

**PB 33 of 2020**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 4)**

*National Health Act 1953*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Dated 29th April 2020

**THEA DANIEL**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Department of Health

1. **Name of Instrument**
2. This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 4)*.
3. This Instrument may also be cited as PB 33 of 2020.
4. **Commencement**

This Instrument commences on 1 May 2020.

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

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

Schedule 1 Amendments

1. Schedule 1, entry for Amoxicillin in the form Capsule 250 mg (as trihydrate)
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amoxicillin | Capsule 250 mg (as trihydrate) | Oral | a | Alphamox 250 | AF | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | AMILOXYN | RF | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxil | AS | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin AN | EA | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin Sandoz | SZ | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | APO-Amoxycillin | TX | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Cilamox | AL | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Alphamox 250 | AF | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | AMILOXYN | RF | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | Amoxil | AS | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | Amoxycillin AN | EA | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | Amoxycillin Sandoz | SZ | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | APO-Amoxycillin | TX | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |
|  |  |  | a | Cilamox | AL | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |

1. Schedule 1, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate)
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule 500 mg (as trihydrate) | Oral | a | Alphamox 500 | AF | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | AMILOXYN | RF | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxil | AS | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin AN | EA | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin generichealth 500 | GQ | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Amoxycillin Sandoz | SZ | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | APO-Amoxycillin | TX | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Cilamox | AL | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |
|  |  |  | a | Alphamox 500 | AF | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | AMILOXYN | RF | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | Amoxil | AS | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | Amoxycillin AN | EA | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | Amoxycillin generichealth 500 | GQ | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | Amoxycillin Sandoz | SZ | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | APO-Amoxycillin | TX | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |
|  |  |  | a | Cilamox | AL | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |

1. Schedule 1, entry for Amoxicillin in the form Tablet 1 g (as trihydrate)
   1. insert in numerical order in the column headed “Circumstances” (all instances): C10416
2. Schedule 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | a | AlphaClav Duo | AF | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AMCLAVOX DUO 500/125 | RW | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AMOXICLAV AMNEAL 500/125 | ED | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Amoxycillin/Clavulanic Acid 500/125 APOTEX | TY | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Amoxyclav AN 500/125 | EA | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | APO-Amoxycillin/ Clavulanic Acid 500/125 | TX | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Augmentin Duo | AS | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Curam Duo 500/125 | SZ | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Moxiclav Duo 500/125 | LN | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AlphaClav Duo | AF | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | AMCLAVOX DUO 500/125 | RW | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | AMOXICLAV AMNEAL 500/125 | ED | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Amoxycillin/Clavulanic Acid 500/125 APOTEX | TY | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Amoxyclav AN 500/125 | EA | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | APO-Amoxycillin/ Clavulanic Acid 500/125 | TX | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Augmentin Duo | AS | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Curam Duo 500/125 | SZ | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Moxiclav Duo 500/125 | LN | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |

1. Schedule 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | a | AlphaClav Duo Forte | AF | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AMCLAVOX DUO FORTE 875/125 | RW | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AMOXICLAV AMNEAL 875/125 | ED | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Amoxyclav AN 875/125 | EA | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AmoxyClav generichealth 875/125 | HQ | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | APO-Amoxycillin and Clavulanic Acid | TX | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Augmentin Duo forte | AS | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Clavam 875 mg/125 mg | CR | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Curam Duo Forte 875/125 | SZ | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Moxiclav Duo Forte 875/125 | LN | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AlphaClav Duo Forte | AF | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | AMCLAVOX DUO FORTE 875/125 | RW | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | AMOXICLAV AMNEAL 875/125 | ED | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | Amoxyclav AN 875/125 | EA | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | AmoxyClav generichealth 875/125 | HQ | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | APO-Amoxycillin and Clavulanic Acid | TX | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | Augmentin Duo forte | AS | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | Clavam 875 mg/125 mg | CR | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | Curam Duo Forte 875/125 | SZ | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |
|  |  |  | a | Moxiclav Duo Forte 875/125 | LN | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |

