equivalent” for the brand “Orgalutran”:* **a**
2. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1;   
   Number of Repeats: 3]*
3. *omit from the column headed “Circumstances”:* **C10435**
4. *omit from the column headed “Circumstances”:* **C10506**
5. *insert in numerical order in the column headed “Circumstances”:* **C11387 C11431**
6. *omit from the column headed “Purposes”:* **P10435**
7. *omit from the column headed “Purposes”:* **P10506**
8. *insert in numerical order in the column headed “Purposes”:* **P11387 P11431**
9. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1;   
   Number of Repeats: 5]*
10. *omit from the column headed “Circumstances”:* **C10435**
11. *omit from the column headed “Circumstances”:* **C10506**
12. *insert in numerical order in the column headed “Circumstances”:* **C11387 C11431**
13. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1;   
    Number of Repeats: 3]*
14. *omit from the column headed “Circumstances”:* **C10435**
15. *omit from the column headed “Circumstances”:* **C10506**
16. *insert in numerical order in the column headed “Circumstances”:* **C11387 C11431**
17. *omit from the column headed “Purposes”:* **P10435**
18. *omit from the column headed “Purposes”:* **P10506**
19. *insert in numerical order in the column headed “Purposes”:* **P11387 P11431**
20. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1;   
    Number of Repeats: 5]*
21. *omit from the column headed “Circumstances”:* **C10435**
22. *omit from the column headed “Circumstances”:* **C10506**
23. *insert in numerical order in the column headed “Circumstances”:* **C11387 C11431**
24. Schedule 1, Part 1, after entry for Indacaterol with glycopyrronium
    1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Indacaterol with glycopyrronium and mometasone | Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 68 micrograms (for use in Breezhaler) | Inhalation by mouth |  | Enerzair Breezhaler | NV | MP NP | C11470 |  | 30 | 5 | 30 |  |  |
|  | Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 136 micrograms (for use in Breezhaler) | Inhalation by mouth |  | Enerzair Breezhaler | NV | MP NP | C11470 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Ipilimumab in the form Injection concentrate for I.V. infusion 50 mg in 10 mL
   1. insert in numerical order in the column headed “Circumstances”: C11391 C11394 C11478
2. Schedule 1, Part 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Irinotecan Accord | OC | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, omit entry for Nadroparin
2. Schedule 1, Part 1, entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nepiten | AF | MP NP | C5324 |  | 56 | 5 | 28 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nepiten | AF | MP NP | C5324 |  | 28 | 5 | 28 |  |  |

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”:* **C10117**
3. *omit from the column headed “Circumstances”:* **C10165**
4. *insert in numerical order in the column headed “Circumstances”:* **C11392 C11434 C11468 C11469 C11477**
5. Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg *[Maximum Quantity: 30; Number of Repeats: 1]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Maxor EC Tabs | AF | MP | C8774 C8775 C8776 C8780 C8866 C11310 | P8774 P8775 | 30 | 1 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8866 | P8774 P8775 | 30 | 1 | 30 |  |  |

1. Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Maxor EC Tabs | AF | MP | C8774 C8775 C8776 C8780 C8866 C11310 | P8776 P8780 P8866 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8866 | P8776 P8780 P8866 | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Omeprazole in the form Tablet 20 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Maxor EC Tabs | AF | MP | C8774 C8775 C8776 C8780 C8866 C11310 | P11310 | 60 | 5 | 30 |  |  |

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

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

1. Schedule 1, Part 1, entry for Paracetamol
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Suppositories 500 mg, 24 | Rectal |  | Panadol | GC | MP NP | C6167 |  | 4 | 3 | 1 |  |  |

1. Schedule 1, Part 1, entry for Phenobarbital in the form Injection 200 mg (as sodium) in 1 mL
   1. omit from the column headed “Brand”: Fawns and McAllan Proprietary Limited substitute: Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd)
2. Schedule 1, Part 1, entry for Posaconazole
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Posaconazole ARX | XT | MP NP | C5169 C5395 C5396 |  | 24 | 0 | 24 |  |  |

1. Schedule 1, Part 1, entry for Ribociclib in the form Tablet 200 mg *[Maximum Quantity: 21; Number of Repeats: 5]*
2. *omit from the column headed “Circumstances”:* **C10018 C10037 C10038 C10044 C10054 C10057** *substitute:* **C11458 C11459 C11471 C11498 C11499 C11500 C11506 C11507 C11508**
3. *omit from the column headed “Purposes”:* **P10037 P10038** *substitute:* **P11471 P11498 P11506**
4. Schedule 1, Part 1, entry for Ribociclib in the form Tablet 200 mg *[Maximum Quantity: 42; Number of Repeats: 5]*
5. *omit from the column headed “Circumstances”:* **C10018 C10037 C10038 C10044 C10054 C10057** *substitute:* **C11458 C11459 C11471 C11498 C11499 C11500 C11506 C11507 C11508**
6. *omit from the column headed “Purposes”:* **P10044 P10054** *substitute:* **P11459 P11500 P11508**
7. Schedule 1, Part 1, entry for Ribociclib in the form Tablet 200 mg *[Maximum Quantity: 63; Number of Repeats: 5]*
8. *omit from the column headed “Circumstances”:* **C10018 C10037 C10038 C10044 C10054 C10057** *substitute:* **C11458 C11459 C11471 C11498 C11499 C11500 C11506 C11507 C11508**
9. *omit from the column headed “Purposes”:* **P10018 P10057** *substitute:* **P11458 P11499 P11507**
10. Schedule 1, Part 1, entry for Rituximab in the form Solution for I.V. infusion 100 mg in 10 mL
11. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mabthera | RO | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | PB(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Mabthera | RO | MP | C7399 C7400 C9451 C9542 C10227 |  | See Note 3 | See Note 3 | 2 |  | PB(100) |

1. Schedule 1, Part 1, entry for Rituximab in the form Solution for I.V. infusion 500 mg in 50 mL
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mabthera | RO | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Mabthera | RO | MP | C7399 C7400 C9451 C9542 C10227 |  | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. Schedule 1, Part 1, after entry for Romiplostim in the form Powder for injection 625 micrograms
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Romosozumab | Injection 105 mg in 1.17 mL single use pre-filled syringe | Injection |  | Evenity | AN | MP | C11487 C11496 |  | 2 | 5 | 2 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rosuvastatin Lupin | GQ | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. Schedule 1, Part 1, entry for Secukinumab
   1. 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 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P10489 P11390 | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P9064 P9429 | 1 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P9063 P9105 P9430 P9431 P10431 P11432 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P8831 P9064 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P6696 P8830 P8892 P9063 P9105 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P9069 P9078 P9155 P9414 P9428 P9503 | 4 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P11389 P11447 P11502 | 5 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C6696 C8830 C8831 C8892 C9063 C9064 C9069 C9078 C9105 C9155 C9414 C9428 C9429 C9430 C9431 C9503 C10431 C10489 C11089 C11096 C11113 C11122 C11138 C11154 C11389 C11390 C11432 C11447 C11502 | P9069 P9078 P9155 P11089 P11096 P11113 P11122 P11138 P11154 | 8 | 0 | 2 |  |  |

