

PB 84 of 2025

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

National Health Act 1953

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

Dated 28 July 2025

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

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

1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (August Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 84 of 2025.

2. Commencement

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

|  |  |
| --- | --- |
| **Commencement Information** |  |
| **Column 1** | **Column 2** | **Column 3** |
| **Provisions** | **Commencement** | **Date/Details** |
| 1. The whole of this instrument | 1 August 2025 | 1 August 2025 |

Note: This table relates only to the provisions of this instrument as originally made.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

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

3. Authority

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

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

[1] Schedule 1, Part 1, entries for Abemaciclib in each of the forms: Tablet 50 mg; Tablet 100 mg; and Tablet 150 mg

(a) omit from the column headed “Circumstances”: C16771

(b) insert in numerical order in the column headed “Circumstances”: C16932

[2] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 250 mg [Brand: Abiraterone-Teva]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Abiraterone | Tablet containing abiraterone acetate 250 mg | Oral | ZYRON | NB | MP | C13945 |  | 120 | 2 |  | 120 |  |  |

[3] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 500 mg [Brand: Abiraterone-Teva]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Abiraterone | Tablet containing abiraterone acetate 500 mg | Oral | ZYRON | NB | MP | C13945 |  | 60 | 2 |  | 60 |  |  |

[4] Schedule 1, Part 1, entries for Aciclovir in the form Tablet 800 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Aciclovir | Tablet 800 mg | Oral | Aciclovir APOTEX | TY | MP NP | C5959 C5967 |  | 35 | 0 |  | 35 |  |  |

[5] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.2 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

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

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

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

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[8] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[*Brand: Hadlima*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[9] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[*Brand: Humira*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[10] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[*Brand: Hyrimoz*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[11] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[*Brand: Yuflyma*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[12] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[*Brand: Hadlima*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[13] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[*Brand: Humira*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[14] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[*Brand: Hyrimoz*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[15] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[*Brand: Yuflyma*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[16] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[*Brand: Abrilada*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[17] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[*Brand: Amgevita*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[18] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[*Brand: Hadlima*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[19] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[*Brand: Hyrimoz*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[20] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[*Brand: Abrilada*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[21] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[*Brand: Amgevita*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[22] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[*Brand: Hadlima*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

[23] Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[*Brand: Hyrimoz*; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15450

(b) omit from the column headed “Purposes”: P15450

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

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Afatinib | Tablet 50 mg | Oral | Giotrif | BY | MP | C7613 C16404 |  | 28 | 3 |  | 28 |  |  |

[25] Schedule 1, Part 1, entries for Amino acid formula with vitamins and minerals without lysine and low in tryptophan

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with vitamins and minerals without lysine and low in tryptophan | Sachets containing oral powder 24 g, 30 (GA gel) | Oral | GA gel | VF | MP NP | C5323 C11482 |  | 4 | 5 |  | 1 |  |  |

[26] Schedule 1, Part 1, entries for Arsenic

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Arsenic | Injection concentrate containing arsenic trioxide 10 mg in 10 mL | Injection | Arsenic Trioxide-AFT | AE | MP | C4793 C5997 C6018 |  | See Note 3 | See Note 3 |  | 10 |  | D(100) |

[27] Schedule 1, Part 1, omit entries for Betaxolol

[28] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 3.5 mg

omit:

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

[29] Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15518

(b) omit from the column headed “Purposes”: P15518

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

(a) omit from the column headed “Circumstances”: C15518

(b) omit from the column headed “Purposes”: P15518

[31] Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 60 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C15518

(b) omit from the column headed “Purposes”: P15518

[32] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate) [Brand: ARX-Dabigatran]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dabigatran etexilate | Capsule 75 mg (as mesilate) | Oral | Dabigatran Viatris | AF | MP NP | C4402 |  | 60 | 0 |  | 60 |  |  |

[33] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 110 mg (as mesilate) [Brand: Dabigatran Sandoz; Maximum Quantity: 120; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dabigatran etexilate | Capsule 110 mg (as mesilate) | Oral | Dabigatran Viatris | AF | MP NP | C4402 | P4402 | 60 | 0 |  | 60 |  |  |
| Dabigatran etexilate | Capsule 110 mg (as mesilate) | Oral | Dabigatran Viatris | AF | MP NP | C4269 | P4269 | 60 | 5 |  | 60 |  |  |
| Dabigatran etexilate | Capsule 110 mg (as mesilate) | Oral | Dabigatran Viatris | AF | MP NP | C14301 | P14301 | 120 | 5 |  | 60 |  |  |

[34] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 150 mg (as mesilate) [Brand: Dabigatran Sandoz; Maximum Quantity: 120; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dabigatran etexilate | Capsule 150 mg (as mesilate) | Oral | Dabigatran Viatris | AF | MP NP | C4269 | P4269 | 60 | 5 |  | 60 |  |  |
| Dabigatran etexilate | Capsule 150 mg (as mesilate) | Oral | Dabigatran Viatris | AF | MP NP | C14301 | P14301 | 120 | 5 |  | 60 |  |  |

[35] Schedule 1, Part 1, entries for Denosumab

insert as first entry:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Denosumab | Injection 60 mg in 1 mL pre-filled syringe | Injection | Jubbonti | SZ | MP NP | C6524 C6548 |  | 1 | 0 |  | 1 |  |  |

[36] Schedule 1, Part 1, after entry for Denosumab in the form Injection 60 mg in 1 mL pre-filled syringe [Brand: Prolia]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Denosumab | Injection 120 mg in 1.7 mL | Injection | Wyost | SZ | MP NP | C16512 C16514 C16608 |  | 1 | 5 |  | 1 |  |  |

[37] Schedule 1, Part 1, after entry for Drospirenone *[Pack Quantity: 4]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Drospirenone | Pack containing 24 tablets 4 mg and 4 inert tablets, 3 | Oral | Slinda | HB | MP MW NP |  |  | 1 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | Isabelle | GQ | MP MW NP |  |  | 3 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | Isabelle | GQ | MP MW NP |  |  | 3 | 3 |  | 3 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | Rosalee | SZ | MP MW NP |  |  | 3 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | Rosalee | SZ | MP MW NP |  |  | 3 | 3 |  | 3 |  |  |

[38] Schedule 1, Part 1, after entry for Drospirenone with ethinylestradiol in the form Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets [Brand: Yasmin; Pack Quantity: 3]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Drospirenone with ethinylestradiol | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | Yelena | XT | MP MW NP |  |  | 3 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | Yelena | XT | MP MW NP |  |  | 3 | 3 |  | 3 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | Bella | GQ | MP MW NP |  |  | 3 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | Bella | GQ | MP MW NP |  |  | 3 | 3 |  | 3 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | Rosie | SZ | MP MW NP |  |  | 3 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | Rosie | SZ | MP MW NP |  |  | 3 | 3 |  | 3 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | YANA | XT | MP MW NP |  |  | 3 | 3 |  | 1 |  |  |
| Drospirenone with ethinylestradiol | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | YANA | XT | MP MW NP |  |  | 3 | 3 |  | 3 |  |  |

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

insert in numerical order in the column headed “Circumstances”: C16814 C16953

[40] Schedule 1, Part 1, after entry for Edaravone *[Maximum Quantity: 28; Number of Repeats: 0]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Eflornithine | Tablet 192 mg (as hydrochloride) | Oral | Ifinwil | NE | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 100 |  | D(100) |