1. Schedule 1, entry for Benralizumab
   1. insert as first entry:

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

1. Schedule 1, after entry for Brexpiprazole in the form Tablet 4 mg
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Brigatinib | Pack containing 7 tablets 90 mg and 21 tablets 180 mg | Oral |  | Alunbrig | TK | MP | C10384 |  | 1 | 0 | 1 |  |  |
|  | Tablet 30 mg | Oral |  | Alunbrig | TK | MP | C7346 |  | 112 | 3 | 28 |  |  |
|  | Tablet 90 mg | Oral |  | Alunbrig | TK | MP | C7346 |  | 28 | 3 | 28 |  |  |
|  | Tablet 180 mg | Oral |  | Alunbrig | TK | MP | C7346 |  | 28 | 3 | 28 |  |  |

1. Schedule 1, after entry for Buprenorphine in the form Injection (modified release) 96 mg in 0.27 mL pre-filled syringe
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection (modified release) 100mg in 0.5 mL pre-filled syringe | Injection |  | Sublocade | IR | MP NP | C9212 |  | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. Schedule 1, after entry for Buprenorphine in the form Injection (modified release) 128 mg in 0.36 mL pre-filled syringe
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection (modified release) 300mg in 1.5 mL pre-filled syringe | Injection |  | Sublocade | IR | MP NP | C9212 |  | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. Schedule 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) *[Maximum Quantity: 40; Number of Repeats: 0]*
   1. omit from the column headed “Purposes” (all instances): P10316 substitute: P10412
   2. omit from the column headed “Maximum Quantity” (all instances): CN10316 substitute: CN10412
   3. omit from the column headed “Number of Repeats” (all instances): CN10316 substitute: CN10412
2. Schedule 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) *[Maximum Quantity: 40; Number of Repeats: 0]*
3. omit from the column headed “Purposes” (all instances): P10331 substitute: P10410
4. omit from the column headed “Maximum Quantity” (all instances): CN10331 substitute: CN10410
5. omit from the column headed “Number of Repeats” (all instances): CN10331 substitute: CN10410
6. Schedule 1, entry for Diltiazem in the form Tablet containing diltiazem hydrochloride 60 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Diltiazem Actavis | ED | MP NP |  |  | 90 | 5 | 90 |  |  |

1. Schedule 1, entry for Evolocumab in the form Injection 140 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]*
2. omit from the column headed “Circumstances”: C6597 C8064 C8078 C8094 C8108 substitute: C10343 C10358 C10370 C10377 C10379 C10380 C10385 C10388 C10389
3. omit from the column headed “Purposes”: P8064 P8078 P8108 substitute: P10343 P10358 P10377 P10379 P10385 P10389
4. Schedule 1, entry for Evolocumab in the form Injection 140 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 3; Number of Repeats: 5]*
5. omit from the column headed “Circumstances”: C6597 C8064 C8078 C8094 C8108 substitute: C10343 C10358 C10370 C10377 C10379 C10380 C10385 C10388 C10389
6. omit from the column headed “Purposes”: P6597 P8094 substitute: P10370 P10380 P10388
7. Schedule 1, entry for Evolocumab in the form Injection 420 mg in 3.5 mL single use pre-filled cartridge

omit from the column headed “Circumstances”: C6597 C8064 C8078 C8094 C8108 substitute: C10343 C10358 C10370 C10377 C10379 C10380 C10385 C10388 C10389

1. Schedule 1, entry for Fluticasone propionate with salmeterol in the form Pressurised inhalation containing fluticasone propionate 125micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Seroflo 125/25 | YC | MP NP | C4930 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, entry for Fluticasone propionate with salmeterol in the form Pressurised inhalation containing fluticasone propionate 250micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Seroflo 250/25 | YC | MP NP | C4930 C10121 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, entry for Folinic acid
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection containing calcium folinate equivalent to 1000 mg folinic acid in 100 mL | Injection |  | Calcium Folinate Ebewe | SZ | MP |  |  | 1 | 1 | 1 |  |  |

1. Schedule 1, entry for Furosemide in the form Injection 20 mg in 2 mL
2. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Frusemide-Claris | BX | MP NP |  |  | 5 | 0 | 5 |  |  |

