

PB 111 of 2024

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

National Health Act 1953

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

Dated 30 October 2024

**NIKOLAI TSYGANOV**  
Assistant Secretary  
Pricing and PBS Policy Branch  
Technology Assessment and Access Division

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1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (November Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 111 of 2024.

2. Commencement

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

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

Note: This table relates only to the provisions of this instrument as originally made.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

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

3. Authority

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

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

[1] Schedule 1, Part 1, entries for Amiodarone in the form Tablet containing amiodarone hydrochloride 100 mg

omit from the column headed “Circumstances” (all instances): C5665 substitute (all instances): C15967

[2] Schedule 1, Part 1, entries for Amiodarone in the form Tablet containing amiodarone hydrochloride 200 mg

**(a)** omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amiodarone | Tablet containing amiodarone hydrochloride 200 mg | Oral | APO-Amiodarone | TX | MP NP | C5665 |  | 30 | 5 |  | 30 |  |  |

**(b)** omit from the column headed “Circumstances” (all instances): C5665 substitute (all instances): C15967

[3] Schedule 1, Part 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 10 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amitriptyline | Tablet containing amitriptyline hydrochloride 10 mg | Oral | APO-Amitriptyline 10 | TX | MP NP |  |  | 50 | 2 |  | 50 |  |  |

[4] Schedule 1, Part 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amitriptyline | Tablet containing amitriptyline hydrochloride 25 mg | Oral | APO-Amitriptyline 25 | TX | MP NP |  |  | 50 | 2 |  | 50 |  |  |

[5] Schedule 1, Part 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amitriptyline | Tablet containing amitriptyline hydrochloride 50 mg | Oral | APO-Amitriptyline 50 | TX | MP NP |  |  | 50 | 2 |  | 50 |  |  |

[6] Schedule 1, Part 1, entry for Amlodipine in the form Tablet 5 mg (as besilate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amlodipine | Tablet 5 mg (as besilate) | Oral | BTC Amlodipine | JB | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Amlodipine | Tablet 5 mg (as besilate) | Oral | BTC Amlodipine | JB | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[7] Schedule 1, Part 1, entry for Amlodipine in the form Tablet 10 mg (as besilate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Amlodipine | Tablet 10 mg (as besilate) | Oral | BTC Amlodipine | JB | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Amlodipine | Tablet 10 mg (as besilate) | Oral | BTC Amlodipine | JB | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[8] Schedule 1, Part 1, entries for Anastrozole

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Anastrozole | Tablet 1 mg | Oral | Anastrozole GH | GQ | MP NP | C5522 | P5522 | 30 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | Anastrozole GH | GQ | MP NP | C14895 | P14895 | 60 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | Anastrozole Sandoz | SZ | MP NP | C5522 | P5522 | 30 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | Anastrozole Sandoz | SZ | MP NP | C14895 | P14895 | 60 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | ANASTROZOLE-WGR | WG | MP NP | C5522 | P5522 | 30 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | ANASTROZOLE-WGR | WG | MP NP | C14895 | P14895 | 60 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | APO‑Anastrozole | TX | MP NP | C5522 | P5522 | 30 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | APO‑Anastrozole | TX | MP NP | C14895 | P14895 | 60 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | Arianna 1 | AF | MP NP | C5522 | P5522 | 30 | 5 |  | 30 |  |  |
| Anastrozole | Tablet 1 mg | Oral | Arianna 1 | AF | MP NP | C14895 | P14895 | 60 | 5 |  | 30 |  |  |

[9] Schedule 1, Part 1, entry for Apixaban in the form Tablet 2.5 mg [Maximum Quantity: 120; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14308

**(b)** insert in numerical order in the column headed “Circumstances”: C14301

**(c)** omit from the column headed “Purposes”: P14308

**(d)** insert in numerical order in the column headed “Purposes”: P14301

[10] Schedule 1, Part 1, entry for Apixaban in the form Tablet 5 mg [Maximum Quantity: 60; Number of Repeats: 5]

**(a)** insert in numerical order in the column headed “Circumstances”: C4268

**(b)** omit from the column headed “Circumstances”: C5083

**(c)** insert in numerical order in the column headed “Purposes”: P4268

**(d)** omit from the column headed “Purposes”: P5083

[11] Schedule 1, Part 1, entry for Apixaban in the form Tablet 5 mg [Maximum Quantity: 120; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14302 C14308

**(b)** insert in numerical order in the column headed “Circumstances”: C14301 C14318

**(c)** omit from the column headed “Purposes”: P14302 P14308

**(d)** insert in numerical order in the column headed “Purposes”: P14301 P14318

[12] Schedule 1, Part 1, entry for Atenolol in the form Tablet 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atenolol | Tablet 50 mg | Oral | APO-Atenolol | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atenolol | Tablet 50 mg | Oral | APO-Atenolol | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[13] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 10 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 10 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 10 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[14] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 20 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 20 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 20 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[15] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 40 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 40 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 40 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[16] Schedule 1, Part 1, entry for Atorvastatin in the form Tablet 80 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 80 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 80 mg (as calcium) | Oral | Blooms the Chemist Atorvastatin | IB | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[17] Schedule 1, Part 1, entries for Atropine in the form Injection containing atropine sulfate monohydrate 600 micrograms in 1 mL

omit from the column headed “Brand” (all instances): Atropine Injection (Pfizer) substitute (all instances): Atropine Injection (Bridgewest)

[18] Schedule 1, Part 1, entry for Auranofin in each of the forms: Capsule 3 mg; and Tablet 3 mg

insert in the column headed “Circumstances”: C15956

[19] Schedule 1, Part 1, entry for Avelumab

**(a)** omit from the column headed “Circumstances”: C8947 C10023

**(b)** insert in numerical order in the column headed “Circumstances”: C16053 C16085

[20] Schedule 1, Part 1, entries Azacitidine in each of the forms: Tablet 200 mg; and Tablet 300 mg

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[21] Schedule 1, Part 1, fourth entry for Bimatoprost with timolol

omit from the column headed “Listed drug”: Bimatoprost with timolol`` substitute: Bimatoprost with timolol

[22] Schedule 1, Part 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bosentan | Tablet 62.5 mg (as monohydrate) | Oral | BOSLEER | RW | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 |  | 60 |  | D(100) |

[23] Schedule 1, Part 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)

omit:

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

[24] Schedule 1, Part 1, entry for Buprenorphine in each of the forms: Injection (modified release) 8 mg in 0.16 mL pre-filled syringe; Injection (modified release) 16 mg in 0.32 mL pre-filled syringe; Injection (modified release) 24 mg in 0.48 mL pre-filled syringe; and Injection (modified release) 32 mg in 0.64 mL pre-filled syringe

omit from the column headed “Circumstances”: C15385 substitute: C16051

[25] Schedule 1, Part 1, entry for Buprenorphine in each of the forms: Injection (modified release) 64 mg in 0.18 mL pre-filled syringe; and Injection (modified release) 96 mg in 0.27 mL pre-filled syringe

omit from the column headed “Circumstances”: C15356 substitute: C16015

[26] Schedule 1, Part 1, entry for Buprenorphine in the form Injection (modified release) 100 mg in 0.5 mL pre-filled syringe

omit from the column headed “Circumstances”: C15439 substitute: C16050

[27] Schedule 1, Part 1, entry for Buprenorphine in each of the forms: Injection (modified release) 128 mg in 0.36 mL pre-filled syringe; and Injection (modified release) 160 mg in 0.45 mL pre-filled syringe

omit from the column headed “Circumstances”: C15356 substitute: C16015

[28] Schedule 1, Part 1, entry for Buprenorphine in the form Injection (modified release) 300 mg in 1.5 mL pre-filled syringe

omit from the column headed “Circumstances”: C15439 substitute: C16050

[29] Schedule 1, Part 1, entry for Buprenorphine in each of the forms: Tablet (sublingual) 400 micrograms (as hydrochloride); Tablet (sublingual) 2 mg (as hydrochloride); and Tablet (sublingual) 8 mg (as hydrochloride)

omit from the column headed “Circumstances”: C15355 substitute: C16009

[30] Schedule 1, Part 1, entry for Buprenorphine with naloxone in each of the forms: Film (soluble) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride); and Film (soluble) 8 mg (as hydrochloride)-2 mg (as hydrochloride)

omit from the column headed “Circumstances”: C15355 substitute: C16009

[31] Schedule 1, Part 1, entry for Calcitriol

**(a)** omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Calcitriol | Capsule 0.25 microgram | Oral | APO-Calcitriol | TX | MP NP | C5089 C5114 C5255 C5401 C5402 | P5089 P5114 P5255 P5401 P5402 | 100 | 3 |  | 100 |  |  |
| Calcitriol | Capsule 0.25 microgram | Oral | APO-Calcitriol | TX | MP NP | C14231 C14259 C14287 C14296 C14322 | P14231 P14259 P14287 P14296 P14322 | 200 | 3 |  | 100 |  |  |