[41] Schedule 1, Part 1, after entry for Escitalopram in the form Tablet 10 mg (as oxalate) [Brand: Escitalopram Sandoz; Maximum Quantity: 56; Number of Repeats: 2]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Escitalopram | Tablet 10 mg (as oxalate) | Oral | ESCITALOPRAM-WGR | WG | MP NP | C4690 C4703 C4755 C4756 C4757 | P4690 P4703 P4755 P4756 P4757 | 28 | 5 |  | 28 |  |  |
| Escitalopram | Tablet 10 mg (as oxalate) | Oral | ESCITALOPRAM-WGR | WG | MP NP | C15550 C15551 C15666 C15669 C15696 | P15550 P15551 P15666 P15669 P15696 | 56 | 2 |  | 28 |  |  |

[42] Schedule 1, Part 1, after entry for Escitalopram in the form Tablet 20 mg (as oxalate) [Brand: Escitalopram Sandoz; Maximum Quantity: 56; Number of Repeats: 2]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Escitalopram | Tablet 20 mg (as oxalate) | Oral | ESCITALOPRAM-WGR | WG | MP NP | C4690 C4703 C4755 C4756 C4757 | P4690 P4703 P4755 P4756 P4757 | 28 | 5 |  | 28 |  |  |
| Escitalopram | Tablet 20 mg (as oxalate) | Oral | ESCITALOPRAM-WGR | WG | MP NP | C15550 C15551 C15666 C15669 C15696 | P15550 P15551 P15666 P15669 P15696 | 56 | 2 |  | 28 |  |  |

[43] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 2.1 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fentanyl | Transdermal patch 2.1 mg | Transdermal | Durogesic 12 | JC | MP NP | C15994 C15996 C16000 | P15994 P15996 P16000 | 5 | 0 | V15994 V15996 V16000 | 5 |  |  |
| Fentanyl | Transdermal patch 2.1 mg | Transdermal | Durogesic 12 | JC | MP NP | C11696 | P11696 | 10 | 0 | V11696 | 5 |  |  |

[44] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 4.2 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fentanyl | Transdermal patch 4.2 mg | Transdermal | Durogesic 25 | JC | MP NP | C15994 C15996 C16000 | P15994 P15996 P16000 | 5 | 0 | V15994 V15996 V16000 | 5 |  |  |
| Fentanyl | Transdermal patch 4.2 mg | Transdermal | Durogesic 25 | JC | MP NP | C11696 | P11696 | 10 | 0 | V11696 | 5 |  |  |

[45] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 8.4 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fentanyl | Transdermal patch 8.4 mg | Transdermal | Durogesic 50 | JC | MP NP | C15994 C15996 C16000 | P15994 P15996 P16000 | 5 | 0 | V15994 V15996 V16000 | 5 |  |  |
| Fentanyl | Transdermal patch 8.4 mg | Transdermal | Durogesic 50 | JC | MP NP | C11696 | P11696 | 10 | 0 | V11696 | 5 |  |  |

[46] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 12.6 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fentanyl | Transdermal patch 12.6 mg | Transdermal | Durogesic 75 | JC | MP NP | C15994 C15996 C16000 | P15994 P15996 P16000 | 5 | 0 | V15994 V15996 V16000 | 5 |  |  |
| Fentanyl | Transdermal patch 12.6 mg | Transdermal | Durogesic 75 | JC | MP NP | C11696 | P11696 | 10 | 0 | V11696 | 5 |  |  |

[47] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 16.8 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fentanyl | Transdermal patch 16.8 mg | Transdermal | Durogesic 100 | JC | MP NP | C15994 C15996 C16000 | P15994 P15996 P16000 | 5 | 0 | V15994 V15996 V16000 | 5 |  |  |
| Fentanyl | Transdermal patch 16.8 mg | Transdermal | Durogesic 100 | JC | MP NP | C11696 | P11696 | 10 | 0 | V11696 | 5 |  |  |

[48] Schedule 1, Part 1, entries for Fluorouracil

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fluorouracil | Injection 500 mg in 10 mL | Injection | Fluorouracil Accord | OC | MP | C6266 C6297 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Fluorouracil | Injection 1000 mg in 20 mL | Injection | Fluorouracil Accord | OC | MP | C6266 C6297 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Fluorouracil | Injection 2500 mg in 50 mL | Injection | Fluorouracil Accord | OC | MP | C6266 C6297 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Fluorouracil | Injection 5000 mg in 100 mL | Injection | Fluorouracil Accord | OC | MP | C6266 C6297 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[49] Schedule 1, Part 1, after entry for Fosinopril in the form Tablet containing fosinopril sodium 20 mg [Brand: Monace 20]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Foslevodopa with foscarbidopa | Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL | Injection | Vyalev | VE | MP NP | C16882 | P16882 | 28 | 5 |  | 7 |  |  |
| Foslevodopa with foscarbidopa | Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL | Injection | Vyalev | VE | MP | C16812 | P16812 | 28 | 5 |  | 7 |  |  |
| Foslevodopa with foscarbidopa | Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL | Injection | Vyalev | VE | MP | C16812 C16883 | P16812 P16883 | 28 | 5 |  | 7 |  | C(100) |
| Foslevodopa with foscarbidopa | Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL | Injection | Vyalev | VE | MP NP | C16951 | P16951 | 56 | 5 |  | 7 |  |  |
| Foslevodopa with foscarbidopa | Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL | Injection | Vyalev | VE | MP | C16853 | P16853 | 56 | 5 |  | 7 |  |  |
| Foslevodopa with foscarbidopa | Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL | Injection | Vyalev | VE | MP | C16853 C16972 | P16853 P16972 | 56 | 5 |  | 7 |  | C(100) |

[50] Schedule 1, Part 1, entries for Granisetron in the form Concentrated injection 3 mg (as hydrochloride) in 3 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Granisetron | Concentrated injection 3 mg (as hydrochloride) in 3 mL | Injection | Granisetron-AFT | AE | MP NP | C4077 C4092 |  | 1 | 0 | V4077 | 1 |  |  |
| Granisetron | Concentrated injection 3 mg (as hydrochloride) in 3 mL | Injection | Granisetron-AFT | AE | MP | C4139 |  | 1 | 0 | V4139 | 1 |  | C(100) |

[51] Schedule 1, Part 1, entries for Hydromorphone in the form Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)

omit from the column headed “Form” (all instances): Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)
substitute (all instances): Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A)

[52] Schedule 1, Part 1, entries for Insect allergen extract-yellow jacket venom

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Insect allergen extract-yellow jacket venom | Injection set containing 550 micrograms with diluent | Injection | Hymenoptera Yellow Jacket Venom | DE | MP |  |  | 1 | 0 |  | 1 |  |  |

[53] Schedule 1, Part 1, entries for Ipilimumab

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ipilimumab | Injection concentrate for I.V. infusion 50 mg in 10 mL | Injection | Yervoy | BQ | MP | C6562 C6585 C8555 C11391 C11478 C11930 C16936 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Ipilimumab | Injection concentrate for I.V. infusion 200 mg in 40 mL | Injection | Yervoy | BQ | MP | C6562 C6585 C16936 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[54] Schedule 1, Part 1, after entry for Isotretinoin in the form Capsule 20 mg [Brand: Dermatane]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Isotretinoin | Capsule 20 mg | Oral | Isotretinoin Dr.Reddy's | RZ | MP | C5224 |  | 60 | 3 |  | 30 |  |  |
| Isotretinoin | Capsule 20 mg | Oral | Isotretinoin Dr.Reddy's | RZ | MP | C5224 |  | 60 | 3 |  | 60 |  |  |