1. omit from the column headed “Schedule Equivalent” for the brand “Lasix”: **a**
2. Schedule 1, entry for Hydroxychloroquine
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hydroxychloroquine | Tablet containing hydroxychloroquine sulfate 200mg | Oral | a | APO- Hydroxychloroquine | TX | MP | C10417 C10418 C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  |  |  |  | NP | C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  | a | Hequinel | RW | MP | C10417 C10418 C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  |  |  |  | NP | C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  | a | Hydroxychloroquine AN | EA | MP | C10417 C10418 C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  |  |  |  | NP | C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  | a | Hydroxychloroquine GH | GQ | MP | C10417 C10418 C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  |  |  |  | NP | C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  | a | Plaquenil | SW | MP | C10417 C10418 C10419 C10420 |  | 100 | 1 | 100 |  |  |
|  |  |  |  |  |  | NP | C10419 C10420 |  | 100 | 1 | 100 |  |  |

1. Schedule 1, entry for Lapatinib
2. omit from the column headed “Circumstances”: C9544
3. insert in numerical order in the column headed “Circumstances”: C10394
4. Schedule 1, entry for Levodopa with carbidopa in the form Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100mL | Intra-intestinal |  | Duodopa | VE | MP NP | C10197 C10386 | P10197 | 28 | 5 | 7 |  |  |
|  |  |  |  |  |  | MP | C10138 C10161 C10363 C10375 | P10138 P10161 | 28 | 5 | 7 |  | C(100) |
|  |  |  |  |  |  | MP NP | C10197 C10386 | P10386 | 56 | 5 | 7 |  |  |
|  |  |  |  |  |  | MP | C10138 C10161 C10363 C10375 | P10363 P10375 | 56 | 5 | 7 |  | C(100) |

1. Schedule 1, entry for Mirtazapine in the form Tablet 15 mg (orally disintegrating)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | MIRTANZA ODT | RF | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Mirtazapine in the form Tablet 30 mg (orally disintegrating)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | MIRTANZA ODT | RF | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Mirtazapine in the form Tablet 45 mg (orally disintegrating)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | MIRTANZA ODT | RF | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Lukair | AL | MP NP | C6666 |  | 28 | 5 | 28 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Singulair | AF | MP NP | C6666 |  | 28 | 5 | 28 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Lukair | AL | MP NP | C6674 C7781 |  | 28 | 5 | 28 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Singulair | AF | MP NP | C6674 C7781 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Naloxone in the form Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule
   1. omit from the column headed “Schedule Equivalent” for the brand “NARCAN”: a
2. Schedule 1, entry for Nystatin
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Cream 100,000 units per g, 15 g | Application |  | Mycostatin | LN | MP NP | C6434 |  | 2 | 3 | 1 |  |  |

1. Schedule 1, entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 20/5 | CR | MP NP | C4373 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/5 | CR | MP NP | C4373 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (asbesilate)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/10 | CR | MP NP | C4373 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Pasireotide in each of the forms: Injection (modified release) 20 mg (as embonate), vial and diluent syringe; Injection (modified release) 40 mg (as embonate), vial and diluent syringe; and Injection (modified release) 60 mg (as embonate), vial and diluent syringe
   1. omit from the column headed “Responsible Person”: **NV** substitute: **RJ**
2. Schedule 1, entry for Pertuzumab
3. omit from the column headed “Circumstances”: C9517 C9579
4. insert in numerical order in the column headed “Circumstances”: C10414
5. Schedule 1, entry for Rituximab in the form Solution for subcutaneous injection containing rituximab 1400 mg in 11.7 mL
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Solution for subcutaneous injection containing rituximab 1400 mg in 11.7 mL | Injection |  | Mabthera SC | RO | MP | C6011 C6161 C7399 C7400 C10227 | P10227 | 1 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP | C6011 C6161 C7399 C7400 C10227 | P7399 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6011 C6161 C7399 C7400 C10227 | P7400 | 1 | 6 | 1 |  |  |
|  |  |  |  |  |  | MP | C6011 C6161 C7399 C7400 C10227 | P6011 | 1 | 7 | 1 |  |  |
|  |  |  |  |  |  | MP | C6011 C6161 C7399 C7400 C10227 | P6161 | 1 | 11 | 1 |  |  |