**(b)** omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Calcitriol | Capsule 0.25 microgram | Oral | Kosteo | RW | MP NP | C5089 C5114 C5255 C5401 C5402 | P5089 P5114 P5255 P5401 P5402 | 100 | 3 |  | 100 |  |  |
| Calcitriol | Capsule 0.25 microgram | Oral | Kosteo | RW | MP NP | C14231 C14259 C14287 C14296 C14322 | P14231 P14259 P14287 P14296 P14322 | 200 | 3 |  | 100 |  |  |

[32] Schedule 1, Part 1, entry for Cefazolin in the form Powder for injection 1 g (as sodium)

**(a)** omit from the column headed “Circumstances”: C5861 C5882

**(b)** omit from the column headed “Circumstances”: C5891

**(c)** insert in numerical order in the column headed “Circumstances”: C15964 C16029 C16030

[33] Schedule 1, Part 1, entry for Cefazolin in the form Powder for injection 2 g (as sodium)

**(a)** omit from the column headed “Circumstances”: C5826

**(b)** omit from the column headed “Circumstances”: C5881 C5890

**(c)** insert in numerical order in the column headed “Circumstances”: C15964 C16029 C16030

[34] Schedule 1, Part 1, entry for Cefepime in each of the forms: Powder for injection 1 g (as hydrochloride); and Powder for injection 2 g (as hydrochloride)

omit from the column headed “Circumstances”: C5842 substitute: C16067

[35] Schedule 1, Part 1, entry for Cefotaxime [Authorised Prescriber: MP NP]

omit from the column headed “Circumstances”: C5826 C5881 C5890 substitute: C15964 C16029 C16030

[36] Schedule 1, Part 1, entries for Ceftriaxone

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ceftriaxone | Powder for injection 500 mg (as sodium) | Injection | Ceftriaxone‑AFT | AE | MP NP | C5855 | P5855 | 1 | 0 |  | 1 |  |  |
| Ceftriaxone | Powder for injection 500 mg (as sodium) | Injection | Ceftriaxone‑AFT | AE | MP NP | C15964 C16029 C16030 | P15964 P16029 P16030 | 5 | 0 |  | 1 |  |  |
| Ceftriaxone | Powder for injection 1 g (as sodium) | Injection | Ceftriaxone Viatris | AL | MP NP | C15964 C16029 C16030 |  | 5 | 0 |  | 10 |  |  |
| Ceftriaxone | Powder for injection 2 g (as sodium) | Injection | Ceftriaxone Viatris | AL | MP NP | C15964 C16029 C16030 |  | 5 | 0 |  | 5 |  |  |
| Ceftriaxone | Powder for injection 2 g (as sodium) | Injection | Ceftriaxone Viatris | AL | MP NP | C15964 C16029 C16030 |  | 5 | 0 |  | 10 |  |  |

[37] Schedule 1, Part 1, entry for Ceritinib

omit from the column headed “Circumstances”: C6732 C7369 substitute: C7346 C15759

[38] Schedule 1, Part 1, after entry for Chloramphenicol

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Chlormethine | Gel 160 micrograms (as hydrochloride) per g, 60 g | Application | Ledaga | JZ | MP | C16054 C16145 |  | 2 | 5 |  | 1 |  |  |

[39] Schedule 1, Part 1, entry for Chlorpromazine in each of the forms: Injection containing chlorpromazine hydrochloride 50 mg in 2 mL; Oral solution containing chlorpromazine hydrochloride 25 mg per 5 mL, 100 mL; Tablet containing chlorpromazine hydrochloride 25 mg; and Tablet containing chlorpromazine hydrochloride 100 mg

insert in the column headed “Circumstances”: C15956

[40] Schedule 1, Part 1, entry for Choriogonadotropin alfa in the form Solution for injection 250 micrograms in 0.5 mL pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 0]*

insert in the column headed “Section 100/ Prescriber Bag only”: C100

[41] Schedule 1, Part 1, after entry for Choriogonadotropin alfa in the form Solution for injection 250 micrograms in 0.5 mL pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 5]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Choriogonadotropin alfa | Solution for injection 250 micrograms in 0.5 mL pre-filled syringe (S19A) | Injection | Ovidrel (USA) | SG | MP | C14124 | P14124 | 1 | 0 |  | 1 |  | C(100) |
| Choriogonadotropin alfa | Solution for injection 250 micrograms in 0.5 mL pre-filled syringe (S19A) | Injection | Ovidrel (USA) | SG | MP | C14096 | P14096 | 4 | 5 |  | 1 |  |  |

[42] Schedule 1, Part 1, entry for Ciprofloxacin in the form Tablet 250 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ciprofloxacin | Tablet 250 mg (as hydrochloride) | Oral | APX-Ciprofloxacin | TY | MP NP | C5614 C5615 C5666 C5687 C5688 C5689 C5722 C5780 |  | 14 | 0 |  | 14 |  |  |

[43] Schedule 1, Part 1, entry for Ciprofloxacin in the form Tablet 500 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ciprofloxacin | Tablet 500 mg (as hydrochloride) | Oral | APX-Ciprofloxacin | TY | MP NP | C5614 C5615 C5687 C5688 C5689 C5722 C5780 |  | 14 | 0 |  | 14 |  |  |

[44] Schedule 1, Part 1, entry for Ciprofloxacin in the form Tablet 750 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ciprofloxacin | Tablet 750 mg (as hydrochloride) | Oral | APX-Ciprofloxacin | TY | MP NP | C5614 C5615 C5687 C5688 C5689 C5722 C5780 |  | 14 | 0 |  | 14 |  |  |

[45] Schedule 1, Part 1, after entry for Citalopram in the form Tablet 10 mg (as hydrobromide) [Brand: Celapram; Maximum Quantity: 56; Number of Repeats: 2]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Citalopram | Tablet 10 mg (as hydrobromide) | Oral | CITALOPRAM-WGR | WG | MP NP | C4755 | P4755 | 28 | 5 |  | 28 |  |  |
| Citalopram | Tablet 10 mg (as hydrobromide) | Oral | CITALOPRAM-WGR | WG | MP NP | C15666 | P15666 | 56 | 2 |  | 28 |  |  |

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

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Citalopram | Tablet 20 mg (as hydrobromide) | Oral | CITALOPRAM-WGR | WG | MP NP | C4755 | P4755 | 28 | 5 |  | 28 |  |  |
| Citalopram | Tablet 20 mg (as hydrobromide) | Oral | CITALOPRAM-WGR | WG | MP NP | C15666 | P15666 | 56 | 2 |  | 28 |  |  |

[47] Schedule 1, Part 1, after entry for Citalopram in the form Tablet 40 mg (as hydrobromide) [Brand: Citalopram Sandoz; Maximum Quantity: 56; Number of Repeats: 2]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Citalopram | Tablet 40 mg (as hydrobromide) | Oral | CITALOPRAM-WGR | WG | MP NP | C4755 | P4755 | 28 | 5 |  | 28 |  |  |
| Citalopram | Tablet 40 mg (as hydrobromide) | Oral | CITALOPRAM-WGR | WG | MP NP | C15666 | P15666 | 56 | 2 |  | 28 |  |  |

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

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

**(a)** omit from the column headed “Circumstances”: C14308 substitute: C14301

**(b)** omit from the column headed “Purposes”: P14308 substitute: P14301

[56] Schedule 1, Part 1, after entry for Dapagliflozin with metformin in the form Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride [Maximum Quantity: 56; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dapagliflozin with sitagliptin | Tablet containing 10 mg dapagliflozin (as propanediol monohydrate) with 100 mg sitagliptin (as phosphate monohydrate) | Oral | Sidapvia 10/100 | AP | MP NP | C15269 | P15269 | 28 | 5 |  | 28 |  |  |
| Dapagliflozin with sitagliptin | Tablet containing 10 mg dapagliflozin (as propanediol monohydrate) with 100 mg sitagliptin (as phosphate monohydrate) | Oral | Sidapvia 10/100 | AP | MP NP | C15270 | P15270 | 56 | 5 |  | 28 |  |  |