1. Schedule 1, Part 1, entry for Sertraline in the form Tablet 50 mg (as hydrochloride)
   1. omit from the column headed “Schedule Equivalent” (all instances): a
2. Schedule 1, Part 1, after entry for Sertraline in the form Tablet 50 mg (as hydrochloride)
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 50 mg (as hydrochloride) (USP) | Oral |  | Sertraline tablets USP (Medsurge) | DZ | MP NP | C4755 C6277 C6289 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Sertraline in the form Tablet 100 mg (as hydrochloride)
   1. omit from the column headed “Schedule Equivalent” (all instances): a
2. Schedule 1, Part 1, after entry for Sertraline in the form Tablet 100 mg (as hydrochloride)
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 100 mg (as hydrochloride) (USP) | Oral |  | Sertraline tablets USP (Medsurge) | DZ | MP NP | C4755 C6277 C6289 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Somatropin in the form Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Norditropin SimpleXx | NO | MP | C5146 C5147 C5190 C5230 C5239 C5299 C5302 C5382 C8334 C8335 C8336 C8337 C8343 C8347 C8349 C8357 C8358 C8360 C8361 C8362 C8365 C8368 C8369 C8376 C8377 C8380 C8393 C8394 C8398 C8402 C8403 C8407 C8415 C8416 C8417 C8418 C8419 C8420 C8422 C8423 C8424 C8425 C8426 C8433 C9221 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Somatropin in the form Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Norditropin SimpleXx | NO | MP | C5146 C5147 C5190 C5230 C5239 C5299 C5302 C5382 C8334 C8335 C8336 C8337 C8343 C8347 C8349 C8357 C8358 C8360 C8361 C8362 C8365 C8368 C8369 C8376 C8377 C8380 C8393 C8394 C8398 C8402 C8403 C8407 C8415 C8416 C8417 C8418 C8419 C8420 C8422 C8423 C8424 C8425 C8426 C8433 C9221 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Somatropin in the form Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Norditropin SimpleXx | NO | MP | C5146 C5147 C5190 C5230 C5239 C5299 C5302 C5382 C8334 C8335 C8336 C8337 C8343 C8347 C8349 C8357 C8358 C8360 C8361 C8362 C8365 C8368 C8369 C8376 C8377 C8380 C8393 C8394 C8398 C8402 C8403 C8407 C8415 C8416 C8417 C8418 C8419 C8420 C8422 C8423 C8424 C8425 C8426 C8433 C9221 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg *[Maximum Quantity: 60;   
   Number of Repeats: 2]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Tenofovir Sandoz | SZ | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 C10362 | P10362 | 60 | 2 | 30 |  | D(100) |

1. Schedule 1, Part 1, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg *[Maximum Quantity: 60;   
   Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Tenofovir Sandoz | SZ | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 C10362 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 | 30 |  | D(100) |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Terimide | AF | MP | C10150 C10199 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, Part 1, entry for Teriparatide
   1. omit from the column headed “Circumstances”: C4113 C6305 substitute: C11464 C11486
2. Schedule 1, Part 1, entry for Zoledronic acid in the form Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Zoledronic Acid SUN | RA | MP | C5710 C6308 C6313 C6318 |  | 1 | 0 | 1 |  |  |

1. Schedule 1, Part 2, omit entry for Aciclovir
2. Schedule 1, Part 2 after entry for Aciclovir

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 20 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) |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11591 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11591 | P9715 P11509 P11531 P11555 P11571 P11576 P11577 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C9715 C9717 C9798 C11509 C11518 C11531 C11547 C11548 C11555 C11571 C11576 C11577 C11591 | P9717 P11518 P11547 P11548 P11591 | 2 | 5 | 2 |  |  |
|  | Injection 40 mg in 0.8 mL pre-filled pen | Injection |  | Humira | VE | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11518 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11587 P11591 P11593 P11594 P11602 P11603 P11609 P11618 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6946 | 4 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P11534 P11624 | 4 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6946 | 4 | 2 | 4 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P11534 P11624 | 4 | 5 | 4 |  |  |
|  |  |  |  |  |  | MP | C6696 C6946 C6963 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C10892 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11534 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 C11624 | P6963 P9679 P9714 P9715 P10892 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 6 |  |  |
|  | Injection 40 mg in 0.8 mL pre-filled syringe | Injection |  | Humira | VE | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 2 |  | C(100) |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9798 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P8631 P8638 P8678 P8702 P9064 P9069 P9078 P9155 P9386 P9409 P9414 P9428 P9429 P9498 P9503 P9564 | 2 | 3 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P11089 P11096 P11107 P11113 P11122 P11138 P11154 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P6696 P8608 P8627 P9063 P9380 P9431 P9717 P11518 P11538 P11541 P11542 P11545 P11547 P11548 P11551 P11552 P11560 P11569 P11572 P11587 P11591 P11593 P11594 P11602 P11603 P11609 P11618 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C6696 C8608 C8627 C8631 C8638 C8678 C8702 C9063 C9064 C9069 C9078 C9155 C9380 C9386 C9409 C9414 C9428 C9429 C9431 C9498 C9503 C9564 C9679 C9714 C9715 C9717 C9798 C11089 C11096 C11107 C11113 C11122 C11138 C11154 C11509 C11513 C11514 C11518 C11531 C11538 C11541 C11542 C11544 C11545 C11547 C11548 C11550 C11551 C11552 C11555 C11560 C11569 C11571 C11572 C11574 C11576 C11577 C11587 C11591 C11593 C11594 C11602 C11603 C11609 C11618 | P9679 P9714 P9715 P11509 P11513 P11514 P11531 P11544 P11550 P11555 P11571 P11574 P11576 P11577 | 6 | 0 | 6 |  |  |