1. Schedule 1, entry for Roxithromycin
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Roxithromycin | Tablet for oral suspension 50 mg | Oral |  | Rulide D | SW | PDP MP NP |  |  | 10 | 0 | 10 |  |  |
|  | Tablet 150 mg | Oral | a | APO-Roxithromycin | TX | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Biaxsig | AV | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Chem mart Roxithromycin | CH | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Roxar 150 | RW | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Roximycin | AF | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Roxithromycin AN | EA | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Roxithromycin Sandoz | SZ | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Roxithromycin-GA | ED | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Rulide | SW | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Terry White Chemists Roxithromycin | TW | MP NP PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  | a | APO-Roxithromycin | TX | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Biaxsig | AV | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Chem mart Roxithromycin | CH | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Roxar 150 | RW | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Roximycin | AF | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Roxithromycin AN | EA | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Roxithromycin Sandoz | SZ | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Roxithromycin-GA | ED | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Rulide | SW | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  |  |  | a | Terry White Chemists Roxithromycin | TW | MP NP |  | P10404 | 20 CN10404 | 0 CN10404 | 10 |  |  |
|  | Tablet 300 mg | Oral | a | APO-Roxithromycin | TX | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Biaxsig | AV | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Chem mart Roxithromycin | CH | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Roxar 300 | RW | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Roximycin | AF | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Roxithromycin AN | EA | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Roxithromycin Sandoz | SZ | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Roxithromycin-GA | ED | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Rulide | SW | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | Terry White Chemists Roxithromycin | TW | MP NP PDP |  |  | 5 | 0 | 5 |  |  |
|  |  |  | a | APO-Roxithromycin | TX | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Biaxsig | AV | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Chem mart Roxithromycin | CH | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Roxar 300 | RW | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Roximycin | AF | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Roxithromycin AN | EA | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Roxithromycin Sandoz | SZ | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Roxithromycin-GA | ED | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Rulide | SW | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |
|  |  |  | a | Terry White Chemists Roxithromycin | TW | MP NP |  | P10404 | 10 CN10404 | 0 CN10404 | 5 |  |  |

1. Schedule 1, entry for Sapropterin
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sapropterin | Powder for oral solution 500 mg (as dihydrochloride) | Oral |  | Kuvan | IO | MP | C8898 C8926 C10355 C10364 C10391 | P8898 P10391 | 30 | 0 | 30 |  |  |
|  |  |  |  |  |  | MP | C8898 C8926 C10355 C10364 C10391 | P8926 P10355 P10364 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8926 C10355 C10364 |  | 30 | 5 | 30 |  |  |
|  | Tablet (soluble) containing sapropterin dihydrochloride 100mg | Oral |  | Kuvan | IO | MP | C8898 C8926 C10076 C10364 C10390 | P8898 | 90 | 0 | 30 |  |  |
|  |  |  |  |  |  | MP | C8898 C8926 C10076 C10364 C10390 | P10076 | 180 | 0 | 30 |  |  |
|  |  |  |  |  |  | MP | C8898 C8926 C10076 C10364 C10390 | P8926 P10364 P10390 | 180 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8926 C10364 C10390 |  | 180 | 5 | 30 |  |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 80 mg
2. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Lipex 80 | AL | MP NP |  |  | 30 | 5 | 30 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Zocor | MQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Lipex 80 | AL | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Zocor | MQ | MP |  | P7598 | 30 | 11 | 30 |  |  |