[57] Schedule 1, Part 1, entry for Diazepam in the form Tablet 2 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Diazepam | Tablet 2 mg | Oral | APO-Diazepam | TX | MP NP PDP |  |  | 50 | 0 |  | 50 |  |  |
| Diazepam | Tablet 2 mg | Oral | APO-Diazepam | TX | MP NP |  | P6176 | 50 CN6176 | 3 CN6176 |  | 50 |  |  |

[58] Schedule 1, Part 1, entry for Diazepam in the form Tablet 5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Diazepam | Tablet 5 mg | Oral | APO-Diazepam | TX | MP NP PDP |  |  | 50 | 0 |  | 50 |  |  |
| Diazepam | Tablet 5 mg | Oral | APO-Diazepam | TX | MP NP |  | P6176 | 50 CN6176 | 3 CN6176 |  | 50 |  |  |

[59] Schedule 1, Part 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Diclofenac | Tablet (enteric coated) containing diclofenac sodium 25 mg | Oral | APO-Diclofenac | TX | PDP |  |  | 100 | 0 |  | 50 |  |  |
| Diclofenac | Tablet (enteric coated) containing diclofenac sodium 25 mg | Oral | APO-Diclofenac | TX | MP NP |  |  | 100 | 3 |  | 50 |  |  |

[60] Schedule 1, Part 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Diclofenac | Tablet (enteric coated) containing diclofenac sodium 50 mg | Oral | APO-Diclofenac | TX | PDP |  |  | 50 | 0 |  | 50 |  |  |
| Diclofenac | Tablet (enteric coated) containing diclofenac sodium 50 mg | Oral | APO-Diclofenac | TX | MP NP |  |  | 50 | 3 |  | 50 |  |  |

[61] Schedule 1, Part 1, entry for Digoxin in each of the forms: Paediatric oral solution 50 micrograms per mL, 60 mL; Tablet 62.5 micrograms; and Tablet 250 micrograms

insert in the column headed “Circumstances” (all instances): C15956

[62] Schedule 1, Part 1, entry for Disopyramide in each of the forms: Capsule 100 mg; and Capsule 100 mg (s19A)

insert in the column headed “Circumstances”: C15956

[63] Schedule 1, Part 1, entries for Electrolyte replacement, oral in the form Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10

omit from the column headed “Responsible Person” (all instances): AF substitute (all instances): XT

[64] Schedule 1, Part 1, entry for Entecavir in the form Tablet 0.5 mg (as monohydrate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Entecavir | Tablet 0.5 mg (as monohydrate) | Oral | ENTECLUDE | RW | MP NP | C4993 C5036 |  | 60 | 5 |  | 30 |  | D(100) |

[65] Schedule 1, Part 1, entry for Entecavir in the form Tablet 1 mg (as monohydrate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Entecavir | Tablet 1 mg (as monohydrate) | Oral | ENTECLUDE | RW | MP NP | C5037 C5044 |  | 60 | 5 |  | 30 |  | D(100) |

[66] Schedule 1, Part 1, entry for Entrectinib

omit from the column headed “Circumstances”: C13184 C13276 substitute: C13186 C15776

[67] Schedule 1, Part 1, entry for Eptinezumab [Maximum Quantity: 1; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C14189 substitute: C16018

**(b)** omit from the column headed “Purposes”: P14189 substitute: P16018

[68] Schedule 1, Part 1, entries for Estradiol in the form Tablet 2 mg

omit from the column headed “Responsible Person” (all instances): GO substitute (all instances): XT

[69] Schedule 1, Part 1, after entry for Estradiol in the form Tablet containing estradiol valerate 2 mg *[Maximum Quantity: 112; Number of Repeats: 2]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal gel 500 micrograms in 0.5 g sachet, 28 | Transdermal | Sandrena | OX | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Estradiol | Transdermal gel 500 micrograms in 0.5 g sachet, 28 | Transdermal | Sandrena | OX | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |

[70] Schedule 1, Part 1, after entry for Estradiol in the form Transdermal patches 585 micrograms, 8 [Brand: Estradot 37.5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 585 micrograms, 24 (S19A) | Transdermal | Estramon 37.5 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

[71] Schedule 1, Part 1, after entry for Estradiol in the form Transdermal patches 780 micrograms, 8

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 780 micrograms, 24 (S19A) | Transdermal | Estramon 50 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

[72] Schedule 1, Part 1, after entry for Estradiol in the form Transdermal patches 1.17 mg, 8 [Brand: Estradot 75]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 1.17 mg, 24 (S19A) | Transdermal | Estramon 75 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

[73] Schedule 1, Part 1, after entry for Estradiol in the form Transdermal patches 1.56 mg, 8 [Brand: Estradot 100]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol | Transdermal patches 1.56 mg, 24 (S19A) | Transdermal | Estramon 100 (Germany) | DZ | MP NP |  |  | 1 | 1 |  | 1 |  |  |

[74] Schedule 1, Part 1, entry for Estradiol and estradiol with dydrogesterone in each of the forms: Pack containing 14 tablets estradiol 1 mg and 14 tablets estradiol 1 mg with dydrogesterone 10 mg; and Pack containing 14 tablets estradiol 2 mg and 14 tablets estradiol 2 mg with dydrogesterone 10 mg

omit from the column headed “Responsible Person” (all instances): GO substitute (all instances): XT

[75] Schedule 1, Part 1, entry for Exemestane [Brand: APO-Exemestane; Authorised Prescriber: MP NP; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14992 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14992 substitute: P14895

[76] Schedule 1, Part 1, entry for Exemestane [Brand: Aromasin; Authorised Prescriber: MP NP; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14992 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14992 substitute: P14895

[77] Schedule 1, Part 1, entry for Exemestane [Brand: Exemestane GH; Authorised Prescriber: MP NP; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14992 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14992 substitute: P14895

[78] Schedule 1, Part 1, entry for Exemestane [Brand: Exemestane Sandoz; Authorised Prescriber: MP NP; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14992 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14992 substitute: P14895

[79] Schedule 1, Part 1, entry for Exemestane [Brand: EXEMESTANE-WGR; *Authorised Prescriber: MP NP;* Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14992 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14992 substitute: P14895

[80] Schedule 1, Part 1, entries for Ezetimibe

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ezetimibe | Tablet 10 mg | Oral | APO-Ezetimibe | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | APO-Ezetimibe | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | BTC Ezetimibe | BG | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | BTC Ezetimibe | BG | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | EZEMICHOL | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | EZEMICHOL | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Ezetimibe GH | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Ezetimibe GH | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Ezetimibe Sandoz | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Ezetimibe Sandoz | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | EZETIMIBE-WGR | WG | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | EZETIMIBE-WGR | WG | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Ezetrol | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Ezetrol | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Pharmacor Ezetimibe 10 | CR | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Pharmacor Ezetimibe 10 | CR | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Zient 10mg | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe | Tablet 10 mg | Oral | Zient 10mg | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[81] Schedule 1, Part 1, entries for Ezetimibe and rosuvastatin

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+10mg | AF | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+10mg | AF | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | Oral | Pharmacor Ezetimibe Rosuvastatin Composite Pack | CR | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | Oral | Pharmacor Ezetimibe Rosuvastatin Composite Pack | CR | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+20mg | AF | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+20mg | AF | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | Oral | Pharmacor Ezetimibe Rosuvastatin Composite Pack | CR | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | Oral | Pharmacor Ezetimibe Rosuvastatin Composite Pack | CR | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+40mg | AF | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+40mg | AF | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | Oral | Pharmacor Ezetimibe Rosuvastatin Composite Pack | CR | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | Oral | Pharmacor Ezetimibe Rosuvastatin Composite Pack | CR | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+5mg | AF | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) | Oral | Ezalo Composite Pack 10mg+5mg | AF | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  |  | 1 | 5 |  | 1 |  |  |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) | Oral | Rosuzet Composite Pack | AL | MP NP |  | P14238 | 2 | 5 |  | 1 |  |  |