1. Schedule 1, Part 2, after entry for Minocycline
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nadroparin | Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL pre-filled syringe | Injection |  | Fraxiparine | AS | MP NP |  |  | 20 | 0 | 2 |  |  |
|  |  |  |  |  | MP NP |  | P6014 | 20 | 3 | 2 |  |  |
|  | Injection containing nadroparin calcium (2,850 I.U. anti-Xa) in 0.3 mL pre-filled syringe | Injection |  | Fraxiparine | AS | MP NP |  |  | 20 | 0 | 2 |  |  |
|  |  |  |  |  | MP NP |  | P6014 | 20 | 3 | 2 |  |  |
|  | Injection containing nadroparin calcium (3,800 I.U. anti-Xa) in 0.4 mL pre-filled syringe | Injection |  | Fraxiparine | AS | MP NP |  |  | 20 | 0 | 2 |  |  |
|  |  |  |  |  | MP NP |  | P6014 | 20 | 3 | 2 |  |  |
|  | Injection containing nadroparin calcium (5,700 I.U. anti-Xa) in 0.6 mL pre-filled syringe | Injection |  | Fraxiparine | AS | MP NP |  |  | 20 | 0 | 2 |  |  |
|  |  |  |  |  | MP NP |  | P6014 | 20 | 3 | 2 |  |  |
|  | Injection containing nadroparin calcium (7,600 I.U. anti-Xa) in 0.8 mL pre-filled syringe | Injection |  | Fraxiparine | AS | MP NP |  |  | 10 | 1 | 2 |  |  |
|  |  |  |  |  | MP NP |  | P6014 | 20 | 3 | 2 |  |  |
|  | Injection containing nadroparin calcium (9,500 I.U. anti-Xa) in 1 mL pre-filled syringe | Injection |  | Fraxiparine | AS | MP NP |  |  | 10 | 1 | 2 |  |  |
|  |  |  |  |  | MP NP |  | P6014 | 20 | 3 | 2 |  |  |
|  | Injection containing nadroparin calcium (11,400 I.U. anti-Xa) in 0.6 mL pre-filled syringe | Injection |  | Fraxiparine Forte | AS | MP NP |  |  | 10 | 1 | 2 |  |  |
|  | Injection containing nadroparin calcium (15,200 I.U. anti-Xa) in 0.8 mL pre-filled syringe | Injection |  | Fraxiparine Forte | AS | MP NP |  |  | 10 | 1 | 2 |  |  |
|  | Injection containing nadroparin calcium (19,000 I.U. anti-Xa) in 1 mL pre-filled syringe | Injection |  | Fraxiparine Forte | AS | MP NP |  |  | 10 | 1 | 2 |  |  |

1. Schedule 1, Part 2, after entry for Oxazepam in the form Tablet 30 mg
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Paracetamol | Suppositories 500 mg, 24 | Rectal |  | Panadol | GC | MP NP | C6167 |  | 4 | 3 | 1 |  |  |

1. Schedule 3, details relevant to Responsible Person code FK

*omit from the column headed “Responsible Person”:* A. Menarini Australia Pty Limited *substitute:* A.Menarini Australia Pty Limited

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

*insert:*

|  |  |  |
| --- | --- | --- |
| XT | Arrotex Pharmaceuticals Pty Ltd | 30 605 552 234 |