1. Schedule 1, entry for Tenofovir
   1. substitute:

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

1. Schedule 1, entry for Trastuzumab in each of the forms: Powder for I.V. infusion 60 mg; and Powder for I.V. infusion 150 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Trazimera | PF | MP | C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296 |  | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. Schedule 1, entry for Trastuzumab emtansine in each of the forms: Powder for I.V. infusion 100 mg; and Powder for I.V. infusion 160 mg
   1. omit from the column headed “Circumstances”: C9577
2. Schedule 1, after entry for Umeclidinium with vilanterol
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Upadacitinib | Tablet 15 mg | Oral |  | Rinvoq | VE | MP | C8638 C8680 C10340 C10341 C10356 C10376 C10393 | P8638 P10340 P10376 P10393 | 28 | 3 | 28 |  |  |
|  |  |  |  |  |  | MP | C8638 C8680 C10340 C10341 C10356 C10376 C10393 | P8680 P10341 P10356 | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride) *[Maximum Quantity: 20; Number of Repeats: 0]*
   1. insert in numerical order in the column headed “Circumstances” for the brand “Valaciclovir Sandoz”: C5940
2. Schedule 1, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride) *[Maximum Quantity: 30; Number of Repeats: 5]*
3. insert in numerical order in the column headed “Circumstances” for the brand “Valaciclovir Sandoz”: C5940
4. insert in numerical order in the column headed “Purposes” for the brand “Valaciclovir Sandoz”: P5940
5. Schedule 1, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride) *[Maximum Quantity: 42; Number of Repeats: 0]*
   1. insert in numerical order in the column headed “Circumstances” for the brand “Valaciclovir Sandoz”: C5940
6. Schedule 4, Part 1, entry for Amoxicillin
7. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P10326 | CN10326 | Infection Patient must be a male with acute cystitis; OR Patient must have pyelonephritis; OR Patient must have a tooth avulsion; OR Patient must have salmonella enteritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy following initial intravenous antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10326 |

1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P10402 | CN10402 | Infection Patient must be a male with acute cystitis; OR Patient must have pyelonephritis; OR Patient must have a tooth avulsion; OR Patient must have salmonella enteritis; OR Patient must have community acquired pneumonia; OR Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10402 |
|  |  | P10404 | CN10404 | Infection Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10404 |
|  | C10416 |  |  | Community acquired pneumonia Patient must have community acquired pneumonia. | Compliance with Authority Required procedures - Streamlined Authority Code 10416 |

1. Schedule 4, Part 1, entry for Amoxicillin with clavulanic acid
2. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10302 | P10302 |  | Infection Patient must have periorbital (preseptal) cellulitis; OR Patient must have postpartum endometritis; OR Patient must have an exacerbation of bronchiectasis; OR Patient must have pyelonephritis; OR Patient must have pneumonia acquired in hospital or aged care; OR Patient must have a diabetic foot infection; OR Patient must have a condition requiring prolonged oral antibiotic therapy following initial intravenous antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10302 |
|  | C10319 | P10319 |  | Acute cystitis Patient must be a male with acute cystitis. | Compliance with Authority Required procedures - Streamlined Authority Code 10319 |

1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10405 | P10405 |  | Infection Patient must be a male with acute cystitis; OR Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10405 |
|  | C10413 | P10413 |  | Infection Patient must have periorbital (preseptal) cellulitis; OR Patient must have postpartum endometritis; OR Patient must have an exacerbation of bronchiectasis; OR Patient must have pyelonephritis; OR Patient must have pneumonia acquired in hospital or aged care; OR Patient must have a diabetic foot infection; OR Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10413 |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Brigatinib | C7346 |  |  | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
|  | C10384 |  |  | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Cefalexin
2. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P10316 | CN10316 | Infection Patient must have impaired renal function; AND Patient must have a pin-site infection; OR Patient must have an infection following cardiac device insertion; OR Patient must have acute otitis externa; OR Patient must have streptococcal pharyngitis or tonsillitis; OR Patient must have mastitis; OR Patient must have periorbital (preseptal) cellulitis; OR Patient must have acute rheumatic fever; OR Patient must have a diabetic foot infection; OR Patient must have a widespread infection of dermatitis; OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR Patient must have impetigo; OR Patient must have pyelonephritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy following initial intravenous antibiotic therapy. Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function. | Compliance with Authority Required procedures - Streamlined Authority Code 10316 |
|  |  | P10331 | CN10331 | Infection Patient must have a pin-site infection; OR Patient must have an infection following cardiac device insertion; OR Patient must have acute otitis externa; OR Patient must have streptococcal pharyngitis or tonsillitis; OR Patient must have mastitis; OR Patient must have periorbital (preseptal) cellulitis; OR Patient must have acute rheumatic fever; OR Patient must have a diabetic foot infection; OR Patient must have a widespread infection of dermatitis; OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR Patient must have impetigo; OR Patient must have pyelonephritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy following initial intravenous antibiotic therapy. Midwives may prescribe under this item for the treatment of mastitis only. | Compliance with Authority Required procedures - Streamlined Authority Code 10331 |