[82] Schedule 1, Part 1, entries for Ezetimibe with atorvastatin

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ezetimibe with atorvastatin | Tablet 10 mg-10 mg | Oral | Atozet | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-10 mg | Oral | Atozet | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-10 mg | Oral | Ezetast | XT | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-10 mg | Oral | Ezetast | XT | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-10 mg | Oral | Ezetimibe/Atorvastatin GH 10/10 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-10 mg | Oral | Ezetimibe/Atorvastatin GH 10/10 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-20 mg | Oral | Atozet | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-20 mg | Oral | Atozet | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-20 mg | Oral | Ezetast | XT | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-20 mg | Oral | Ezetast | XT | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-20 mg | Oral | Ezetimibe/Atorvastatin GH 10/20 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-20 mg | Oral | Ezetimibe/Atorvastatin GH 10/20 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-40 mg | Oral | Atozet | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-40 mg | Oral | Atozet | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-40 mg | Oral | Ezetast | XT | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-40 mg | Oral | Ezetast | XT | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-40 mg | Oral | Ezetimibe/Atorvastatin GH 10/40 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-40 mg | Oral | Ezetimibe/Atorvastatin GH 10/40 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-80 mg | Oral | Atozet | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-80 mg | Oral | Atozet | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-80 mg | Oral | Ezetast | XT | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-80 mg | Oral | Ezetast | XT | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-80 mg | Oral | Ezetimibe/Atorvastatin GH 10/80 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with atorvastatin | Tablet 10 mg-80 mg | Oral | Ezetimibe/Atorvastatin GH 10/80 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[83] Schedule 1, Part 1, entries for Ezetimibe with simvastatin

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | APO-Ezetimibe/Simvastatin 10/10 | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | APO-Ezetimibe/Simvastatin 10/10 | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/10 | WG | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/10 | WG | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EZETORIN | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EZETORIN | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EzSimva GH 10/10 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | EzSimva GH 10/10 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/10 | CR | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/10 | CR | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Vytorin | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Vytorin | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Zeklen 10/10 mg | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Zeklen 10/10 mg | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Zimybe 10/10 | MQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg | Oral | Zimybe 10/10 | MQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | APO-Ezetimibe/Simvastatin 10/20 | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | APO-Ezetimibe/Simvastatin 10/20 | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/20 | WG | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/20 | WG | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EZETORIN | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EZETORIN | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EzSimva GH 10/20 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | EzSimva GH 10/20 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/20 | CR | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/20 | CR | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Vytorin | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Vytorin | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Zeklen 10/20 mg | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Zeklen 10/20 mg | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Zimybe 10/20 | MQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-20 mg | Oral | Zimybe 10/20 | MQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | APO-Ezetimibe/Simvastatin 10/40 | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | APO-Ezetimibe/Simvastatin 10/40 | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/40 | WG | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/40 | WG | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EZETORIN | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EZETORIN | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EzSimva GH 10/40 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | EzSimva GH 10/40 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/40 | CR | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/40 | CR | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Vytorin | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Vytorin | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Zeklen 10/40 mg | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Zeklen 10/40 mg | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Zimybe 10/40 | MQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-40 mg | Oral | Zimybe 10/40 | MQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | APO-Ezetimibe/Simvastatin 10/80 | TX | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | APO-Ezetimibe/Simvastatin 10/80 | TX | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EZETIMIBE/SIMVASTATIN SANDOZ | SZ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/80 | WG | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EZETIMIBE/SIMVASTATIN-WGR 10/80 | WG | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EZETORIN | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EZETORIN | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EzSimva GH 10/80 | GQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | EzSimva GH 10/80 | GQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/80 | CR | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Pharmacor Ezetimibe Simvastatin 10/80 | CR | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Vytorin | AL | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Vytorin | AL | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Zeklen 10/80 mg | AF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Zeklen 10/80 mg | AF | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Zimybe 10/80 | MQ | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Ezetimibe with simvastatin | Tablet 10 mg-80 mg | Oral | Zimybe 10/80 | MQ | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[84] Schedule 1, Part 1, entries for Famciclovir in the form Tablet 250 mg [Brand: Ezovir]

omit from the column headed “Responsible Person” (all instances): AF substitute (all instances): XT

[85] Schedule 1, Part 1, entries for Famciclovir in the form Tablet 500 mg [Brand: Ezovir]

omit from the column headed “Responsible Person”: AF substitute: XT

[86] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 200 micrograms (as citrate) [Maximum Quantity: 9; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[87] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 200 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[88] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 400 micrograms (as citrate) [Maximum Quantity: 9; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[89] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 400 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[90] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 600 micrograms (as citrate)

omit from the column headed “Circumstances”: C5904 substitute: C6027

[91] Schedule 1, Part 1, entry for Fentanyl in the form Lozenge 800 micrograms (as citrate)

omit from the column headed “Circumstances”: C5904 substitute: C6027

[92] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 100 micrograms (as citrate) [Maximum Quantity: 20; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[93] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 100 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[94] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 200 micrograms (as citrate) [Maximum Quantity: 20; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[95] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 200 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[96] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 300 micrograms (as citrate) [Maximum Quantity: 10; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[97] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 300 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[98] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 400 micrograms (as citrate) [Maximum Quantity: 10; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[99] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 400 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[100] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 600 micrograms (as citrate) [Maximum Quantity: 10; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[101] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 600 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[102] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 800 micrograms (as citrate) [Maximum Quantity: 10; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5915 substitute: C6026

**(b)** omit from the column headed “Purposes”: P5915 substitute: P6026

[103] Schedule 1, Part 1, entry for Fentanyl in the form Tablet (sublingual) 800 micrograms (as citrate) [Maximum Quantity: 60; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5904 substitute: C6027

**(b)** omit from the column headed “Purposes”: P5904 substitute: P6027

[104] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 1.28 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[105] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.063 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[106] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.1 mg [Brand: APO-Fentanyl; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[107] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.1 mg [Brand: Durogesic 12; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[108] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.1 mg [Brand: Fentanyl Sandoz; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute:C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[109] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 2.55 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[110] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 4.125 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[111] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 4.2 mg [Brand: APO-Fentanyl; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[112] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 4.2 mg [Brand: Durogesic 25; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[113] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 4.2 mg [Brand: Fentanyl Sandoz; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[114] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 5.10 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[115] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 7.65 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[116] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 8.25 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[117] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 8.4 mg [Brand: APO-Fentanyl; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[118] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 8.4 mg [Brand: Durogesic 50; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[119] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 8.4 mg [Brand: Fentanyl Sandoz; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[120] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 10.20 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[121] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 12.375 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[122] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 12.6 mg [Brand: APO-Fentanyl; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[123] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 12.6 mg [Brand: Durogesic 75; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[124] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 12.6 mg [Brand: Fentanyl Sandoz; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[125] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 16.5 mg [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[126] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 16.8 mg [Brand: APO-Fentanyl; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[127] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 16.8 mg [Brand: Durogesic 100; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[128] Schedule 1, Part 1, entry for Fentanyl in the form Transdermal patch 16.8 mg [Brand: Fentanyl Sandoz; Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[129] Schedule 1, Part 1, entry for Flecainide in the form Tablet containing flecainide acetate 50 mg

omit from the column headed “Circumstances” (all instances): C5550 C5584 substitute (all instances): C15965 C15966

[130] Schedule 1, Part 1, entry for Flecainide in the form Tablet containing flecainide acetate 100 mg

omit from the column headed “Circumstances” (all instances): C5550 C5584 substitute (all instances): C15965 C15966

[131] Schedule 1, Part 1, entries for Fluconazole in the form Capsule 50 mg

**(a)** omit from the column headed “Circumstances” (all instances): C5978

**(b)** omit from the column headed “Circumstances” (all instances): C6002

**(c)** omit from the column headed “Circumstances” (all instances): C7898

**(d)** insert in numerical order in the column headed “Circumstances” (all instances): C15975 C15984 C16034

[132] Schedule 1, Part 1, entry for Fluconazole in the form Capsule 50 mg [Brand: Dizole 50]

omit from the column headed “Responsible Person”: AF substitute: XT

[133] Schedule 1, Part 1, entries for Fluconazole in the form Capsule 100 mg

**(a)** omit from the column headed “Circumstances” (all instances): C5978

**(b)** omit from the column headed “Circumstances” (all instances): C6002

**(c)** omit from the column headed “Circumstances” (all instances): C7898

**(d)** insert in numerical order in the column headed “Circumstances” (all instances): C15975 C15984 C16034

[134] Schedule 1, Part 1, entry for Fluconazole in the form Capsule 100 mg [Brand: Dizole 100]

omit from the column headed “Responsible Person”: AF substitute: XT

[135] Schedule 1, Part 1, entries for Fluconazole in the form Capsule 200 mg

**(a)** omit from the column headed “Circumstances” (all instances): C5978

**(b)** omit from the column headed “Circumstances” (all instances): C6002

**(c)** omit from the column headed “Circumstances” (all instances): C7898

**(d)** insert in numerical order in the column headed “Circumstances” (all instances): C15975 C15984 C16034

[136] Schedule 1, Part 1, entry for Fluconazole in the form Capsule 200 mg [Brand: Dizole 200]

omit from the column headed “Responsible Person”: AF substitute: XT

[137] Schedule 1, Part 1, after entry for Fluconazole in the form Capsule 200 mg [Brand: Fluconazole Sandoz]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fluconazole | Capsule 200 mg | Oral | FLUCONAZOLE-WGR | WG | MP NP | C5989 C6023 C6030 C15975 C15984 C16034 |  | 28 | 5 |  | 28 |  |  |