1. Schedule 4, Part 1, entry for Adalimumab

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Adalimumab | C6696 | P6696 |  | Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot 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; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C6946 | P6946 |  | Moderate to severe hidradenitis suppurativa Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment – balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment. Must be treated by a dermatologist. A maximum of 12 weeks of treatment will be authorised under this restriction. | Compliance with Authority Required procedures |
| C6963 | P6963 |  | Moderate to severe hidradenitis suppurativa Initial treatment 2 - Recommencement of treatment Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND The treatment must be limited to a maximum duration of 16 weeks. Must be treated by a dermatologist. Assessment of disease severity must be no more than 1 month old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include: (i) the Hurley stage grading; and (ii) the AN count. | Compliance with Written Authority Required procedures |
| C8608 | P8608 |  | Complex refractory Fistulising Crohn disease Continuing treatment - balance of supply 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 insufficient therapy with this drug under the 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 restriction. | Compliance with Authority Required procedures |
| C8627 | P8627 |  | Severe active rheumatoid arthritis Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the 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 restriction. | Compliance with Authority Required procedures |
| C8631 | P8631 |  | Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month 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 reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C8638 | P8638 |  | Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 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 24 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 24 months) to complete 16 weeks of 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 |
| C8678 | P8678 |  | Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. | Compliance with Written Authority Required procedures |
| C8702 | P8702 |  | Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: 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; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month 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 reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C9063 | P9063 |  | Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the 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 restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C9064 | P9064 |  | Severe psoriatic arthritis 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 psoriatic arthritis. | Compliance with Authority Required procedures |
| C9069 | P9069 |  | Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month 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 reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9078 | P9078 |  | Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9155 | P9155 |  | Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum 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. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: 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; and either (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 of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An 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 |
| C9380 | P9380 |  | Severe active juvenile idiopathic arthritis Continuing Treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the 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 restriction. | Compliance with Authority Required procedures |
| C9384 | P9384 |  | Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply 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 insufficient therapy with this drug for this condition under the 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 restriction. | Compliance with Authority Required procedures |
| C9386 | P9386 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 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 24 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 24 months) to complete 16 weeks of 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 |
| C9409 | P9409 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 measures of joint count must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| 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 |
| 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 |
| 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 |
| 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 |
| C9431 | P9431 |  | Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the 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 restriction. 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 |
| C9498 | P9498 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| 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 |
| C9564 | P9564 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: 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; AND either (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 joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month 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 reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An 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 |
| C9679 | P9679 |  | Severe Crohn disease Balance of supply 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 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; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. | Compliance with Authority Required procedures |
| C9714 | P9714 |  | Complex refractory Fistulising Crohn disease Initial 1 (new patient or Recommencement of treatment after more than 5 years break in therapy ), Initial 2 (Change or Recommencement of treatment after a break in therapy of less than 5 years) - Balance of supply 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 insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) 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 of less 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. | Compliance with Authority Required procedures |
| C9715 | P9715 |  | Moderate to severe ulcerative colitis 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 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. 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. | Compliance with Authority Required procedures |
| C9717 | P9717 |  | Moderate to severe ulcerative colitis Continuing treatment - balance of supply 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction. | Compliance with Authority Required procedures |
| C9798 | P9798 |  | Severe Crohn disease Balance of supply for paediatric patient 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; OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. | Compliance with Authority Required procedures |
| C10582 | P10582 |  | 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). At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for 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. 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 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 (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C10583 | P10583 |  | 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; or (ii) 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 provided 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. 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 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 authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. 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 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 |
| C10619 | P10619 |  | 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; or (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 measures of joint count must be no more than 4 weeks old at the time of this application. 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. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for 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 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. 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 |
| C10838 | P10838 |  | Moderate to severe hidradenitis suppurativa Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and must be provided no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | Compliance with Written Authority Required procedures |
| C10892 | P10892 |  | Moderate to severe hidradenitis suppurativa Initial treatment 1 - New patient Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND The treatment must be limited to a maximum duration of 16 weeks. Must be treated by a dermatologist. Assessment of disease severity must be no more than 1 month old at the time of application. An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. | Compliance with Written Authority Required procedures |
| C11089 | P11089 |  | Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be 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 are rated as severe or very severe; or (ii) the skin area affected is 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 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11096 | P11096 |  | Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11107 | P11107 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement 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, Whole body (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, Whole body (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, Whole body (recommencement of treatment after a break in biological medicine of more 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 1, Face, hand, foot (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, Face, hand, foot (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, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); 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 dermatologist. | Compliance with Authority Required procedures |
| C11113 | P11113 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed 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: (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) ciclosporin 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11122 | P11122 |  | Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed 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: (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) ciclosporin 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis 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 are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11138 | P11138 |  | Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11154 | P11154 |  | Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11509 | P11509 |  | Severe Crohn disease 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 Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition. The PCDAI assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11513 | P11513 |  | 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 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; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. 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. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. 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. 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 |
| C11514 | P11514 |  | Complex refractory Fistulising Crohn disease Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2) 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 Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy. It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C11516 | P11516 |  | Severe Crohn disease Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of severe Crohn disease; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 40 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. The PCDAI assessment must be no more than 1 month old at the time of application. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. | Compliance with Authority Required procedures - Streamlined Authority Code 11516 |
| C11518 | P11518 |  | Severe Crohn disease Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of severe Crohn disease; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 40 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition. The PCDAI assessment must be no more than 1 month old at the time of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where a response assessment is not provided within this 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. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11520 | P11520 |  | Severe active juvenile idiopathic arthritis First 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). 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 submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 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. 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 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 (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11521 | P11521 |  | Severe active juvenile idiopathic arthritis Subsequent 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). 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 submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 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. 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 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 (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11523 | P11523 |  | Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have 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 per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. 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 11523 |
| C11524 | P11524 |  | Complex refractory Fistulising Crohn disease Subsequent continuing 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 agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. A maximum of 24 weeks treatment will be authorised under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11524 |
| C11526 | P11526 |  | Severe active juvenile idiopathic arthritis Subsequent 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 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 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). 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 submitted with the initial treatment application. 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 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 (once with each agent) 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 11526 |
| C11529 | P11529 |  | Moderate to severe hidradenitis suppurativa 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 a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 11529 |
| C11531 | P11531 |  | Severe Crohn disease Initial treatment - Initial 1 (new patient) Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation of initial treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition. 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au). A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11534 | P11534 |  | Moderate to severe hidradenitis suppurativa Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and must be provided no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | Compliance with Written Authority Required procedures |
| C11538 | P11538 |  | Severe active juvenile idiopathic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11541 | P11541 |  | Severe psoriatic arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received 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. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11542 | P11542 |  | Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received 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. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11544 | P11544 |  | Severe Crohn disease Initial treatment - Initial 1 (new patient) 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 aged 18 years or older. 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 not receive more than 16 weeks of treatment under this restriction; 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. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. 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. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month 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 Department of Human Services 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. 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 |
| C11545 | P11545 |  | 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; 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 |
| C11547 | P11547 |  | Moderate to severe ulcerative colitis First continuing 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. 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. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures |
| C11548 | P11548 |  | Moderate to severe ulcerative colitis Subsequent continuing 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. 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. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures |
| C11550 | P11550 |  | Complex refractory Fistulising Crohn disease Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) 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 confirmed 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 an externally draining enterocutaneous or rectovaginal fistula. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 1 month old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11551 | P11551 |  | Complex refractory Fistulising Crohn disease First continuing 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 previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy. It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. A maximum of 24 weeks treatment will be authorised under this restriction. | Compliance with Written Authority Required procedures |
| C11552 | P11552 |  | Severe chronic plaque psoriasis First continuing treatment, Whole body 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11555 | P11555 |  | Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have a documented history of severe Crohn disease; AND Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation of initial treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment. The PCDAI assessment must be no more than 1 month old at the time of application. 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 an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11558 | P11558 |  | 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 Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the 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; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. 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 for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. 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 |
| C11559 | P11559 |  | Complex refractory Fistulising Crohn disease Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) 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 confirmed 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 an externally draining enterocutaneous or rectovaginal fistula. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 1 month old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11560 | P11560 |  | Severe active juvenile idiopathic arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11569 | P11569 |  | Severe Crohn disease First continuing 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; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test 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; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11571 | P11571 |  | Moderate to severe ulcerative colitis 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. 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 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Patient must be 6 years of age or older. Applications for authorisation must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. 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 evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Department of Human Services website. | Compliance with Written Authority Required procedures |
| C11572 | P11572 |  | Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. 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(s); 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 sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11574 | P11574 |  | 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 Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the 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; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. 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 for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. 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 |
| C11576 | P11576 |  | Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Patient must be 6 years of age or older. Applications for authorisation of change or recommencement treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. 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. Details of the accepted toxicities including severity can be found on the Department of Human Services website. | Compliance with Written Authority Required procedures |
| C11577 | P11577 |  | Moderate to severe ulcerative colitis 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; 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; OR 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 more than once if aged 6 to 17 years. Patient must be 6 years of age or older. Applications for authorisation must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. 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 for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11579 | P11579 |  | Moderate to severe ulcerative colitis Subsequent continuing 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. 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 or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be 6 years of age or older. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised 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. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) 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 11579 |
| C11587 | P11587 |  | 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 |
| C11591 | P11591 |  | Severe Crohn disease First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of severe Crohn disease; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 40 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition. The PCDAI assessment must be no more than 1 month old at the time of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where a response assessment is not provided within this 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. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11593 | P11593 |  | Severe Crohn disease Subsequent continuing 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; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test 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; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11594 | P11594 |  | Complex refractory Fistulising Crohn disease Subsequent continuing 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 previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy. It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. A maximum of 24 weeks treatment will be authorised under this restriction. | Compliance with Written Authority Required procedures |
| C11595 | P11595 |  | Severe Crohn disease Initial treatment - Initial 1 (new patient) Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation of initial treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition. 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au). A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11602 | P11602 |  | Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C11603 | P11603 |  | Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C11604 | P11604 |  | Severe active juvenile idiopathic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have 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 per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The 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. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. | Compliance with Authority Required procedures - Streamlined Authority Code 11604 |
| C11605 | P11605 |  | Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have 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 per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 11605 |
| C11606 | P11606 |  | Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot 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 their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11606 |
| C11609 | P11609 |  | Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. 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(s); 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 sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11613 | P11613 |  | Complex refractory Fistulising Crohn disease Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2) 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 Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy. It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this 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. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C11615 | P11615 |  | Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have a documented history of severe Crohn disease; AND Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation of initial treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment. The PCDAI assessment must be no more than 1 month old at the time of application. 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 an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11618 | P11618 |  | Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11622 | P11622 |  | Severe Crohn disease Initial treatment - Initial 1 (new patient) 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 aged 18 years or older. 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 not receive more than 16 weeks of treatment under this restriction; 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. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. 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. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month 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 Department of Human Services 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. 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 |
| C11623 | P11623 |  | Moderate to severe ulcerative colitis 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; 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; OR 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 more than once if aged 6 to 17 years. Patient must be 6 years of age or older. Applications for authorisation must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. 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 for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11624 | P11624 |  | Moderate to severe hidradenitis suppurativa First continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and must be provided no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | Compliance with Written Authority Required procedures |
| C11631 | P11631 |  | Severe Crohn disease Subsequent continuing 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 previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; 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; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 11631 |
| 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 |
| C11635 | P11635 |  | Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11635 |
| C11636 | P11636 |  | Severe Crohn disease 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 Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist; AND Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition. The PCDAI assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised. A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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. | Compliance with Written Authority Required procedures |
| C11638 | P11638 |  | Moderate to severe ulcerative colitis 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. 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 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Patient must be 6 years of age or older. Applications for authorisation must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. 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 evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Department of Human Services website. | Compliance with Written Authority Required procedures |
| C11640 | P11640 |  | 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 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; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. 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. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. 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. 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 |
| C11641 | P11641 |  | Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) 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)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Patient must be 6 years of age or older. Applications for authorisation of change or recommencement treatment must be in writing and must include: (a) two completed authority prescription forms; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. 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. Details of the accepted toxicities including severity can be found on the Department of Human Services website. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan
   1. insert in numerical order after existing text:

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| --- | --- | --- | --- | --- | --- |
|  | C11482 |  |  | Pyridoxine dependent epilepsy Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy; AND The condition must be treated by or in consultation with a metabolic physician. |  |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C4833 |  |  | Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4833 |
|  | C9561 |  |  | Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 9561 |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C11385 |  |  | Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 11385 |
|  | C11445 |  |  | Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 11445 |

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

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| --- | --- | --- | --- | --- | --- |
|  | C8680 | P8680 |  | Severe active rheumatoid arthritis Continuing and Initial Grandfathered patients treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial treatment - Grandfathered patients; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Patient must be aged 18 years or older. | Compliance with Authority Required procedures |

1. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C8727 | P8727 |  | Severe active rheumatoid arthritis Initial treatment - Grandfathered patients Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2018; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy, and measurement of response to the prior course of non-PBS-subsidised therapy with this drug. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. | Compliance with Written Authority Required procedures |

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

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|  | C11488 | P11488 |  | Severe active rheumatoid arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Patient must be aged 18 years or older. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Certolizumab pegol
2. *omit entry for Circumstances Code “C10458” and substitute:*

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|  | C10458 | P10458 |  | Non-radiographic axial spondyloarthritis Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2020; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had 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 initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The condition must have been diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, prior to having commenced non-PBS-subsidised treatment with this biological medicine; AND The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI) prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent) prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium) prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The treatment must not exceed a maximum of 24 weeks with this drug 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 non-radiographic axial spondyloarthritis. 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) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must have been determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must have been no more than 1 month old at the time of initiating non-PBS subsidised treatment with this biological medicine for this condition. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which seeks details of: (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a BASDAI score and CRP level that substantiates failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised treatment with this biological medicine for this condition; and (iii) the MRI report; and (iv) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |

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|  | C10468 | P10468 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; 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 have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); 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 non-radiographic axial spondyloarthritis. 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 be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of: (i) the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline C-reactive protein (CRP) level; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (v) the MRI report; and (vi) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |

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|  | C10507 | P10507 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in 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 non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. 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. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. | Compliance with Authority Required procedures |

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|  | C11386 | P11386 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; 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 have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); 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 non-radiographic axial spondyloarthritis. 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 be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. The authority application must include: (a) a completed authority prescription; and (b) a completed PBS authority application form relevant to the indication and treatment phase (the latest version located at the website mentioned in the administrative note). The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
|  | C11430 | P11430 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in 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 non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. 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. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Dupilumab
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|  | C11372 |  |  | Chronic severe atopic dermatitis Initial treatment of the face and/or hands The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days; OR The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification, in the authority application. These 4 symptom sub-score ratings must have been assessed within the past 4 weeks. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. | Compliance with Authority Required procedures |

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|  | C11375 |  |  | Chronic severe atopic dermatitis Initial treatment of the whole body Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days; AND Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical corticosteroids of medium to high potency for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the qualifying PGA, EASI and DLQI scores in the authority application. These baseline scores must have been measured within the past 4 weeks. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. | Compliance with Authority Required procedures |

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|  | C11378 |  |  | Chronic severe atopic dermatitis Transitioning from non-PBS to PBS-subsidised supply - treatment of the whole body (Grandfather listing) Patient must have been receiving treatment with this biological medicine for this PBS indication prior to 1 March 2021; AND Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; OR Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this indication, prior to commencing non-PBS-subsidised therapy with this biological medicine. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the qualifying PGA, EASI and DLQI scores in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine must be documented in the patient's medical records. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
|  | C11379 |  |  | Chronic severe atopic dermatitis Transitioning from non-PBS to PBS-subsidised supply - treatment of the face and/or hands (Grandfather listing) Patient must have been receiving treatment with this biological medicine for this PBS indication prior to 1 March 2021; AND The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; OR The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days corticosteroid therapy, prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical corticosteroid therapy of medium to high potency for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; OR Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine; AND The treatment must be the sole PBS-subsidised biological medicine for this condition; AND Patient must not have experienced an inadequate response to this biological medicine in this indication, prior to commencing non-PBS-subsidised therapy with this biological medicine. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification that were present prior to having commenced non-PBS-subsidised therapy, in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |

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|  | C11425 |  |  | Chronic severe atopic dermatitis Transitioning from non-PBS to PBS-subsidised supply - treatment of the whole body (Grandfather listing) Patient must have been receiving treatment with this biological medicine for this PBS indication prior to 1 March 2021; AND Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; OR Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this indication, prior to commencing non-PBS-subsidised therapy with this biological medicine. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the qualifying PGA, EASI and DLQI scores in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine must be documented in the patient's medical records. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
|  | C11443 |  |  | Chronic severe atopic dermatitis Initial treatment of the whole body Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 day; AND Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the qualifying PGA, EASI and DLQI scores in the authority application. These baseline scores must have been measured within the past 4 weeks. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. | Compliance with Authority Required procedures |
|  | C11479 |  |  | Chronic severe atopic dermatitis Transitioning from non-PBS to PBS-subsidised supply - treatment of the face and/or hands (Grandfather listing) Patient must have been receiving treatment with this biological medicine for this PBS indication prior to 1 March 2021; AND The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; OR The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; OR Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine; AND Patient must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine; AND The treatment must be the sole PBS-subsidised biological medicine for this condition; AND Patient must not have experienced an inadequate response to this biological medicine in this indication, prior to commencing non-PBS-subsidised therapy with this biological medicine. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification that were present prior to having commenced non-PBS-subsidised therapy, in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
|  | C11480 |  |  | Chronic severe atopic dermatitis Initial treatment of the face and/or hands The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification, in the authority application. These 4 symptom sub-score ratings must have been assessed within the past 4 weeks. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, after entry for Fotemustine
   1. insert:

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| Fulvestrant | C11473 |  |  | Locally advanced or metastatic breast cancer The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable. Patient must not be premenopausal. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 11473 |

1. Schedule 4, Part 1, entry for Golimumab
2. *omit entry for Circumstances Code “C9770” and substitute:*

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|  | C9770 | P9770 |  | Moderate to severe ulcerative colitis Continuing 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 previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug. Patient must be aged 18 years or older. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. 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 Authority Required procedures |

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|  | C10435 | P10435 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; 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 have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug 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 non-radiographic axial spondyloarthritis. 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 be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of: (i) the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline C-reactive protein (CRP) level; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (v) the MRI report; and (vi) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |

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|  | C10506 | P10506 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break 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 failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug 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 non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. 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. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. | Compliance with Authority Required procedures |

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

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|  | C11387 | P11387 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break 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 failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug 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 non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. 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. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. | Compliance with Authority Required procedures |
|  | C11431 | P11431 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; 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 have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug 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 non-radiographic axial spondyloarthritis. 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 be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. The authority application must include: (a) a completed authority prescription; and (b) a completed PBS authority application form relevant to the indication and treatment phase (the latest version located at the website mentioned in the administrative note). The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, after entry for Indacaterol with glycopyrronium
   1. insert:

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| Indacaterol with glycopyrronium and mometasone | C11470 |  |  | Severe asthma Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented. Patient must be aged 18 years or older. Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist. | Compliance with Authority Required procedures |

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

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|  | C11391 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing combination treatment (with nivolumab) of first-line drug therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with nivolumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11391 |
|  | C11394 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy) Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021; AND The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with nivolumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11394 |
|  | C11478 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial combination treatment (with nivolumab) as first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with nivolumab. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 11478 |

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

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|  | C10117 |  |  | Locally advanced or metastatic non-small cell lung cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have stable or responding disease. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 10117 |

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|  | C10165 |  |  | Locally advanced or metastatic non-small cell lung cancer Initial treatment Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 10165 |

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

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|  | C11392 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial combination treatment (with ipilimumab) as first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11392 |
|  | C11434 |  |  | Locally advanced or metastatic non-small cell lung cancer Initial treatment as second-line drug therapy Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 11434 |
|  | C11468 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing combination treatment (with ipilimumab) of first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11468 |
|  | C11469 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy) Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021; AND The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND Patient must not have received treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer prior to initiating treatment with this drug for this PBS indication; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11469 |
|  | C11477 |  |  | Locally advanced or metastatic non-small cell lung cancer Continuing treatment as second-line drug therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have stable or responding disease. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 11477 |

1. Schedule 4, Part 1, entry for Pembrolizumab
2. *omit entry for Circumstances Code “C10683” and substitute:*

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|  | C10683 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment - 6 weekly treatment regimen Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have stable or responding disease; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10683 |

1. *omit entry for Circumstances Code “C10697” and substitute:*

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|  | C10697 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment - 3 weekly treatment regimen Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have stable or responding disease; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10697 |

1. Schedule 4, Part 1, entry for Ribociclib
   1. substitute:

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| Ribociclib | C11458 | P11458 |  | Locally advanced or metastatic breast cancer Transitioning from non-PBS to PBS-subsidised supply - 'Grandfather' treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2021; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must have been untreated with each of: (i) abemaciclib, (ii) palbociclib, (iii) ribociclib, at the time non-PBS supply was initiated; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time of non-PBS supply was initiated; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant, where the patient had never been treated with endocrine therapy for advanced/metastatic disease at the time non-PBS supply was initiated; OR The treatment must be in combination with fulvestrant only, where at the time non-PBS supply was initiated, the patient had recurrent/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease; AND The treatment must not be in combination with abemaciclib or palbociclib. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11459 | P11459 |  | Locally advanced or metastatic breast cancer Transitioning from non-PBS to PBS-subsidised supply - 'Grandfather' treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2021; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must have been untreated with each of: (i) abemaciclib, (ii) palbociclib, (iii) ribociclib, at the time non-PBS supply was initiated; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time of non-PBS supply was initiated; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant, where the patient had never been treated with endocrine therapy for advanced/metastatic disease at the time non-PBS supply was initiated; OR The treatment must be in combination with fulvestrant only, where at the time non-PBS supply was initiated, the patient had recurrent/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11471 | P11471 |  | Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11498 | P11498 |  | Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with each of: (i) abemaciclib, (ii) palbociclib, (iii) ribociclib; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11499 | P11499 |  | Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; AND The treatment must not be in combination with abemaciclib or palbociclib. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11500 | P11500 |  | Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with each of: (i) abemaciclib, (ii) palbociclib, (iii) ribociclib; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11506 | P11506 |  | Locally advanced or metastatic breast cancer Transitioning from non-PBS to PBS-subsidised supply - 'Grandfather' treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2021; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must have been untreated with each of: (i) abemaciclib, (ii) palbociclib, (iii) ribociclib, at the time non-PBS supply was initiated; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time of non-PBS supply was initiated; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant, where the patient had never been treated with endocrine therapy for advanced/metastatic disease at the time non-PBS supply was initiated; OR The treatment must be in combination with fulvestrant only, where at the time non-PBS supply was initiated, the patient had recurrent/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11507 | P11507 |  | Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with each of: (i) abemaciclib, (ii) palbociclib, (iii) ribociclib; OR Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with abemaciclib or palbociclib. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C11508 | P11508 |  | Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; AND The treatment must not be in combination with abemaciclib or palbociclib; AND Patient must require dosage reduction requiring a pack of 42 tablets. Patient must not be premenopausal. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, after entry for Rizatriptan
   1. insert:

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| Romosozumab | C11487 |  |  | Severe established osteoporosis Initial treatment Patient must be at very high risk of fracture; AND Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND Patient must have had 2 or more fractures due to minimal trauma; AND Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a lifetime maximum of 12 months therapy; AND Patient must not have received treatment with teriparatide; OR Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy. Must be treated by a specialist; OR Must be treated by a consultant physician. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated. Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum. Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application. | Compliance with Authority Required procedures |
|  | C11496 |  |  | Severe established osteoporosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a lifetime maximum of 12 months therapy. Must be treated by a specialist; OR Must be treated by a consultant physician. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Secukinumab
2. *insert after entry for Circumstances Code “C9503”:*

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|  | C10431 | P10431 |  | Non-radiographic axial spondyloarthritis 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 for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. | Compliance with Authority Required procedures |
|  | C10489 | P10489 |  | Non-radiographic axial spondyloarthritis Continuing treatment or Grandfather patient - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Grandfathered 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 continuing treatment restriction or the grandfather restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |

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

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| --- | --- | --- | --- | --- | --- |
|  | C11389 | P11389 |  | Non-radiographic axial spondyloarthritis 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 had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; 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 one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 20 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter. State in the application whether a loading dose regimen is intended or not. Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing. Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1. | Compliance with Authority Required procedures |
|  | C11390 | P11390 |  | Non-radiographic axial spondyloarthritis 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 patients) restriction to complete 20 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 20 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 20 weeks treatment; AND The treatment must provide no more than the balance of up to 20 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
|  | C11432 | P11432 |  | Non-radiographic axial spondyloarthritis Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had 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 initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The condition must have been diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, prior to having commenced non-PBS-subsidised treatment with this biological medicine; AND The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI) prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent) prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium) prior to commencing non-PBS-subsidised treatment with this biological medicine; AND The treatment must not exceed a maximum of 24 weeks with this drug 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 non-radiographic axial spondyloarthritis. 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) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must have been determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must have been no more than 1 month old at the time of initiating non-PBS subsidised treatment with this biological medicine for this condition. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must include: (a) a completed authority prescription; and (b) a completed PBS authority application form relevant to the indication and treatment phase (the latest version located at the website mentioned in the administrative note). The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
|  | C11447 | P11447 |  | Non-radiographic axial spondyloarthritis 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 failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 20 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. 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. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter. State in the application whether a loading dose regimen is intended or not. Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing. Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1. | Compliance with Authority Required procedures |
|  | C11502 | P11502 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; 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 have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 20 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter. State in the application whether a loading dose regimen is intended or not. Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing. Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1. 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 be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. 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. The authority application must include: (a) a completed authority prescription; and (b) a completed PBS authority application form relevant to the indication and treatment phase (the latest version located at the website mentioned in the administrative note). The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Teriparatide
   1. substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Teriparatide | C11464 |  |  | Severe established osteoporosis Initial treatment Patient must be at very high risk of fracture; AND Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND Patient must have had 2 or more fractures due to minimal trauma; AND Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a lifetime maximum of 18 months therapy; AND Patient must not have received treatment with romosozumab; OR Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy. Must be treated by a specialist; OR Must be treated by a consultant physician. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated. Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum. Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application. | Compliance with Authority Required procedures |
|  | C11486 |  |  | Severe established osteoporosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a lifetime maximum of 18 months therapy. Must be treated by a specialist; OR Must be treated by a consultant physician. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Ustekinumab
   1. omit entry for Circumstances Code “C9657” and substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C9657 | P9657 |  | Severe Crohn disease Continuing 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; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test 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; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 3 - General statement for drugs for the treatment of hepatitis C
   1. substitute:

**Part 3—General statement for drugs for the treatment of hepatitis C**

**1        Criteria for eligibility for drugs for the treatment of chronic hepatitis C**

The criteria for patient eligibility for drugs for the treatment of chronic hepatitis C are that:

(1)          the patient has been assessed in accordance with paragraph 2 of this Part; and

(2)     the patient is:

(a)       treated by a medical practitioner or an authorised nurse practitioner who is experienced in the treatment of patients with chronic hepatitis C infection; or

(b)       treated by a medical practitioner or an authorised nurse practitioner in consultation with:

                                                                                                        (i)       a gastroenterologist; or

                                                                                                        (ii)      a hepatologist; or

                                                                                                        (iii)     an infectious diseases physician.

**2        Assessment of patient**

For the purpose of subparagraph 1(2) of this Part, the patient has been assessed if the treating medical practitioner has:

(1)          documented the following information in the patient’s medical records:

(a)           evidence of chronic hepatitis C infection; and

(b)           where possible, evidence of the patient’s hepatitis C virus genotype; and

(2)          chosen a regimen in accordance with paragraph 3 of this Part; and

(3)          collected the following information for the purposes of the authority application:

(a)           whether the patient is:

                                                                                                        (i)           cirrhotic; or

                                                                                                        (ii)         non-cirrhotic

(b)           details of the previous treatment regimen (**only**for requests for sofosbuvir with velpatasvir and voxilaprevir or glecaprevir with pibrentasvir for treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

(4)          In this paragraph, evidence of chronic hepatitis C infection is documentation of:

(a)           repeat test results showing antibody to hepatitis C virus (anti-HCV) positive; and

(b)           test result showing hepatitis C virus ribonucleic acid (RNA) positive.

**3        Treatment regimen**

For the purpose of subparagraph 2(2) of this Part, the treating medical practitioner has chosen a regimen in accordance with this paragraph if the patient:

(1)          is a kind of patient mentioned for an Item in column 2 of the following table; and

(2)          is to receive one of the regimens mentioned in column 3 of the same Item of the following table.