1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P10410 | CN10410 | Infection Patient must have a pin-site infection; OR Patient must have an infection following cardiac device insertion; OR Patient must have acute otitis externa; OR Patient must have streptococcal pharyngitis or tonsillitis; OR Patient must have mastitis; OR Patient must have periorbital (preseptal) cellulitis; OR Patient must have acute rheumatic fever; OR Patient must have a diabetic foot infection; OR Patient must have a widespread infection of dermatitis; OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR Patient must have impetigo; OR Patient must have pyelonephritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy. Midwives may prescribe under this item for the treatment of mastitis only. | Compliance with Authority Required procedures - Streamlined Authority Code 10410 |
|  |  | P10412 | CN10412 | Infection Patient must have impaired renal function; AND Patient must have a pin-site infection; OR Patient must have an infection following cardiac device insertion; OR Patient must have acute otitis externa; OR Patient must have streptococcal pharyngitis or tonsillitis; OR Patient must have mastitis; OR Patient must have periorbital (preseptal) cellulitis; OR Patient must have acute rheumatic fever; OR Patient must have a diabetic foot infection; OR Patient must have a widespread infection of dermatitis; OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR Patient must have impetigo; OR Patient must have pyelonephritis; OR Patient must have a condition requiring prolonged oral antibiotic therapy. Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function. | Compliance with Authority Required procedures - Streamlined Authority Code 10412 |

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

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| Evolocumab | C10343 | P10343 |  | Non-familial hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have symptomatic atherosclerotic cardiovascular disease; AND Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre; AND Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher | Compliance with Authority Required procedures |
|  | C10358 | P10358 |  | Non-familial hypercholesterolaemia Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
|  | C10370 | P10370 |  | Familial homozygous hypercholesterolaemia Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information. Must be treated by a specialist physician. The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |
|  | C10377 | P10377 |  | Familial heterozygous hypercholesterolaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in conjunction with dietary therapy and exercise. | Compliance with Authority Required procedures - Streamlined Authority Code 10377 |
|  | C10379 | P10379 |  | Familial heterozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. | Compliance with Authority Required procedures |
|  | C10380 | P10380 |  | Familial homozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7; AND Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information. Must be treated by a specialist physician. The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information | Compliance with Authority Required procedures |
|  | C10385 | P10385 |  | Non-familial hypercholesterolaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in conjunction with dietary therapy and exercise. | Compliance with Authority Required procedures - Streamlined Authority Code 10385 |
|  | C10388 | P10388 |  | Familial homozygous hypercholesterolaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in conjunction with dietary therapy and exercise. | Compliance with Authority Required procedures - Streamlined Authority Code 10388 |
|  | C10389 | P10389 |  | Familial heterozygous hypercholesterolaemia Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | Compliance with Authority Required procedures |

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

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| Hydroxychloroquine | C10417 |  |  | Autoimmune disorder  Initial treatment  The treatment must be authorised by a medical practitioner who is recognised under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in dermatology, intensive care medicine, paediatrics and child health, physician, or emergency medicine; AND  Patient must have an autoimmune disorder. | Compliance with Authority Required procedures - Streamlined Authority Code 10417 |
|  | C10418 |  |  | Malaria  Initial treatment  The treatment must be authorised by a medical practitioner who is recognised under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in dermatology, intensive care medicine, paediatrics and child health, physician, or emergency medicine; AND  Patient must require treatment of acute attack; OR  Patient must require suppressive therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10418 |
|  | C10419 |  |  | Autoimmune disorder  Continuing treatment  Patient must have previously been treated with PBS-subsidised therapy with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10419 |
|  | C10420 |  |  | Malaria  Continuing treatment  Patient must have previously been treated with PBS-subsidised therapy with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10420 |