[138] Schedule 1, Part 1, entry for Fluconazole in the form Powder for oral suspension 50 mg in 5 mL, 35 mL

**(a)** omit from the column headed “Circumstances”: C6006

**(b)** omit from the column headed “Circumstances”: C6045

**(c)** omit from the column headed “Circumstances”: C7934

**(d)** insert in numerical order in the column headed “Circumstances”: C16114 C16141 C16148

[139] Schedule 1, Part 1, entry for Flutamide

omit from the column headed “Circumstances”: C5816 substitute: C5729

[140] Schedule 1, Part 1, entry for Fremanezumab in the form Solution for injection 225 mg in 1.5 mL single dose pre-filled pen [Maximum Quantity: 1; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C14472 substitute: C16104

**(b)** omit from the column headed “Purposes”: P14472 substitute: P16104

[141] Schedule 1, Part 1, entry for Fremanezumab in the form Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe [Maximum Quantity: 1; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C14472 substitute: C16104

**(b)** omit from the column headed “Purposes”: P14472 substitute: P16104

[142] Schedule 1, Part 1, after entry for Fulvestrant [Brand: FULVESTRANT ACCORD]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fulvestrant | Injection 250 mg in 5 mL pre-filled syringe | Injection | FULVESTRANT-AFT | AE | MP | C11473 |  | 2 | 5 |  | 2 |  |  |

[143] Schedule 1, Part 1, entry for Galcanezumab [Maximum Quantity: 2; Number of Repeats: 1]

**(a)** omit from the column headed “Circumstances”: C12064 substitute: C16018

**(b)** omit from the column headed “Purposes”: P12064 substitute: P16018

[144] Schedule 1, Part 1, entries for Gliclazide in the form Tablet 80 mg

**(a)** omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Gliclazide | Tablet 80 mg | Oral | APO-Gliclazide | TX | MP NP |  |  | 100 | 5 |  | 100 |  |  |
| Gliclazide | Tablet 80 mg | Oral | APO-Gliclazide | TX | MP NP |  | P14238 | 200 | 5 |  | 100 |  |  |

**(b)** omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Gliclazide | Tablet 80 mg | Oral | Glyade | AF | MP NP |  |  | 100 | 5 |  | 100 |  |  |
| Gliclazide | Tablet 80 mg | Oral | Glyade | AF | MP NP |  | P14238 | 200 | 5 |  | 100 |  |  |

[145] Schedule 1, Part 1, after entry for Glycomacropeptide and essential amino acids with vitamins and minerals in the form Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk)

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Glycomacropeptide formula with amino acids and low phenylalanine | Sachets containing oral powder 12.5 g, 30 (PKU GMPro MIX-IN) | Oral | PKU GMPro MIX-IN | SB | MP NP | C4295 |  | 5 | 5 |  | 1 |  |  |
| Glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine | Sachets containing oral powder 33.4 g, 30 (PKU GMPro Ultra) | Oral | PKU GMPro ULTRA | SB | MP NP | C4295 |  | 4 | 5 |  | 1 |  |  |

[146] Schedule 1, Part 1, entries for Ibuprofen in the form Tablet 400 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ibuprofen | Tablet 400 mg | Oral | MEDICHOICE Ibuprofen 400 mg | NB | MP NP MW PDP |  |  | 30 | 0 |  | 30 |  |  |
| Ibuprofen | Tablet 400 mg | Oral | MEDICHOICE Ibuprofen 400 mg | NB | PDP |  | P6256 P6282 | 90 | 0 |  | 30 |  |  |
| Ibuprofen | Tablet 400 mg | Oral | MEDICHOICE Ibuprofen 400 mg | NB | MP NP |  | P6149 P6214 P6283 | 90 | 3 |  | 30 |  |  |

[147] Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate)

insert as first entries:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Imatinib | Capsule 400 mg (as mesilate) | Oral | ARX-IMATINIB | XT | MP | C9203 C9207 C9319 C12525 C12527 C12542 C12543 C13132 | P9203 P9207 P9319 P12525 P12527 P12542 P12543 P13132 | 30 | 2 |  | 30 |  |  |
| Imatinib | Capsule 400 mg (as mesilate) | Oral | ARX-IMATINIB | XT | MP | C9204 C9206 C9209 C9238 C9240 C9243 C9274 C9276 C9278 C9296 C12536 C12541 | P9204 P9206 P9209 P9238 P9240 P9243 P9274 P9276 P9278 P9296 P12536 P12541 | 30 | 5 |  | 30 |  |  |

[148] Schedule 1, Part 1, entry for Insulin neutral with insulin isophane in the form Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5 | Injection | Mixtard 30/70 Penfill 3 mL | NO | MP NP |  |  | 5 | 1 |  | 1 |  |  |

[149] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 75 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Irbesartan | Tablet 75 mg | Oral | Karvea | SW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Irbesartan | Tablet 75 mg | Oral | Karvea | SW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[150] Schedule 1, Part 1, entry for Isoniazid

insert in the column headed “Circumstances”: C15956

[151] Schedule 1, Part 1, entry for Itraconazole in the form Capsule 50 mg

omit from the column headed “Circumstances”: C5988 C6005 C6016 C6022 C6035 C6037 C6057 substitute: C15978 C16035 C16073 C16099 C16101 C16102 C16119

[152] Schedule 1, Part 1, entry for Itraconazole in the form Capsule 100 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Itraconazole | Capsule 100 mg | Oral | APO-Itraconazole | TX | MP NP | C5988 C6005 C6016 C6022 C6035 C6037 C6057 |  | 60 | 5 |  | 60 |  |  |

[153] Schedule 1, Part 1, entries for Itraconazole in the form Capsule 100 mg

omit from the column headed “Circumstances” (all instances): C5988 C6005 C6016 C6022 C6035 C6037 C6057 substitute (all instances): C15978 C16035 C16073 C16099 C16101 C16102 C16119

[154] Schedule 1, Part 1, entries for Itraconazole in the form Capsule 100 mg

omit from the column headed “Circumstances” (all instances): C5988 C6005 C6016 C6022 C6035 C6037 C6057 substitute (all instances): C15978 C16035 C16073 C16099 C16101 C16102 C16119

[155] Schedule 1, Part 1, entries for Lanreotide in the form Injection 60 mg (as acetate) in single dose pre-filled syringe

**(a)** omit from the column headed “Circumstances” (all instances): C7509 C7532

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C15955 C16024 C16055 C16057

[156] Schedule 1, Part 1, entries for Lanreotide in the form Injection 90 mg (as acetate) in single dose pre-filled syringe

**(a)** omit from the column headed “Circumstances” (all instances): C7509 C7532

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C15955 C16024 C16055 C16057

[157] Schedule 1, Part 1, entries for Lanreotide in the form Injection 120 mg (as acetate) in single dose pre-filled syringe

**(a)** omit from the column headed “Circumstances” (all instances): C7509 C7532

**(b)** omit from the column headed “Circumstances” (all instances): C10075

**(c)** insert in numerical order in the column headed “Circumstances” (all instances): C15955 C16024 C16055 C16056 C16057 C16133

[158] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 5 mg [Brand: Revlimid]

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[159] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 10 mg [Brand: Revlimid]

omit from the column headed “Responsible Person” (all instances): CJ substitute(all instances): BQ

[160] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 15 mg [Brand: Revlimid]

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[161] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 25 mg [Brand: Revlimid]