[55] Schedule 1, Part 1, entry for Migalastat

omit from the column headed “Number of Repeats”: 5 substitute: 6

[56] Schedule 1, Part 1, entries for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | Oral | Montelukast Mylan | AF | MP NP | C6666 | P6666 | 28 | 5 |  | 28 |  |  |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | Oral | Montelukast Mylan | AF | MP NP | C15642 | P15642 | 56 | 5 |  | 28 |  |  |

[57] Schedule 1, Part 1, entries for Morphine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Morphine | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A) | Oral | RA-Morph (NZ) | WZ | MP NP | C10764 C10770 C10777 | P10764 P10770 P10777 | 200 | 0 | V10764 V10770 V10777 | 200 |  |  |
| Morphine | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A) | Oral | RA-Morph (NZ) | WZ | PDP | C10859 |  | 200 | 0 |  | 200 |  |  |
| Morphine | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A) | Oral | RA-Morph (NZ) | WZ | MP NP | C11697 | P11697 | 400 | 1 | V11697 | 200 |  |  |

[58] Schedule 1, Part 1, entries 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

(a) omit from the column headed “Circumstances”: C10119 C10120

(b) omit from the column headed “Circumstances”: C14816

(c) insert in numerical order in the column headed “Circumstances”: C16935 C16961 C16962

[59] Schedule 1, Part 1, entry for Nivolumab with relatlimab

(a) omit from the column headed “Circumstances”: C16188

(b) insert in numerical order in the column headed “Circumstances”: C16881

[60] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg | Oral | Olmekar HCT 20/5/12.5 | RF | MP NP | C4311 | P4311 | 30 | 5 |  | 30 |  |  |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg | Oral | Olmekar HCT 20/5/12.5 | RF | MP NP | C14272 | P14272 | 60 | 5 |  | 30 |  |  |

[61] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg | Oral | Olmekar HCT 40/10/12.5 | RF | MP NP | C4311 | P4311 | 30 | 5 |  | 30 |  |  |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg | Oral | Olmekar HCT 40/10/12.5 | RF | MP NP | C14272 | P14272 | 60 | 5 |  | 30 |  |  |

[62] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg | Oral | Olmekar HCT 40/10/25 | RF | MP NP | C4311 | P4311 | 30 | 5 |  | 30 |  |  |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg | Oral | Olmekar HCT 40/10/25 | RF | MP NP | C14837 | P14837 | 60 | 5 |  | 30 |  |  |

[63] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg | Oral | Olmekar HCT 40/5/12.5 | RF | MP NP | C4311 | P4311 | 30 | 5 |  | 30 |  |  |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg | Oral | Olmekar HCT 40/5/12.5 | RF | MP NP | C14272 | P14272 | 60 | 5 |  | 30 |  |  |

[64] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg | Oral | Olmekar HCT 40/5/25 | RF | MP NP | C4311 | P4311 | 30 | 5 |  | 30 |  |  |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg | Oral | Olmekar HCT 40/5/25 | RF | MP NP | C14272 | P14272 | 60 | 5 |  | 30 |  |  |

[65] Schedule 1, Part 1, entries for Omalizumab

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Omalizumab | Injection 75 mg in 0.5 mL single dose pre-filled pen | Injection | Xolair | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Omalizumab | Injection 75 mg in 0.5 mL single dose pre-filled syringe | Injection | Omlyclo | EW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Omalizumab | Injection 75 mg in 0.5 mL single dose pre-filled syringe | Injection | Xolair | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Omalizumab | Injection 150 mg in 1 mL single dose pre-filled pen | Injection | Xolair | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Omalizumab | Injection 150 mg in 1 mL single dose pre-filled syringe | Injection | Omlyclo | EW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |
| Omalizumab | Injection 300 mg in 2 mL single dose pre-filled pen | Injection | Xolair | NV | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[66] Schedule 1, Part 1, entries for Paroxetine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Paroxetine | Tablet 20 mg (as hydrochloride) | Oral | Noumed Paroxetine | VO | MP NP | C4755 C6277 C6636 | P4755 P6277 P6636 | 30 | 5 |  | 30 |  |  |
| Paroxetine | Tablet 20 mg (as hydrochloride) | Oral | Noumed Paroxetine | VO | MP NP | C15582 C15666 C15722 | P15582 P15666 P15722 | 60 | 2 |  | 30 |  |  |

[67] Schedule 1, Part 1, entry for Pembrolizumab

(a) omit from the column headed “Circumstances”: C14817 C14818

(b) insert in numerical order in the column headed “Circumstances”: C16933 C16950

[68] Schedule 1, Part 1, omit entries for Quinapril with hydrochlorothiazide

[69] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 15 mg [Brand: iXarola; Maximum Quantity: 56; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rivaroxaban | Tablet 15 mg | Oral | Relaban | NB | MP NP | C4269 | P4269 | 28 | 5 |  | 28 |  |  |
| Rivaroxaban | Tablet 15 mg | Oral | Relaban | NB | MP NP | C14301 | P14301 | 56 | 5 |  | 28 |  |  |

[70] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 20 mg [Brand: iXarola; Maximum Quantity: 56; Number of Repeats: 5]

insert:

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

[71] Schedule 1, Part 1, after entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate) [Brand: RIXALT]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rizatriptan | Tablet (orally disintegrating) 10 mg (as benzoate) | Oral | Rizatriptan-Au | DZ | MP NP | C5141 |  | 4 | 5 |  | 2 |  |  |

[72] Schedule 1, Part 1, omit entry for Tenecteplase

[73] Schedule 1, Part 1, entries for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir APOTEX | TX | MP NP | C10362 | P10362 | 60 | 2 |  | 30 |  | D(100) |
| Tenofovir | Tablet containing tenofovir disoproxil fumarate 300 mg | Oral | Tenofovir APOTEX | TX | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 |  | 30 |  | D(100) |

[74] Schedule 1, Part 1, entries for Tenofovir with emtricitabine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A) | Oral | Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) | KQ | MP NP | C11143 |  | 30 | 2 |  | 30 |  |  |
| Tenofovir with emtricitabine | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A) | Oral | Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) | KQ | MP NP | C6985 C6986 |  | 60 | 5 |  | 30 |  | C(100) |