1. Schedule 4, Part 1, entry for Lapatinib
2. omit:

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|  | C9544 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion; AND The treatment must be in combination with capecitabine; AND Patient must have received prior therapy with a taxane for at least 3 cycles; OR Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; AND The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease; (ii) date of last treatment with a taxane and total number of cycles; (iii) dates of treatment with trastuzumab and pertuzumab; and (iv) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | Compliance with Written Authority Required procedures |

1. insert in numerical order after existing text:

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|  | C10394 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion; AND The treatment must be in combination with capecitabine; AND Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; OR Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; AND The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and (ii) date of last treatment with a taxane and total number of cycles; or (iii) dates of treatment with trastuzumab and pertuzumab; or (iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or (v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Levodopa with carbidopa
2. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10136 | P10136 |  | Advanced Parkinson disease Maintenance therapy Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND Patient must have been commenced on treatment in a hospital-based movement disorder clinic; AND Patient must be undergoing continuous treatment with a dose greater than 2000 mg of levodopa per day without an overnight break. | Compliance with Authority Required procedures - Streamlined Authority Code 10136 |

1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10160 | P10160 |  | Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must be undergoing continuous treatment with a dose greater than 2000 mg of levodopa per day without an overnight break. | Compliance with Authority Required procedures - Streamlined Authority Code 10160 |

1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10169 | P10169 |  | Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must be undergoing continuous treatment with a dose greater than 2000 mg of levodopa per day without an overnight break. | Compliance with Authority Required procedures - Streamlined Authority Code 10169 |

1. insert in numerical order after existing text:

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| --- | --- | --- | --- | --- | --- |
|  | C10363 | P10363 |  | Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10363 |
|  | C10375 | P10375 |  | Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10375 |
|  | C10386 | P10386 |  | Advanced Parkinson disease Maintenance therapy Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND Patient must have been commenced on treatment in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10386 |

1. Schedule 4, Part 1, omit entry for Nystatin
2. Schedule 4, Part 1, entry for Pertuzumab
3. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C9517 |  |  | HER2 positive breast cancer Grandfathering treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; OR Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015; AND Patient must not have received non-PBS-subsidised treatment with trastuzumab for this condition before 1 July 2014; AND Patient must not have received prior therapy with trastuzumab emtansine or lapatinib for this condition; AND The treatment must be in combination with trastuzumab; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Authority applications for treatment must be made in writing and must include a completed authority prescription form. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA) during treatment. | Compliance with Written Authority Required procedures |
|  | C9579 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be in combination with trastuzumab; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one continuous course. However, short treatment breaks are permitted. A patient who has a treatment break of less than 6 weeks in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug. A patient who has a treatment break of more than 6 weeks in PBS-subsidised treatment with this drug is not eligible to receive PBS-subsidised treatment with this drug. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment. | Compliance with Authority Required procedures |

1. insert in numerical order after existing text:

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| --- | --- | --- | --- | --- | --- |
|  | C10414 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be in combination with trastuzumab; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one course. However, treatment breaks are permitted. A patient who has a treatment break in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment. | Compliance with Authority Required procedures |

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

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| --- | --- | --- | --- | --- | --- |
| Roxithromycin |  | P10404 | CN10404 | Infection Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10404 |

1. Schedule 4, Part 1, entry for Sapropterin
2. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C8897 | P8897 |  | Hyperphenylalaninemia (HPA) due to phenylketonuria (PKU) Subsequent continuing Must be treated by a metabolic physician; OR Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition under the Grandfather treatment restriction; AND Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications. Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. | Compliance with Authority Required procedures |