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[162] Schedule 1, Part 1, entry for Letrozole [Brand: ARX-LETROZOLE; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[163] Schedule 1, Part 1, entry for Letrozole [Brand: ARX-LETROZOLE; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[164] Schedule 1, Part 1, entry for Letrozole [Brand: Femara 2.5 mg; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[165] Schedule 1, Part 1, entry for Letrozole [Brand: Femara 2.5 mg; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[166] Schedule 1, Part 1, entry for Letrozole [Brand: Femolet; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[167] Schedule 1, Part 1, entry for Letrozole [Brand: Femolet; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[168] Schedule 1, Part 1, entry for Letrozole [Brand: Gynotril; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[169] Schedule 1, Part 1, entry for Letrozole [Brand: Gynotril; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[170] Schedule 1, Part 1, entry for Letrozole [Brand: Letrozole APOTEX; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[171] Schedule 1, Part 1, entry for Letrozole [Brand: Letrozole APOTEX; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[172] Schedule 1, Part 1, entry for Letrozole [Brand: Letrozole GH; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[173] Schedule 1, Part 1, entry for Letrozole [Brand: Letrozole GH; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[174] Schedule 1, Part 1, entry for Letrozole [Brand: Letrozole Sandoz; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[175] Schedule 1, Part 1, entry for Letrozole [Brand: Letrozole Sandoz; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[176] Schedule 1, Part 1, entry for Letrozole [Brand: LETROZOLE-WGR; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[177] Schedule 1, Part 1, entry for Letrozole [Brand: LETROZOLE-WGR; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[178] Schedule 1, Part 1, entry for Letrozole [Brand: Pharmacor Letrozole 2.5; Maximum Quantity: 30; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C5464 substitute: C5522

**(b)** omit from the column headed “Purposes”: P5464 substitute: P5522

[179] Schedule 1, Part 1, entry for Letrozole [Brand: Pharmacor Letrozole 2.5; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14943 substitute: C14895

**(b)** omit from the column headed “Purposes”: P14943 substitute: P14895

[180] Schedule 1, Part 1, entry for Lidocaine in the form Infusion containing lidocaine hydrochloride 500 mg in 5 mL

insert in the column headed “Circumstances”: C15956

[181] Schedule 1, Part 1, entries for Macrogol 3350 in the form Sachets containing powder for oral solution 13.125 g with electrolytes, 30 [Brand: Molaxole]

omit from the column headed “Responsible Person” (all instances): GO substitute (all instances): XT

[182] Schedule 1, Part 1, entries for Macrogol 3350 in the form Sachets containing powder for oral solution 13.125 g with electrolytes, 30

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Macrogol 3350 | Sachets containing powder for oral solution 13.125 g with electrolytes, 30 | Oral | Movicol | NE | MP NP | C4576 C4577 C4580 C4596 C4601 | P4576 P4577 P4580 P4596 P4601 | 1 | 5 |  | 1 |  |  |
| Macrogol 3350 | Sachets containing powder for oral solution 13.125 g with electrolytes, 30 | Oral | Movicol | NE | MP NP | C6171 | P6171 | 2 | 3 |  | 1 |  |  |
| Macrogol 3350 | Sachets containing powder for oral solution 13.125 g with electrolytes, 30 | Oral | Movicol | NE | MP NP | C15688 C15730 C15745 C15746 C15747 | P15688 P15730 P15745 P15746 P15747 | 2 | 5 |  | 1 |  |  |

[183] Schedule 1, Part 1, entry for Methadone in the form Injection containing methadone hydrochloride 10 mg in 1 mL [Maximum Quantity: 5; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[184] Schedule 1, Part 1, entries for Methadone in the form Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL

omit from the column headed “Circumstances” (all instances): C15358 substitute (all instances): C16083

[185] Schedule 1, Part 1, entry for Methadone in the form Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL [Brand: Aspen Methadone Syrup; Maximum Quantity: 840; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C15358 substitute: C16083

**(b)** omit from the column headed “Purposes”: P15358 substitute: P16083

[186] Schedule 1, Part 1, entry for Methadone in the form Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL [Brand: Biodone Forte]

omit from the column headed “Circumstances”: C15358 substitute: C16083

[187] Schedule 1, Part 1, entry for Methadone in the form Tablet containing methadone hydrochloride 10 mg [Maximum Quantity: 20; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C10745 C10747 C10751 substitute: C15994 C15996 C16000

**(b)** omit from the column headed “Purposes”: P10745 P10747 P10751 substitute: P15994 P15996 P16000

**(c)** omit from the column headed “Variations”: V10745 V10747 V10751 substitute: V15994 V15996 V16000

[188] Schedule 1, Part 1, after entry for Methotrexate in the form Tablet 10 mg [Brand: Chexate; Maximum Quantity: 50; Number of Repeats: 2]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methotrexate | Tablet 10 mg | Oral | Methoblastin | PF | MP NP |  |  | 10 | 5 |  | 10 |  |  |

[189] Schedule 1, Part 1, after entry for Methoxsalen [Maximum Quantity: 12; Number of Repeats: 1]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methoxyflurane | Liquid for inhalation 999 mg per g, 3 mL (with inhaler) | Inhalation by mouth | Penthrox (Combination Pack) | DV | See Note 4 | See Note 4 | See Note 4 | See Note 4 | See Note 4 |  | 1 | 1 | D(MP) |

[190] Schedule 1, Part 1, entry for Methoxyflurane (after entry for Methoxy polyethylene glycol-epoetin beta in the form Injection 360 micrograms in 0.6 mL pre-filled syringe)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methoxyflurane | Liquid for inhalation 999 mg per g, 3 mL (with inhaler) | Inhalation by mouth | Penthrox | DV | See Note 4 | See Note 4 | See Note 4 | See Note 4 | See Note 4 |  | 1 | 1 | D(MP) |

[191] Schedule 1, Part 1, entries for Metronidazole in the form Tablet 200 mg [Brand: Metrogyl 200]

omit from the column headed “Responsible Person” (all instances): AF substitute (all instances): XT

[192] Schedule 1, Part 1, entries for Metronidazole in the form Tablet 400 mg [Brand: Metrogyl 400]

omit from the column headed “Responsible Person” (all instances): AF substitute (all instances): XT

[193] Schedule 1, Part 1, after entry for Morphine in the form Tablet containing morphine sulfate pentahydrate 20 mg *[Maximum Quantity: 20; Number of Repeats: 2]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Morphine | Tablet containing morphine sulfate pentahydrate 30 mg | Oral | Anamorph | RW | MP NP PDP | C10758 | P10758 | 10 | 0 |  | 20 |  |  |
| Morphine | Tablet containing morphine sulfate pentahydrate 30 mg | Oral | Anamorph | RW | PDP | C10859 | P10859 | 20 | 0 |  | 20 |  |  |
| Morphine | Tablet containing morphine sulfate pentahydrate 30 mg | Oral | Anamorph | RW | MP NP | C10764 C10770 C10775 C10777 C10837 C10891 | P10764 P10770 P10775 P10777 P10837 P10891 | 20 | 0 | V10764 V10770 V10775 V10777 V10837 V10891 | 20 |  |  |
| Morphine | Tablet containing morphine sulfate pentahydrate 30 mg | Oral | Anamorph | RW | MP NP | C6168 | P6168 | 20 | 2 |  | 20 |  |  |

[194] Schedule 1, Part 1, entries for Naloxone

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Naloxone | Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule | Injection | Naloxone Hydrochloride (DBL) | PF | MP NP PDP |  |  | 5 | 0 |  | 5 |  |  |
| Naloxone | Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule | Injection | Naloxone Juno | JU | MP NP PDP |  |  | 5 | 0 |  | 5 |  |  |
| Naloxone | Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule | Injection | NALOXONE SXP | XN | MP NP PDP |  |  | 5 | 0 |  | 5 |  |  |
| Naloxone | Injection containing naloxone hydrochloride 2 mg in 2 mL pre-filled syringe | Injection | Prenoxad | FF | MP NP PDP |  |  | 1 | 0 |  | 1 |  |  |
| Naloxone | Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 | Nasal | Nyxoid | MF | MP NP PDP |  |  | 1 | 0 |  | 1 |  |  |

[195] Schedule 1, Part 1, entries for Nifedipine in the form Tablet 30 mg (controlled release)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nifedipine | Tablet 30 mg (controlled release) | Oral | Addos XR 30 | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Nifedipine | Tablet 30 mg (controlled release) | Oral | Addos XR 30 | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[196] Schedule 1, Part 1, entries for Nifedipine in the form Tablet 60 mg (controlled release)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nifedipine | Tablet 60 mg (controlled release) | Oral | Addos XR 60 | RW | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Nifedipine | Tablet 60 mg (controlled release) | Oral | Addos XR 60 | RW | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[197] Schedule 1, Part 1, entry for Olanzapine in each of the forms: Powder for injection 210 mg (as pamoate monohydrate) with diluent; Powder for injection 300 mg (as pamoate monohydrate) with diluent; and Powder for injection 405 mg (as pamoate monohydrate) with diluent

omit from the column headed “Circumstances”: C4304 substitute: C4246

[198] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 2.5 mg

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[199] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 5 mg