| **Item** | **Kind of patient** | **Regimen** |
| --- | --- | --- |
| 1 | Patient:  (a)      all genotypes (pan-genotypic); and  (b)      who is treatment naïve; and  (c)      who is non-cirrhotic. | Either:  (a)      SOFOSBUVIR with VELPATASVIR for 12 weeks; or  (b)      GLECAPREVIR with PIBRENTASVIR for 8 weeks. |
| 2 | Patient:  (a)      all genotypes (pan-genotypic); and  (b)      who is treatment experienced; and  (c)      who is non-cirrhotic. | Either:  (a)      SOFOSBUVIR with VELPATASVIR for 12 weeks; or  (b)      SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or  (c)      GLECAPREVIR with PIBRENTASVIR for 8 weeks; or  (d)      GLECAPREVIR with PIBRENTASVIR for 12 weeks; or  (e)      GLECAPREVIR with PIBRENTASVIR 16 weeks. |
| 3 | Patient:  (a)      with Genotype 1; and  (b)      who is treatment naïve; and  (c)      who is non-cirrhotic. | Either:  (a)      LEDIPASVIR with SOFOSBUVIR for 8 weeks; or  (b)      LEDIPASVIR with SOFOSBUVIR for 12 weeks |
| 4 | Patient:  (a)      with Genotype 1; and  (b)      who is treatment experienced; and  (c)      who is non-cirrhotic. | LEDIPASVIR with SOFOSBUVIR for 12 weeks |
| 5 | Patient:  (a)      with Genotype 2; and  (b)      who is treatment naïve; and  (c)      who is non-cirrhotic. | Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens). |
| 6 | Patient:  (a)      with Genotype 2; and  (b)      who is treatment experienced; and  (c)      who is non-cirrhotic. | Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens). |
| 7 | Patient:  (a)    with Genotype 3; and  (b)    who is treatment naïve; and  (c)    who is non-cirrhotic. | Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens). |
| 8 | Patient:  (a)    with Genotype 3; and  (b)    who is treatment experienced; and  (c)    who is non-cirrhotic. | Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens). |
| 9 | Patient:  (a)    with Genotype 4; and  (b)    who is treatment naïve; and  (c)    who is non-cirrhotic. | Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens). |
| 10 | Patient:  (a)    with Genotype 4; and  (b)    who is treatment experienced; and  (c)    who is non-cirrhotic. | Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens). |
| 11 | Patient:  (a)    with:                           (i)   Genotype 5; or                                        (ii)  Genotype 6; and  (b)    who is treatment naïve; and  (c)    who is non-cirrhotic. | Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens). |
| 12 | Patient:  (a)    with:                           (i)   Genotype 5; or                           (ii)  Genotype 6; and  (b)    who is treatment experienced; and  (c)    who is non-cirrhotic. | Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens). |
| 13 | Patient:  (a)    all genotypes (pan-genotypic); and  (b)    who is treatment naïve; and  (c)    who is cirrhotic. | Either:  (a)    SOFOSBUVIR with VELPATASVIR for 12 weeks; or  (b)    GLECAPREVIR with PIBRENTASVIR for 8 weeks; or  (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks |
| 14 | Patient:  (a)    all genotypes (pan-genotypic); and  (b)    who is treatment experienced; and  (c)    who is cirrhotic. | Either:  (a)    SOFOSBUVIR with VELPATASVIR for 12 weeks; or  (b)    SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or  (c)    GLECAPREVIR with PIBRENTASVIR for 12 weeks; or  (d)    GLECAPREVIR with PIBRENTASVIR 16 weeks. |
| 15 | Patient:  (a)    with Genotype 1; and  (b)    who is treatment naïve; and  (c)    who is cirrhotic. | LEDIPASVIR with SOFOSBUVIR for 12 weeks |
| 16 | Patient:  (a)    with Genotype 1; and  (b)    who is treatment experienced; and  (c)    who is cirrhotic. | LEDIPASVIR with SOFOSBUVIR for 24 weeks |
| 17 | Patient:  (a)    with Genotype 2; and  (b)    who is treatment naïve; and  (c)    who is cirrhotic. | Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens). |
| 18 | Patient:  (a)    with Genotype 2; and  (b)    who is treatment experienced; and  (c)    who is cirrhotic. | Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens). |
| 19 | Patient:  (a)    with Genotype 3; and  (b)    who is treatment naïve; and  (c)    who is cirrhotic. | Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens). |
| 20 | Patient:  (a)    with Genotype 3; and  (b)    who is treatment experienced; and  (c)    who is cirrhotic. | Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens). |
| 21 | Patient:  (a)    with Genotype 4; and  (b)    who is treatment naïve; and  (c)    who is cirrhotic. | Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens). |
| 22 | Patient:  (a)    with Genotype 4; and  (b)    who is treatment experienced; and  (c)    who is cirrhotic. | Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens). |
| 23 | Patient:  (a)    with:                           (i)   Genotype 5; or                           (ii)  Genotype 6; and  (b)            who is treatment naïve; and    (c)            who is cirrhotic. | Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens). |
| 24 | Patient:  (a)    with:                           (i)   Genotype 5; or                           (ii)  Genotype 6; and  (b)    who is treatment experienced; and  (c) who is cirrhotic. | Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens). |

1. Schedule 5, after entry for Abacavir with lamivudine
   1. insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Adalimumab | GRP-24872 | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Humira |
|  |  | Injection 40 mg in 0.8 mL pre-filled pen | Injection | Amgevita Hadlima Humira Hyrimoz Idacio |
|  | GRP-24874 | Injection 20 mg in 0.2 mL pre-filled syringe | Injection | Humira |
|  |  | Injection 20 mg in 0.4 mL pre-filled syringe | Injection | Amgevita  Humira |
|  | GRP-24876 | Injection 40 mg in 0.4 mL pre-filled syringe | Injection | Humira |
|  |  | Injection 40 mg in 0.8 mL pre-filled syringe | Injection | Amgevita Hadlima Humira Hyrimoz Idacio |

1. Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[GRP-17061]*
2. *insert in alphabetical order in the column headed “Brand”:* **APO-Esomeprazole**
3. *insert in alphabetical order in the column headed “Brand”:* **Esopreze**
4. Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[GRP-17188]*
5. *insert in alphabetical order in the column headed “Brand”:* **APO-Esomeprazole**
6. *insert in alphabetical order in the column headed “Brand”:* **Esopreze**
7. Schedule 5, entry for Omeprazole in the form Tablet 20 mg *[GRP-14650]*
   1. insert in alphabetical order in the column headed “Brand”: Maxor EC Tabs
8. Schedule 5, after entry for Salbutamol
   1. insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sertraline | GRP-24879 | Tablet 50 mg (as hydrochloride) | Oral | Auro-Sertraline 50 Eleva 50 NOUMED SERTRALINE Sertraline AN Zoloft |
|  |  | Tablet 50 mg (as hydrochloride) (USP) | Oral | Sertraline tablets USP (Medsurge) |
|  | GRP-24880 | Tablet 100 mg (as hydrochloride) | Oral | Auro-Sertraline 100 Eleva 100 NOUMED SERTRALINE Sertraline AN Zoloft |
|  |  | Tablet 100 mg (as hydrochloride) (USP) | Oral | Sertraline tablets USP (Medsurge) |
|  | GRP-24896 | Tablet 100 mg (as hydrochloride) | Oral | APO-Sertraline Auro-Sertraline 100 Eleva 100 NOUMED SERTRALINE Sertra 100 Sertraline AN Sertraline Sandoz Sertraline generichealth Setrona Zoloft |
|  |  | Tablet 100 mg (as hydrochloride) (USP) | Oral | Sertraline tablets USP (Medsurge) |
|  | GRP-24903 | Tablet 50 mg (as hydrochloride) | Oral | APO-Sertraline Auro-Sertraline 50 Eleva 50 NOUMED SERTRALINE Sertra 50 Sertraline AN Sertraline Sandoz Sertraline generichealth Setrona Zoloft |
|  |  | Tablet 50 mg (as hydrochloride) (USP) | Oral | Sertraline tablets USP (Medsurge) |

1. Schedule 5, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg *[GRP-21636]*
   1. insert in alphabetical order in the column headed “Brand”: Tenofovir Sandoz
2. Schedule 6, after entry for Secukinumab
   1. insert:

|  |  |  |
| --- | --- | --- |
| Selexipag | Tablet 200 micrograms | Oral |
| Selexipag | Tablet 400 micrograms | Oral |
| Selexipag | Tablet 600 micrograms | Oral |
| Selexipag | Tablet 800 micrograms | Oral |
| Selexipag | Tablet 1 mg | Oral |
| Selexipag | Tablet 1.2 mg | Oral |
| Selexipag | Tablet 1.4 mg | Oral |
| Selexipag | Tablet 1.6 mg | Oral |