1. omit from the text in the column headed “Circumstances and Purposes” for the circumstances code “C8898”: Hyperphenylalaninemia substitute:Hyperphenylalaninaemia
2. omit from the text in the column headed “Circumstances and Purposes” for the circumstances code “C8926”: Hyperphenylalaninemia substitute:Hyperphenylalaninaemia
3. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C8988 | P8988 |  | Hyperphenylalaninemia (HPA) due to phenylketonuria (PKU) Grandfather treatment Must be treated by a metabolic physician; OR Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician. Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019; AND Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing; AND Patient must have a documented diagnosis of PKU. Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. Blood phenylalanine levels must be based on measurements taken during stable periods of the condition. Dietary phenylalanine intake must be maintained at a constant level. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the Subsequent continuing treatment criteria. | Compliance with Authority Required procedures |

1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10081 | P10081 |  | Hyperphenylalaninaemia Continuing treatment Must be treated by a metabolic physician; OR Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND Patient must have previously been issued with an authority prescription for this drug; OR Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |

1. insert in numerical order after existing text:

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| --- | --- | --- | --- | --- | --- |
|  | C10355 | P10355 |  | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency Continuing treatment Must be treated by a metabolic physician; OR Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
|  | C10364 | P10364 |  | Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) Subsequent continuing Must be treated by a metabolic physician; OR Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications. Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. | Compliance with Authority Required procedures |
|  | C10390 | P10390 |  | Hyperphenylalaninaemia Continuing treatment Must be treated by a metabolic physician; OR Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
|  | C10391 | P10391 |  | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency Initial treatment Must be treated by a metabolic physician. Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Tenofovir
2. insert in the column headed “Purposes Code” for the circumstances code “C6980”: P6980
3. insert in the column headed “Purposes Code” for the circumstances code “C6982”: P6982
4. insert in the column headed “Purposes Code” for the circumstances code “C6983”: P6983
5. insert in the column headed “Purposes Code” for the circumstances code “C6984”: P6984
6. insert in the column headed “Purposes Code” for the circumstances code “C6992”: P6992
7. insert in the column headed “Purposes Code” for the circumstances code “C6998”: P6998
8. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10362 | P10362 |  | Chronic hepatitis B infection Patient must be in the third trimester of pregnancy; AND Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection. | Compliance with Authority Required procedures - Streamlined Authority Code 10362 |

1. Schedule 4, Part 1, entry for Trastuzumab emtansine
   1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C9577 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Grandfathering treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; OR Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015; OR Patient must have received PBS-subsidised lapatinib for this condition before 1 July 2015; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be as monotherapy; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Authority applications for treatment must be made in writing and must include a completed authority prescription form. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA) during treatment. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, after entry for Umeclidinium with vilanterol
   1. insert:

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| --- | --- | --- | --- | --- | --- |
| Upadacitinib | C8638 | P8638 |  | Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
|  | C8680 | P8680 |  | Severe active rheumatoid arthritis Continuing and Initial Grandfathered patients treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial treatment - Grandfathered patients; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Patient must be aged 18 years or older. | Compliance with Authority Required procedures |
|  | C10340 | P10340 |  | Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must 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 determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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. | Compliance with Written Authority Required procedures |
|  | C10341 | P10341 |  | Severe active rheumatoid arthritis Initial treatment - Grandfathered patients Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 May 2020; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) prior to initiating non-PBS-subsidised treatment with this drug for this condition. This must have included at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must have been methotrexate at a dose of at least 20 mg weekly and one of which must have been: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs prior to initiating non-PBS-subsidised treatment with this drug for this condition. If methotrexate was contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or could not be tolerated at a 20 mg weekly dose, this intensive treatment must have included at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs prior to initiating non-PBS-subsidised treatment with this drug for this condition. If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine were contraindicated according to the relevant TGA-approved Product Information or could not be tolerated at the doses specified above, the intensive treatment must have included at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs used in place of the DMARDS which were contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to have achieved an adequate response to DMARD treatment prior to initiating non-PBS-subsidised treatment with this drug for this condition: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must 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 determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. | Compliance with Written Authority Required procedures |
|  | C10356 | P10356 |  | Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must 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 determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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 has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C10376 | P10376 |  | Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted 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. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must 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 determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. | Compliance with Written Authority Required procedures |
|  | C10393 | P10393 |  | Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment 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 and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must 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 determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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. | Compliance with Written Authority Required procedures |