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[200] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 5 mg (orally disintegrating)

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[201] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 7.5 mg

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[202] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 10 mg

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[203] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 10 mg (orally disintegrating)

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[204] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 15 mg (orally disintegrating)

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

[205] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 20 mg (orally disintegrating)

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246

**(b)** omit from the column headed “Circumstances” (all instances): C5856

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

**(a)** insert in numerical order in the column headed “Circumstances”: C4246

**(b)** omit from the column headed “Circumstances”: C5856

[207] Schedule 1, Part 1, entries for Ozanimod

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[208] Schedule 1, Part 1, after entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate) [Brand: APO-Pantoprazole; Maximum Quantity: 60; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pantoprazole | Tablet (enteric coated) 20 mg (as sodium sesquihydrate) | Oral | APX-PANTOPRAZOLE | TW | MP NP | C5444 C5512 C5529 | P5444 P5512 P5529 | 30 | 5 |  | 30 |  |  |
| Pantoprazole | Tablet (enteric coated) 20 mg (as sodium sesquihydrate) | Oral | APX-PANTOPRAZOLE | TW | MP NP | C15574 C15575 C15633 | P15574 P15575 P15633 | 60 | 5 |  | 30 |  |  |

[209] Schedule 1, Part 1, entries for Paracetamol in the form Tablet 665 mg (modified release) [Brand: Parapane OSTEO]

omit from the column headed “Responsible Person” (all instances): AF substitute (all instances): XT

[210] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 125 mg [Maximum Quantity: 100; Number of Repeats: 1]

**(a)** insert in the column headed “Circumstances”: C15956

**(b)** insert in the column headed “Purposes”: P15956

[211] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 125 mg [Maximum Quantity: 200; Number of Repeats: 1]

**(a)** insert in the column headed “Circumstances”: C16078

**(b)** omit from the column headed “Purposes”: C14238 substitute: C16078

[212] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 250 mg [Maximum Quantity: 100; Number of Repeats: 1]

**(a)** insert in the column headed “Circumstances”: C15956

**(b)** insert in the column headed “Purposes”: P15956

[213] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 250 mg [Maximum Quantity: 200; Number of Repeats: 1]

**(a)** insert in the column headed “Circumstances”: C16078

**(b)** omit from the column headed “Purposes”: C14238 substitute: C16078

[214] Schedule 1, Part 1, entry for Perhexiline

omit from the column headed “Circumstances”: C5592 substitute: C16111

[215] Schedule 1, Part 1, entry for Periciazine in each of the forms: Tablet 2.5 mg; and Tablet 10 mg

insert in the column headed “Circumstances”: C15956

[216] Schedule 1, Part 1, entries for Pioglitazone in the form Tablet 15 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Acpio 15 | RF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Acpio 15 | RF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |

[217] Schedule 1, Part 1, entry for Pioglitazone in the form Tablet 30 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Acpio 30 | RF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Acpio 30 | RF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |

[218] Schedule 1, Part 1, after entry for Pioglitazone in the form Tablet 30 mg (as hydrochloride) [Brand: APOTEX-Pioglitazone; Maximum Quantity: 56; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | ARX-PIOGLITAZONE | XT | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 30 mg (as hydrochloride) | Oral | ARX-PIOGLITAZONE | XT | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |

[219] Schedule 1, Part 1, entry for Pioglitazone in the form Tablet 45 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Acpio 45 | RF | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Acpio 45 | RF | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15321 | P15321 | 28 | 5 |  | 28 |  |  |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | Oral | Actaze | RW | MP NP | C15290 | P15290 | 56 | 5 |  | 28 |  |  |

[220] Schedule 1, Part 1, entries for Pomalidomide in the form Capsule 3 mg [Brand: Pomalyst]

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[221] Schedule 1, Part 1, entries for Pomalidomide in the form Capsule 4 mg [Brand: Pomalyst]

omit from the column headed “Responsible Person” (all instances): CJ substitute (all instances): BQ

[222] Schedule 1, Part 1, entries for Posaconazole

omit from the column headed “Circumstances” (all instances): C5169 C5395 C5396 substitute (all instances): C16072 C16096 C16117

[223] Schedule 1, Part 1, entries for Quetiapine in the form Tablet 25 mg (as fumarate)

**(a)** insert in numerical order in the column headed “Circumstances” (all instances): C4246 C5869

**(b)** omit from the column headed “Circumstances” (all instances): C7893 C7916

[224] Schedule 1, Part 1, after entry for Quetiapine in the form Tablet 25 mg (as fumarate) [Brand: Quetiapine Sandoz Pharma]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 25 mg (as fumarate) | Oral | QUETIAPINE-WGR | WG | MP NP | C4246 C5869 C7927 |  | 60 | 0 |  | 60 |  |  |

[225] Schedule 1, Part 1, entries for Quetiapine in the form Tablet 100 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[226] Schedule 1, Part 1, after entry for Quetiapine in the form Tablet 100 mg (as fumarate) [Brand: Quetiapine Sandoz Pharma]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 100 mg (as fumarate) | Oral | QUETIAPINE-WGR | WG | MP NP | C4246 C5611 C5869 |  | 90 | 5 |  | 90 |  |  |

[227] Schedule 1, Part 1, entries for Quetiapine in the form Tablet 200 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[228] Schedule 1, Part 1, after entry for Quetiapine in the form Tablet 200 mg (as fumarate) [Brand: Quetiapine Sandoz Pharma]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 200 mg (as fumarate) | Oral | QUETIAPINE-WGR | WG | MP NP | C4246 C5611 C5869 |  | 60 | 5 |  | 60 |  |  |

[229] Schedule 1, Part 1, entries for Quetiapine in the form Tablet 300 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[230] Schedule 1, Part 1, after entry for Quetiapine in the form Tablet 300 mg (as fumarate) [Brand: Quetiapine Sandoz Pharma]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quetiapine | Tablet 300 mg (as fumarate) | Oral | QUETIAPINE-WGR | WG | MP NP | C4246 C5611 C5869 |  | 60 | 5 |  | 60 |  |  |

[231] Schedule 1, Part 1, entries for Quetiapine in the form Tablet (modified release) 50 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[232] Schedule 1, Part 1, entries for Quetiapine in the form Tablet (modified release) 150 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[233] Schedule 1, Part 1, entries for Quetiapine in the form Tablet (modified release) 200 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[234] Schedule 1, Part 1, entries for Quetiapine in the form Tablet (modified release) 300 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[235] Schedule 1, Part 1, entries for Quetiapine in the form Tablet (modified release) 400 mg (as fumarate)

**(a)** omit from the column headed “Circumstances” (all instances): C5639

**(b)** insert in numerical order in the column headed “Circumstances” (all instances): C5869

[236] Schedule 1, Part 1, entry for Quinapril in the form Tablet 10 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quinapril | Tablet 10 mg (as hydrochloride) | Oral | Accupril | PF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Quinapril | Tablet 10 mg (as hydrochloride) | Oral | ACQUIN | RF | MP NP |  |  | 30 | 5 |  | 30 |  |  |

[237] Schedule 1, Part 1, entry for Quinapril in the form Tablet 20 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quinapril | Tablet 20 mg (as hydrochloride) | Oral | Accupril | PF | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Quinapril | Tablet 20 mg (as hydrochloride) | Oral | ACQUIN | RF | MP NP |  |  | 30 | 5 |  | 30 |  |  |

[238] Schedule 1, Part 1, omit entry for Ribavirin

[239] Schedule 1, Part 1, entry for Rifampicin in the form Capsule 150 mg [Maximum Quantity: 10; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5536 C5585 substitute: C16037 C16075

**(b)** omit from the column headed “Purposes”: P5536 P5585 substitute: P16037 P16075

[240] Schedule 1, Part 1, entry for Rifampicin in the form Capsule 150 mg [Maximum Quantity: 100; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5552 C11018 substitute: C15973 C16043

**(b)** omit from the column headed “Purposes”: P5552 P11018 substitute: P15973 P16043

[241] Schedule 1, Part 1, entry for Rifampicin in the form Capsule 150 mg [Maximum Quantity: 120; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C11018 substitute: C16043

**(b)** omit from the column headed “Purposes”: P11018 substitute: P16043

[242] Schedule 1, Part 1, entry for Rifampicin in the form Capsule 300 mg [Maximum Quantity: 10; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5536 C5585 substitute: C16037 C16075