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

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ustekinumab | Injection 45 mg in 0.5 mL | Injection | Stelara | JC | MP | C16818 | P16818 | 1 | 0 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL | Injection | Stelara | JC | MP | C12156 C16836 C16856 C16862 C16887 C16896 C16924 C16925 C16927 C16968 C16969 C16976 | P12156 P16836 P16856 P16862 P16887 P16896 P16924 P16925 P16927 P16968 P16969 P16976 | 1 | 1 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL | Injection | Stelara | JC | MP | C11120 C12334 C16819 C16832 C16838 C16857 C16868 C16885 C16894 C16899 C16900 C16901 C16910 C16920 C16922 C16937 C16938 | P11120 P12334 P16819 P16832 P16838 P16857 P16868 P16885 P16894 P16899 P16900 P16901 P16910 P16920 P16922 P16937 P16938 | 1 | 2 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL | Injection | Stelara | JC | MP | C16821 C16824 C16863 C16889 C16890 C16946 | P16821 P16824 P16863 P16889 P16890 P16946 | 2 | 0 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C16818 | P16818 | 1 | 0 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C12156 C16835 C16854 C16856 C16862 C16886 C16887 C16896 C16911 C16925 C16927 C16967 | P12156 P16835 P16854 P16856 P16862 P16886 P16887 P16896 P16911 P16925 P16927 P16967 | 1 | 1 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C11120 C12334 C16819 C16832 C16838 C16857 C16868 C16885 C16894 C16899 C16900 C16901 C16910 C16920 C16922 C16937 C16938 | P11120 P12334 P16819 P16832 P16838 P16857 P16868 P16885 P16894 P16899 P16900 P16901 P16910 P16920 P16922 P16937 P16938 | 1 | 2 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C16821 C16824 C16863 C16889 C16890 | P16821 P16824 P16863 P16889 P16890 | 2 | 0 |  | 1 |  |  |
| Ustekinumab | Injection 45 mg in 0.5 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C16913 | P16913 | 2 | 2 |  | 1 |  |  |
| Ustekinumab | Injection 90 mg in 1 mL single use pre-filled syringe | Injection | Stelara | JC | MP | C14801 C16828 C16829 C16917 C16918 C16944 | P14801 P16828 P16829 P16917 P16918 P16944 | 1 | 0 |  | 1 |  |  |
| Ustekinumab | Injection 90 mg in 1 mL single use pre-filled syringe | Injection | Stelara | JC | MP | C16915 C16916 C16919 C16943 C16973 | P16915 P16916 P16919 P16943 P16973 | 1 | 1 |  | 1 |  |  |
| Ustekinumab | Injection 90 mg in 1 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C14801 C16821 C16824 C16828 C16829 C16863 C16889 C16890 C16917 C16918 C16944 | P14801 P16821 P16824 P16828 P16829 P16863 P16889 P16890 P16917 P16918 P16944 | 1 | 0 |  | 1 |  |  |
| Ustekinumab | Injection 90 mg in 1 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C12156 C16835 C16862 C16886 C16887 C16896 C16909 C16911 C16915 C16916 C16919 C16927 C16943 C16945 C16967 C16973 | P12156 P16835 P16862 P16886 P16887 P16896 P16909 P16911 P16915 P16916 P16919 P16927 P16943 P16945 P16967 P16973 | 1 | 1 |  | 1 |  |  |
| Ustekinumab | Injection 90 mg in 1 mL single use pre-filled syringe | Injection | Steqeyma | EW | MP | C11120 C12334 C16819 C16832 C16838 C16857 C16868 C16894 C16900 C16901 C16913 C16920 C16922 C16938 | P11120 P12334 P16819 P16832 P16838 P16857 P16868 P16894 P16900 P16901 P16913 P16920 P16922 P16938 | 1 | 2 |  | 1 |  |  |
| Ustekinumab | Solution for I.V. infusion 130 mg in 26 mL | Injection | Stelara | JC | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |
| Ustekinumab | Solution for I.V. infusion 130 mg in 26 mL | Injection | Steqeyma | EW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 1 |  | PB(100) |

[76] Schedule 1, Part 1, after entry for Varenicline in the form Box containing 11 tablets 0.5 mg and 42 tablets 1 mg [Brand: VARENAPIX]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Varenicline | Box containing 11 tablets 0.5 mg and 42 tablets 1 mg | Oral | Varenicline Lupin | GQ | MP NP | C6871 |  | 1 | 0 |  | 1 |  |  |

[77] Schedule 1, Part 1, after entry for Varenicline in the form Tablet 1 mg [Brand: VARENAPIX; Maximum Quantity: 112; Number of Repeats: 0]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Varenicline | Tablet 1 mg | Oral | Varenicline Lupin | GQ | MP NP | C6885 | P6885 | 56 | 2 |  | 56 |  |  |
| Varenicline | Tablet 1 mg | Oral | Varenicline Lupin | GQ | MP NP | C7483 | P7483 | 112 | 0 |  | 56 |  |  |

[78] Schedule 1, Part 2, after entry for Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides

insert:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Amino acid formula with vitamins and minerals without lysine and low in tryptophan | Sachets containing oral powder 24 g, 30 (GA gel) | Oral | GA gel | VF | 1 |  |  |
| Betaxolol | Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL | Application to the eye | Betoptic | NV | 1 |  |  |

[79] Schedule 1, Part 2, omit entry for Glycomacropeptide and essential amino acids with vitamins and minerals

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

[81] Schedule 1, Part 2, after entry for Semaglutide

insert:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Tenecteplase | Powder for injection 50 mg with solvent | Injection | Metalyse | BY | 1 |  |  |

[82] Schedule 4, Part 1, entry for Circumstances Code “C4389”

omit from the column headed “Listed Drug”: Quinapril with hydrochlorothiazide

[83] Schedule 4, Part 1, omit entry for Circumstances Code “C5783”

[84] Schedule 4, Part 1, entry for Circumstances Code “C6696”

omit from the column headed “Listed Drug”: Ustekinumab

[85] Schedule 4, Part 1, omit entry for Circumstances Code “C8891”

[86] Schedule 4, Part 1, omit entry for Circumstances Code “C8987”

[87] Schedule 4, Part 1, entry for Circumstances Code “C9063”

omit from the column headed “Listed Drug”: Ustekinumab

[88] Schedule 4, Part 1, omit entry for Circumstances Code “C9116”

[89] Schedule 4, Part 1, omit entry for Circumstances Code “C9122”

[90] Schedule 4, Part 1, omit entry for Circumstances Code “C9160”

[91] Schedule 4, Part 1, omit entry for Circumstances Code “C9175”

[92] Schedule 4, Part 1, omit entry for Circumstances Code “C9176”

[93] Schedule 4, Part 1, omit entry for Circumstances Code “C9655”

[94] Schedule 4, Part 1, omit entry for Circumstances Code “C9656”

[95] Schedule 4, Part 1, omit entry for Circumstances Code “C9657”

[96] Schedule 4, Part 1, omit entry for Circumstances Code “C9710”

[97] Schedule 4, Part 1, omit entry for Circumstances Code “C9711”

[98] Schedule 4, Part 1, omit entry for Circumstances Code “C10119”

[99] Schedule 4, Part 1, omit entry for Circumstances Code “C10120”

[100] Schedule 4, Part 1, omit entry for Circumstances Code “C11119”

[101] Schedule 4, Part 1, omit entry for Circumstances Code “C11145”

[102] Schedule 4, Part 1, omit entry for Circumstances Code “C11153”

[103] Schedule 4, Part 1, omit entry for Circumstances Code “C11161”

[104] Schedule 4, Part 1, entry for Circumstances Code “C12156”

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

[105] Schedule 4, Part 1, omit entry for Circumstances Code “C12285”

[106] Schedule 4, Part 1, omit entry for Circumstances Code “C13927”

[107] Schedule 4, Part 1, omit entry for Circumstances Code “C13952”

[108] Schedule 4, Part 1, omit entry for Circumstances Code “C13955”

[109] Schedule 4, Part 1, omit entry for Circumstances Code “C13988”

[110] Schedule 4, Part 1, omit entry for Circumstances Code “C14018”

[111] Schedule 4, Part 1, entry for Circumstances Code “C14238”

omit from the column headed “Listed Drug”: Betaxolol

[112] Schedule 4, Part 1, omit entry for Circumstances Code “C14415”

[113] Schedule 4, Part 1, omit entry for Circumstances Code “C14442”

[114] Schedule 4, Part 1, omit entry for Circumstances Code “C14543”

[115] Schedule 4, Part 1, omit entry for Circumstances Code “C14558”

[116] Schedule 4, Part 1, omit entry for Circumstances Code “C14572”

[117] Schedule 4, Part 1, omit entry for Circumstances Code “C14573”

[118] Schedule 4, Part 1, omit entry for Circumstances Code “C14628”

[119] Schedule 4, Part 1, omit entry for Circumstances Code “C14636”

[120] Schedule 4, Part 1, omit entry for Circumstances Code “C14643”

[121] Schedule 4, Part 1, omit entry for Circumstances Code “C14758”

[122] Schedule 4, Part 1, omit entry for Circumstances Code “C14787”

[123] Schedule 4, Part 1, omit entry for Circumstances Code “C14806”

[124] Schedule 4, Part 1, omit entry for Circumstances Code “C14808”

[125] Schedule 4, Part 1, omit entry for Circumstances Code “C14816”

[126] Schedule 4, Part 1, omit entry for Circumstances Code “C14817”

[127] Schedule 4, Part 1, omit entry for Circumstances Code “C14818”

[128] Schedule 4, Part 1, omit entry for Circumstances Code “C15450”

[129] Schedule 4, Part 1, omit entry for Circumstances Code “C15518”

[130] Schedule 4, Part 1, omit entry for Circumstances Code “C16188”

[131] Schedule 4, Part 1, omit entry for Circumstances Code “C16771”

[132] Schedule 4, Part 1, after entry for Circumstances Code “C16809”

insert:

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| --- | --- | --- | --- | --- | --- |
| C16812 | P16812 | CN16812 | Foslevodopa with foscarbidopa | Advanced Parkinson diseaseMust be treated by a specialist physician; orMust be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 16812 |
| C16814 | P16814 | CN16814 | Durvalumab | Advanced, metastatic or recurrent endometrial carcinomaContinuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDPatient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.Retain all pathology imaging and investigative test results in the patient's medical records.Patients with a body weight of 30 kg or less during continuing treatment must receive weight-based dosing, equivalent to durvalumab 20 mg/kg, until weight is greater than 30 kg. | Compliance with Authority Required procedures - Streamlined Authority Code 16814 |
| C16818 | P16818 | CN16818 | Ustekinumab | Severe chronic plaque psoriasisFirst continuing, Subsequent continuing treatment - balance of supply (Whole body, or, face/hand/foot)Must be treated by a dermatologist; ANDPatient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed. | Compliance with Authority Required procedures |
| C16819 | P16819 | CN16819 | Ustekinumab | Severe chronic plaque psoriasisInitial 1 treatment (Whole body) - biological medicine-naive patientMust be treated by a dermatologist.Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must have lesions present for at least 6 months from the time of initial diagnosis; ANDPatient must have failed to achieve an adequate response to at least 2 of the following 3 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 or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be under 18 years of age.Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.Where intolerance to phototherapy, methotrexate and/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.Details of the accepted toxicities including severity can be found on the Services Australia website.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);(iii) the PASI score that followed each prior therapy trialled;(iv) the date the PASI scores were determined.Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine. | Compliance with Written Authority Required procedures |
| C16821 | P16821 | CN16821 | Ustekinumab | Severe Crohn diseaseBalance of supplyMust be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; orPatient 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; orPatient 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; orPatient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; ANDThe treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment. orThe treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment. | Compliance with Authority Required procedures |
| C16824 | P16824 | CN16824 | Ustekinumab | Severe Crohn diseaseInitial 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); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; ANDPatient 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; ANDPatient 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; orPatient 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; orPatient 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; ANDPatient must have evidence of intestinal inflammation; orPatient must be assessed clinically as being in a high faecal output state; orPatient 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; ANDThe treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.Patient must be at least 18 years of age.Applications for authorisation must be made in writing and must include:(a) details of the two proposed prescriptions; 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.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorisedWhere fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.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 this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.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 |
| C16828 | P16828 | CN16828 | Ustekinumab | Moderate to severe ulcerative colitisInitial 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); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; ANDPatient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; ANDPatient must have a Mayo clinic score greater than or equal to 6; orPatient 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); ANDThe treatment must not exceed a single dose to be administered at week 8 under this restriction.Patient must be at least 18 years of age.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:(i) the completed current Mayo clinic or partial Mayo clinic 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.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 or partial Mayo clinic score must be no more than 4 weeks 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 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.An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.A maximum of 16 weeks of treatment with this drug will be approved under this criterion.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Written Authority Required procedures |
| C16829 | P16829 | CN16829 | Ustekinumab | Complex refractory Fistulising Crohn diseaseInitial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)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; ANDPatient must have an externally draining enterocutaneous or rectovaginal fistula.Must be treated by a gastroenterologist (code 87). orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].Applications for authorisation must be made in writing and must include:(1) details of the two proposed prescriptions; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorisedWhere fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. | Compliance with Written Authority Required procedures |
| C16832 | P16832 | CN16832 | Ustekinumab | Severe chronic plaque psoriasisInitial 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; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and(ii) details of prior biological treatment, including dosage, date and duration of treatment.If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C16835 | P16835 | CN16835 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment, Whole bodyPatient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as:A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.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 16835 |
| C16836 | P16836 | CN16836 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment, Whole bodyPatient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as:A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current 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 4 weeks 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 Services Australia no later than 4 weeks 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 |
| C16838 | P16838 | CN16838 | Ustekinumab | Severe chronic plaque psoriasisInitial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 yearsMust be treated by a dermatologist.Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; ANDThe condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; orThe condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; ANDPatient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; orThe 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; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be under 18 years of age.The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |
| C16853 | P16853 | CN16853 | Foslevodopa with foscarbidopa | Advanced Parkinson diseaseMust be treated by a specialist physician; orMust be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; ANDPatient must require continuous administration of foslevodopa without an overnight break. orPatient must require a total daily dose of more than 2,400 mg of foslevodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 16853 |
| C16854 | P16854 | CN16854 | Ustekinumab | Severe psoriatic arthritisSubsequent continuing treatmentMust be treated by a rheumatologist; ORMust 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; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.An adequate response to treatment is defined as:an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; andeither 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.If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 16854 |
| C16856 | P16856 | CN16856 | Ustekinumab | Severe psoriatic arthritisFirst continuing, Subsequent continuing treatment - balance of supplyMust be treated by a rheumatologist; orMust be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; ANDThe treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C16857 | P16857 | CN16857 | Ustekinumab | Severe chronic plaque psoriasisInitial 1 treatment (Face, hand, foot) - biological medicine-naive patientMust be treated by a dermatologist.Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; ANDPatient must have failed to achieve an adequate response to at least 2 of the following 3 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 or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be under 18 years of age.Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.Where intolerance to phototherapy, methotrexate and/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.Details of the accepted toxicities including severity can be found on the Services Australia website.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or(b) 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 1 month following cessation of the last pre-requisite therapyProvide in this authority application, and document in the patient's medical records, each of:(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;(iv) the dates that response assessments were determined.Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine. | Compliance with Written Authority Required procedures |
| C16862 | P16862 | CN16862 | Ustekinumab | Severe chronic plaque psoriasisFirst continuing treatment (Whole body) - treatment covering week 28 and onwardsMust be treated by a dermatologist.Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; ANDPatient must have demonstrated an adequate response to treatment; ANDPatient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).An 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. | Compliance with Written Authority Required procedures |
| C16863 | P16863 | CN16863 | Ustekinumab | Severe Crohn diseaseInitial treatment - Initial 1 (new patient)Must be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].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; ANDPatient 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; ANDPatient 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; orPatient 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; orPatient 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; ANDThe treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction; ANDPatient 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; orPatient 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; orPatient 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.Patient must be at least 18 years of age.Applications for authorisation must be made in writing and must include:(a) details of the two proposed prescriptions; 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.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorisedWhere fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.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 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.Details of the accepted toxicities including severity can be found on the Services Australia website.Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.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 |
| C16868 | P16868 | CN16868 | Ustekinumab | Severe chronic plaque psoriasisInitial 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; ANDPatient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; ANDThe 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; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.The most recent PASI assessment must be no more than 4 weeks old at the time of application.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.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 |
| C16881 | P16881 | CN16881 | Nivolumab with relatlimab | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ORPatient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be uveal melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.Patient must weigh 40 kg or more; ANDPatient must be at least 12 years of age.Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams. | Compliance with Authority Required procedures - Streamlined Authority Code 16881 |
| C16882 | P16882 | CN16882 | Foslevodopa with foscarbidopa | Advanced Parkinson diseaseMaintenance therapyThe treatment must have been commenced by a specialist physician; orThe treatment must have been commenced by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease; ANDPatient must have severe disabling motor fluctuations not adequately controlled by oral therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 16882 |
| C16883 | P16883 | CN16883 | Foslevodopa with foscarbidopa | Advanced Parkinson diseaseMust be treated by a specialist physician; orMust be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 16883 |
| C16885 | P16885 | CN16885 | Ustekinumab | Severe psoriatic arthritisInitial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)Must be treated by a rheumatologist; orMust 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; ANDPatient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; ANDThe condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; orThe condition must have a C-reactive protein (CRP) level greater than 15 mg per L; ANDThe 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; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.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) details of the proposed prescription; 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 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 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 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 |
| C16886 | P16886 | CN16886 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment (Whole body)Must be treated by a dermatologist.Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy; ORThe treatment must be in combination with methotrexate; ANDPatient 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 16886 |
| C16887 | P16887 | CN16887 | Ustekinumab | Severe chronic plaque psoriasisFirst continuing treatment (Face, hand, foot) - treatment covering week 28 and onwardsMust be treated by a dermatologist.Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; ANDPatient must have demonstrated an adequate response to treatment; ANDPatient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).An 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C16889 | P16889 | CN16889 | Ustekinumab | Severe Crohn diseaseFirst continuing treatmentMust be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient 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; orPatient 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; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.Applications for authorisation must be made in writing and must include:(a) details of the proposed prescription; 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 Services Australia 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.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 Services Australia 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 |
| C16890 | P16890 | CN16890 | Ustekinumab | Severe Crohn diseaseInitial 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); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; ANDThe treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.Patient must be at least 18 years of age.Applications for authorisation must be made in writing and must include:(a) details of the two proposed prescriptions; 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.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorisedWhere fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.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 Services Australia no later than 4 weeks from the date of completion of treatment.An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.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 |
| C16894 | P16894 | CN16894 | Ustekinumab | Severe chronic plaque psoriasisInitial 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; ANDPatient must not have received PBS-subsidised treatment with a biological medicine for this condition; ANDPatient 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 6 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; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib 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, deucravacitinib 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, deucravacitinib, 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:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:(i) the completed current 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].At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.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 |
| C16896 | P16896 | CN16896 | Ustekinumab | Severe chronic plaque psoriasisFirst continuing treatment, Whole bodyPatient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as:A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current 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 4 weeks 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.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 |
| C16899 | P16899 | CN16899 | Ustekinumab | Severe psoriatic arthritisInitial treatment - Initial 1 (new patient)Must be treated by a rheumatologist; orMust 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; ANDPatient 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; ANDPatient 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; orPatient 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; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.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; andeither(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) details of the proposed prescription; and(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.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 |
| C16900 | P16900 | CN16900 | Ustekinumab | Severe chronic plaque psoriasisInitial 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; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as:A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and(ii) details of prior biological treatment, including dosage, date and duration of treatment.If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C16901 | P16901 | CN16901 | Ustekinumab | Severe chronic plaque psoriasisInitial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 yearsMust be treated by a dermatologist.Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be under 18 years of age.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.Response to preceding supply: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.Change in therapy:If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:(i) there is an absence of an adequate response to that treatment; or(ii) there was an intolerance to that treatment; or(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned aboveRecommencing therapy:If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:(i) an absence of an adequate response; or(ii) an intolerance to that treatment; or(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C16909 | P16909 | CN16909 | Ustekinumab | Complex refractory Fistulising Crohn diseaseSubsequent continuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; ANDPatient must have demonstrated an adequate response to treatment with this drug.Must be treated by a gastroenterologist (code 87); ORMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; ORMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].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. | Compliance with Authority Required procedures - Streamlined Authority Code 16909 |
| C16910 | P16910 | CN16910 | Ustekinumab | Severe psoriatic arthritisInitial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in 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 supplyMust be treated by a rheumatologist; orMust be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; orPatient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; orPatient 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 28 weeks treatment; ANDThe treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C16911 | P16911 | CN16911 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment (Face, hand, foot)Must be treated by a dermatologist.Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy; ORThe treatment must be in combination with methotrexate; ANDPatient 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 16911 |
| C16913 | P16913 | CN16913 | Ustekinumab | Severe Crohn diseaseSubsequent continuing treatmentMust be treated by a gastroenterologist (code 87); ORMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; ORMust 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; ANDPatient 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; ORPatient 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; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.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.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 Services Australia 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 Authority Required procedures - Streamlined Authority Code 16913 |
| C16915 | P16915 | CN16915 | Ustekinumab | Moderate to severe ulcerative colitisFirst continuing treatmentMust be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient 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; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.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 conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.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 |
| C16916 | P16916 | CN16916 | Ustekinumab | Moderate to severe ulcerative colitisFirst continuing, Subsequent continuing treatment - balance of supplyMust be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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 first continuing treatment restriction to complete 24 weeks treatment; orPatient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment; ANDThe treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C16917 | P16917 | CN16917 | Ustekinumab | Moderate to severe ulcerative colitisInitial treatment - Initial 1 (new patient)Must be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].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; ANDPatient 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; orPatient 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; orPatient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 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; ANDPatient must have a Mayo clinic score greater than or equal to 6; orPatient 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); ANDThe treatment must not exceed a single dose to be administered at week 8 under this restriction.Patient must be at least 18 years of age.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:(i) the completed current Mayo clinic or partial Mayo clinic 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).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 or partial Mayo clinic score must be no more than 4 weeks old at the time of application.An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.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.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.A maximum of 16 weeks of treatment with this drug will be approved under this criterion.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. | Compliance with Written Authority Required procedures |
| C16918 | P16918 | CN16918 | Ustekinumab | Moderate to severe ulcerative colitisInitial 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); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; ANDThe treatment must not exceed a single dose to be administered at week 8 under this restriction.Patient must be at least 18 years of age.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:(i) the completed current Mayo clinic or partial Mayo clinic 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.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.An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.A patient 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.A maximum of 16 weeks of treatment with this drug will be approved under this criterion.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Written Authority Required procedures |
| C16919 | P16919 | CN16919 | Ustekinumab | Complex refractory Fistulising Crohn diseaseSubsequent continuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDPatient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; ANDPatient must have demonstrated an adequate response to treatment with this drug.Must be treated by a gastroenterologist (code 87). orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).An 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 most recent fistula assessment must be no more than 1 month old at the time of application.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. | Compliance with Written Authority Required procedures |
| C16920 | P16920 | CN16920 | Ustekinumab | Severe chronic plaque psoriasisInitial 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; ANDPatient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; ANDThe condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.The most recent PASI assessment must be no more than 4 weeks old at the time of application.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the 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 |
| C16922 | P16922 | CN16922 | Ustekinumab | Severe chronic plaque psoriasisInitial 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; ANDPatient must not have received PBS-subsidised treatment with a biological medicine for this condition; ANDPatient 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 6 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; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib 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, deucravacitinib 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, deucravacitinib, 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.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.The authority application must be made in writing and must include:(1) details of the proposed prescription(s); and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and(ii) details of 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 |
| C16924 | P16924 | CN16924 | Ustekinumab | Severe psoriatic arthritisSubsequent continuing treatmentMust be treated by a rheumatologist; orMust 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; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.An adequate response to treatment is defined as:an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; andeither 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) details of the proposed prescription; 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 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 a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C16925 | P16925 | CN16925 | Ustekinumab | Severe psoriatic arthritisFirst continuing treatmentMust be treated by a rheumatologist; orMust 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; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.An adequate response to treatment is defined as:an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; andeither 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) details of the proposed prescription; and(2) a completed Severe Psoriatic 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 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 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 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 |
| C16927 | P16927 | CN16927 | Ustekinumab | Severe chronic plaque psoriasisFirst continuing treatment, Face, hand, footPatient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.The authority application must be made in writing and must include:(a) details of the proposed prescription(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 4 weeks 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.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 |
| C16932 | P16932 | CN16932 | Abemaciclib | Early breast cancerThe treatment must be adjuvant to surgical resection; ANDPatient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; orPatient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; ANDThe condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug; ANDThe condition must be human epidermal growth factor receptor 2 (HER2) negative; ANDThe condition must be hormone receptor positive; ANDThe condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); ANDThe treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; ANDThe treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab, (iii) ribociclib.Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit.Retain all pathology imaging and investigative test results in the patient's medical records.PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C16933 | P16933 | CN16933 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 6 weekly treatment regimenPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ORPatient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 3 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 16933 |
| C16935 | P16935 | CN16935 | Nivolumab | Stage IIIB, IIIC, IIID or Stage IV malignant melanomaInitial treatmentThe treatment must be in addition to complete surgical resection; ANDPatient must have a WHO performance status of 1 or less; ANDPatient must not have received prior PBS-subsidised treatment for this condition; ANDThe treatment must commence within 12 weeks of complete resection; ANDPatient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.When nivolumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 240 mg every 3 weeks for 2 cycles (i.e., 1 repeat). When prescribed as a weight based or flat dose adjuvant regimen, patients must only receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment. | Compliance with Authority Required procedures |
| C16936 | P16936 | CN16936 | Ipilimumab | Stage III or Stage IV malignant melanomaInduction treatmentPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.Prescribed amounts must be consistent with the treatment protocol used for an individual patient.Prescribers may apply through this restriction for patients initiated on 80 mg every 3 weeks for 2 cycles (i.e., 1 repeat). Prescribers may also apply through this restriction when the condition progresses to unresectable/metastatic melanoma at the recommended dosing regimen.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 16936 |
| C16937 | P16937 | CN16937 | Ustekinumab | Severe psoriatic arthritisInitial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)Must be treated by a rheumatologist; orMust 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; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be at least 18 years of age.An adequate response to treatment is defined as:an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; andeither of the following:(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed 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 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 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 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 |
| C16938 | P16938 | CN16938 | Ustekinumab | Severe chronic plaque psoriasisInitial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 yearsMust be treated by a dermatologist.Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; ANDPatient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must not receive more than 28 weeks of treatment under this restriction.Patient must be under 18 years of age.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.Response to preceding supply: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.Change in therapy:If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:(i) there is an absence of an adequate response to that treatment; or(ii) there was an intolerance to that treatment; or(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned aboveRecommencing therapy:If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:(i) an absence of an adequate response; or(ii) an intolerance to that treatment; or(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C16943 | P16943 | CN16943 | Ustekinumab | Complex refractory Fistulising Crohn diseaseFirst continuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDPatient must have demonstrated an adequate response to treatment with this drug.Must be treated by a gastroenterologist (code 87). orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).An 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 most recent fistula assessment must be no more than 1 month old at the time of application.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. | Compliance with Written Authority Required procedures |
| C16944 | P16944 | CN16944 | Ustekinumab | Complex refractory Fistulising Crohn diseaseInitial 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; ANDPatient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.Must be treated by a gastroenterologist (code 87). orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. orMust be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.Applications for authorisation must be made in writing and must include:(1) details of the two proposed prescriptions; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:(i) 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.Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.The most recent fistula assessment must be no more than 4 weeks old at the time of application.A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorisedWhere fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. | Compliance with Written Authority Required procedures |
| C16945 | P16945 | CN16945 | Ustekinumab | Moderate to severe ulcerative colitisSubsequent continuing treatmentMust be treated by a gastroenterologist (code 87); ORMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; ORMust 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; ANDPatient 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; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.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.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 16945 |
| C16946 | P16946 | CN16946 | Ustekinumab | Severe Crohn diseaseSubsequent continuing treatmentMust be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient 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; orPatient 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; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.Applications for authorisation must be made in writing and must include:(a) details of the proposed prescription; 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 Services Australia 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.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 Services Australia 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 |
| C16950 | P16950 | CN16950 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 3 weekly treatment regimenPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ORPatient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 16950 |
| C16951 | P16951 | CN16951 | Foslevodopa with foscarbidopa | Advanced Parkinson diseaseMaintenance therapyThe treatment must have been commenced by a specialist physician; orThe treatment must have been commenced by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease; ANDPatient must have severe disabling motor fluctuations not adequately controlled by oral therapy; ANDPatient must require continuous administration of foslevodopa without an overnight break. orPatient must require a total daily dose of more than 2,400 mg of foslevodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 16951 |
| C16953 | P16953 | CN16953 | Durvalumab | Advanced, metastatic or recurrent endometrial carcinomaInitial treatment covering the first 6 treatment cyclesPatient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; ANDThe condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; ANDThe treatment must be initiated in combination with platinum-containing chemotherapy; ANDThe condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; ANDPatient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; ANDPatient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.Retain all pathology imaging and investigative test results in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 16953 |
| C16961 | P16961 | CN16961 | Nivolumab | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ORPatient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.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 16961 |
| C16962 | P16962 | CN16962 | Nivolumab | Stage IIIB, IIIC, IIID or Stage IV malignant melanomaContinuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDPatient must have undergone surgical resection; ANDPatient must not have experienced disease recurrence; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.When prescribed as a weight based or flat dose adjuvant regimen, patients must receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment. | Compliance with Authority Required procedures |
| C16967 | P16967 | CN16967 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment, Face, hand, footPatient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.The 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 16967 |
| C16968 | P16968 | CN16968 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment (Face, hand, foot)Must be treated by a dermatologist.Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).An 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C16969 | P16969 | CN16969 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment (Whole body)Must be treated by a dermatologist.Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy; orThe treatment must be in combination with methotrexate; ANDPatient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.The authority application must be made in writing and must include:(1) details of the proposed prescription; and(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).An 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. | Compliance with Written Authority Required procedures |
| C16972 | P16972 | CN16972 | Foslevodopa with foscarbidopa | Advanced Parkinson diseaseMust be treated by a specialist physician; orMust be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; ANDPatient must require continuous administration of foslevodopa without an overnight break. orPatient must require a total daily dose of more than 2,400 mg of foslevodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 16972 |
| C16973 | P16973 | CN16973 | Ustekinumab | Moderate to severe ulcerative colitisSubsequent continuing treatmentMust be treated by a gastroenterologist (code 87); orMust be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; orMust 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; ANDPatient 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; ANDPatient must not receive more than 24 weeks of treatment under this restriction.Patient must be at least 18 years of age.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 conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.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 |
| C16976 | P16976 | CN16976 | Ustekinumab | Severe chronic plaque psoriasisSubsequent continuing treatment, Face, hand, footPatient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; ANDPatient must have demonstrated an adequate response to treatment with this drug; ANDThe treatment must be as systemic monotherapy (other than methotrexate); ANDPatient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.Patient must be at least 18 years of age.Must be treated by a dermatologist.An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.The authority application must be made in writing and must include:(a) details of the proposed prescription(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 4 weeks 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 Services Australia no later than 4 weeks 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 |

[133] Schedule 5, entries for Abiraterone

insert in the column headed “Brand” after entry for the Brand “Abiraterone-Teva” (all instances): ZYRON

[134] Schedule 5, entries for Aciclovir

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Aciclovir | GRP-22959 | Eye ointment 30 mg per g, 4.5 g | Application to the eye | ViruPOSXOROX |
| Aciclovir | GRP-15446 | Tablet 200 mg | Oral | Aciclovir APOTEXAciclovir GHAciclovir SandozACICLOVIR-WGRAPO-AciclovirARX-ACICLOVIR |
| Aciclovir | GRP-19838 | Tablet 800 mg | Oral | Aciclovir SandozACICLOVIR-WGRAPO-AciclovirARX-ACICLOVIR |

[135] Schedule 5, entries for Dabigatran etexilate in each of the forms: Capsule 110 mg (as mesilate); and Capsule 150 mg (as mesilate)

insert in the column headed “Brand” after entry for the Brand “Dabigatran Sandoz”: Dabigatran Viatris

[136] Schedule 5, entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate)

insert in the column headed “Brand” after entry for the Brand “ARX-Dabigatran”: Dabigatran Viatris

[137] Schedule 5, after entry for Deferasirox *[GRP-28210]*

insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Denosumab | GRP-29945 | Injection 120 mg in 1.7 mL | Injection | WyostXgeva |
| Denosumab | GRP-29965 | Injection 60 mg in 1 mL pre-filled syringe | Injection | JubbontiProlia |

[138] Schedule 5, after entry for Doxycycline in the form Tablet 50 mg (as monohydrate)

insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Drospirenone with ethinylestradiol | GRP-29943 | Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets | Oral | IsabelleRosaleeYasminYelena |
| Drospirenone with ethinylestradiol | GRP-29944 | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets | Oral | BellaRosieYANA |
| Drospirenone with ethinylestradiol | GRP-29944 | Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets | Oral | Yaz |

[139] Schedule 5, entries for Escitalopram

insert in the column headed “Brand” after entry for the Brand “Escitalopram Sandoz” (all instances): ESCITALOPRAM-WGR

[140] Schedule 5, entry for Fentanyl in the form Transdermal patch 12.6 mg

omit from the column headed “Brand”: Durogesic 75

[141] Schedule 5, entry for Fentanyl in the form Transdermal patch 4.2 mg

omit from the column headed “Brand”: Durogesic 25

[142] Schedule 5, entry for Fentanyl in the form Transdermal patch 8.4 mg

omit from the column headed “Brand”: Durogesic 50

[143] Schedule 5, entry for Fentanyl in the form Transdermal patch 16.8 mg

omit from the column headed “Brand”: Durogesic 100

[144] Schedule 5, entry for Fentanyl in the form Transdermal patch 2.1 mg

omit from the column headed “Brand”: Durogesic 12

[145] Schedule 5, omit entry for Granisetron

[146] Schedule 5, entry for Hydromorphone in the form Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)

omit from the column headed “Form”: Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)
substitute: Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A)

[147] Schedule 5, entries for Isotretinoin in each of the forms: Capsule 10 mg; and Capsule 20 mg

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Isotretinoin | GRP-19867 | Capsule 10 mg | Oral | APO-IsotretinoinDermataneIsotretinoin GXIsotretinoin LupinISOTRETINOIN-WGROratane |
| Isotretinoin | GRP-22820 | Capsule 20 mg | Oral | APO-IsotretinoinDermataneIsotretinoin Dr.Reddy'sIsotretinoin GXIsotretinoin LupinISOTRETINOIN-WGROratanePharmacor IsotretinoinRoaccutane |

[148] Schedule 5, entry for Montelukast *[GRP-19556]*

omit from the column headed “Brand”: Montelukast Mylan

[149] Schedule 5, entries for Morphine

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Morphine | GRP-28497 | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A) | Oral | RA-Morph (NZ) |

[150] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23699]*

omit from the column headed “Brand”: Olmekar HCT 40/5/25

[151] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23700]*

omit from the column headed “Brand”: Olmekar HCT 40/10/12.5

[152] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23701]*

omit from the column headed “Brand”: Olmekar HCT 20/5/12.5

[153] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23703]*

omit from the column headed “Brand”: Olmekar HCT 40/5/12.5

[154] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23710]*

omit from the column headed “Brand”: Olmekar HCT 40/10/25

[155] Schedule 5, after entry for Olmesartan with hydrochlorothiazide *[GRP-21161]*

insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Omalizumab | GRP-29930 | Injection 75 mg in 0.5 mL single dose pre-filled pen | Injection | Xolair |
| Omalizumab | GRP-29930 | Injection 75 mg in 0.5 mL single dose pre-filled syringe | Injection | OmlycloXolair |
| Omalizumab | GRP-29934 | Injection 150 mg in 1 mL single dose pre-filled pen | Injection | Xolair |
| Omalizumab | GRP-29934 | Injection 150 mg in 1 mL single dose pre-filled syringe | Injection | Omlyclo |

[156] Schedule 5, entry for Paroxetine

omit from the column headed “Brand”: Noumed Paroxetine

[157] Schedule 5, entry for Rivaroxaban *[GRP-29164]*

insert in the column headed “Brand” after entry for the Brand “iXarola”: Relaban

[158] Schedule 5, entry for Rivaroxaban *[GRP-29173]*

insert in the column headed “Brand” after entry for the Brand “iXarola”: Relaban

[159] Schedule 5, entry for Rizatripatan in the form Tablet (orally disintegrating) 10 mg (as benzoate)

insert in the column headed “Brand” after entry for the Brand “RIXALT”: Rizatriptan-Au

[160] Schedule 5, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg

omit from the column headed “Brand”: Tenofovir APOTEX

[161] Schedule 5, entries for Tenofovir with emtricitabine

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Tenofovir with emtricitabine | GRP-21638 | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A) | Oral | Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) |

[162] Schedule 5, after entry for Ursodeoxycholic acid in the form Tablet 500 mg

insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ustekinumab | GRP-29946 | Solution for I.V. infusion 130 mg in 26 mL | Injection | StelaraSteqeyma |
| Ustekinumab | GRP-29948 | Injection 90 mg in 1 mL single use pre-filled syringe | Injection | StelaraSteqeyma |

[163] Schedule 5, entries for Varenicline

insert in the column headed “Brand” after entry for the Brand “VARENAPIX” (all instances): Varenicline Lupin