**(b)** omit from the column headed “Purposes”: P5536 P5585 substitute: P16037 P16075

[243] Schedule 1, Part 1, entry for Rifampicin in the form Capsule 300 mg [Maximum Quantity: 100; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C5552 C11018 substitute: C15973 C16043

**(b)** omit from the column headed “Purposes”: P5552 P11018 substitute: P15973 P16043

[244] Schedule 1, Part 1, entry for Rifampicin in the form Capsule 300 mg [Maximum Quantity: 120; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C11018 substitute: C16043

**(b)** omit from the column headed “Purposes”: P11018 substitute: P16043

[245] Schedule 1, Part 1, entry for Rifampicin in the form Syrup 100 mg per 5 mL, 60 mL

omit from the column headed “Circumstances”: C5536 C5585 substitute: C16037 C16075

[246] Schedule 1, Part 1, entries for Riluzole in the form Tablet 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Riluzole | Tablet 50 mg | Oral | APO-Riluzole | TX | MP NP | C5341 C8738 | P5341 P8738 | 56 | 5 |  | 56 |  |  |
| Riluzole | Tablet 50 mg | Oral | APO-Riluzole | TX | MP NP | C15719 | P15719 | 112 | 5 |  | 56 |  |  |

[247] Schedule 1, Part 1, entry for Risperidone in the form Oral solution 1 mg per mL, 100 mL [Brand: Risperdal; Maximum Quantity: 1; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[248] Schedule 1, Part 1, entry for Risperidone in the form Oral solution 1 mg per mL, 100 mL [Brand: Risperidone Lupin; Maximum Quantity: 1; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[249] Schedule 1, Part 1, entry for Risperidone in the form Oral solution 1 mg per mL, 100 mL [Brand: Rixadone; Maximum Quantity: 1; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[250] Schedule 1, Part 1, entries for Risperidone in the form Tablet 0.5 mg

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Risperidone | Tablet 0.5 mg | Oral | APO-Risperidone | TX | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | APO-Risperidone | TX | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | NOUMED RISPERIDONE | VO | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | NOUMED RISPERIDONE | VO | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Ozidal | RA | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Ozidal | RA | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Rispa | RW | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Rispa | RW | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Risperdal | JC | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 20 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Risperdal | JC | MP NP | C4246 | P4246 | 60 | 5 |  | 20 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Risperidone Sandoz | SZ | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Risperidone Sandoz | SZ | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Rispernia | ZS | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Rispernia | ZS | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Rixadone | AF | MP NP | C6898 C10020 C10021 C16048 | P6898 P10020 P10021 P16048 | 60 | 2 |  | 60 |  |  |
| Risperidone | Tablet 0.5 mg | Oral | Rixadone | AF | MP NP | C4246 | P4246 | 60 | 5 |  | 60 |  |  |

[251] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: APO-Risperidone; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[252] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: NOUMED RISPERIDONE; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[253] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: Ozidal; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[254] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: Rispa; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[255] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: Risperdal; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[256] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: Risperidone Sandoz; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[257] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: Rispernia; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[258] Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg [Brand: Rixadone; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6899

**(b)** insert in numerical order in the column headed “Circumstances”: C16048

**(c)** omit from the column headed “Purposes”: P6899

**(d)** insert in numerical order in the column headed “Purposes”: P16048

[259] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: APO-Risperidone; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[260] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: NOUMED RISPERIDONE; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 *substitute*: P6898 P16048

[261] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: Ozidal; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[262] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: Rispa; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[263] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: Risperdal; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[264] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: Risperidone Sandoz; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[265] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: Rispernia; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[266] Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg [Brand: Rixadone; Maximum Quantity: 60; Number of Repeats: 2]

**(a)** omit from the column headed “Circumstances”: C6897 C6938 substitute: C6898 C16048

**(b)** omit from the column headed “Purposes”: P6897 P6938 substitute: P6898 P16048

[267] Schedule 1, Part 1, entry for Rivaroxaban in the form Tablet 15 mg [Brand: Rivaroxaban-Teva; Maximum Quantity: 42; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C4260

**(b)** insert in numerical order in the column headed “Circumstances”: C5098

**(c)** omit from the column headed “Purposes”: P4260

**(d)** insert in numerical order in the column headed “Purposes”: P5098

[268] Schedule 1, Part 1, entry for Rivaroxaban in the form Tablet 15 mg [Brand: Xarelto; Maximum Quantity: 42; Number of Repeats: 0]

**(a)** omit from the column headed “Circumstances”: C4260

**(b)** insert in numerical order in the column headed “Circumstances”: C5098

**(c)** omit from the column headed “Purposes”: P4260

**(d)** insert in numerical order in the column headed “Purposes”: P5098

[269] Schedule 1, Part 1, entry for Romosozumab

omit from the column headed “Circumstances”: C13819 C13820 substitute: C16021 C16022 C16023 C16087 C16132

[270] Schedule 1, Part 1, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg [Brand: ARX-SEVELAMER; Maximum Quantity: 360; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14984 substitute: C14872

**(b)** omit from the column headed “Purposes”: P14984 substitute: P14872

[271] Schedule 1, Part 1, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg [Brand: Sevelamer Apotex; Maximum Quantity: 360; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14984 substitute: C14872

**(b)** omit from the column headed “Purposes”: P14984 substitute: P14872

[272] Schedule 1, Part 1, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg [Brand: Sevelamer Lupin; Maximum Quantity: 360; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14984 substitute: C14872

**(b)** omit from the column headed “Purposes”: P14984 substitute: P14872

[273] Schedule 1, Part 1, entry for Sevelamer in the form Tablet containing sevelamer hydrochloride 800 mg [Brand: Renagel; Maximum Quantity: 360; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C14984 substitute: C14872

**(b)** omit from the column headed “Purposes”: P14984 substitute: P14872

[274] Schedule 1, Part 1, entries for Sotalol in the form Tablet containing sotalol hydrochloride 80 mg

omit from the column headed “Circumstances” (all instances): C5664 substitute (all instances): C15967

[275] Schedule 1, Part 1, entries for Sotalol in the form Tablet containing sotalol hydrochloride 160 mg

omit from the column headed “Circumstances” (all instances): C5664 substitute (all instances): C15967

[276] Schedule 1, Part 1, entry for Tamoxifen [Brand: Genox 20; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C6381 substitute: C5522

**(b)** omit from the column headed “Purposes”: P6381 substitute: P5522

[277] Schedule 1, Part 1, entry for Tamoxifen [Brand: GenRx Tamoxifen; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C6381 substitute: C5522

**(b)**  omit from the column headed “Purposes”: P6381 substitute: P5522

[278] Schedule 1, Part 1, entry for Tamoxifen [Brand: Nolvadex-D; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** insert in numerical order in the column headed “Circumstances”: C5522

**(b)** omit from the column headed “Circumstances”: C6449

**(c)** insert in numerical order in the column headed “Purposes”: P5522

**(d)**  omit from the column headed “Purposes”: P6449

[279] Schedule 1, Part 1, entry for Tamoxifen [Brand: Tamosin; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C6381 substitute: C5522

**(b)** omit from the column headed “Purposes”: P6381 substitute: P5522

[280] Schedule 1, Part 1, entry for Tamoxifen [Brand: Tamoxifen Sandoz; Maximum Quantity: 60; Number of Repeats: 5]

**(a)** omit from the column headed “Circumstances”: C6381 substitute: C5522

**(b)** omit from the column headed “Purposes”: P6381 substitute: P5522

[281] Schedule 1, Part 1, entry for Thalidomide in each of the forms: Capsule 50 mg; and Capsule 100 mg

omit from the column headed “Responsible Person”: CJ substitute: BQ

[282] Schedule 1, Part 1, after entry for Timolol in the form Eye drops 5 mg (as maleate) per mL, 5 mL

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Timolol | Eye drops 5 mg (as maleate) per mL, 5 mL (S19A) | Application to the eye | Timolol (Brown & Burk, UK) | LM | MP AO |  |  | 1 | 5 |  | 1 |  |  |

[283] Schedule 1, Part 1, entries for Tirofiban

omit from the column headed “Circumstances” (all instances): C5691 C5782 C5809 substitute (all instances): C16063 C16123 C16147

[284] Schedule 1, Part 1, entries for Valaciclovir in the form Tablet 500 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Valaciclovir | Tablet 500 mg (as hydrochloride) | Oral | Valaciclovir generichealth | GQ | MP NP | C5940 C5961 | P5940 P5961 | 30 | 5 |  | 30 |  |  |
| Valaciclovir | Tablet 500 mg (as hydrochloride) | Oral | Valaciclovir generichealth | GQ | MP NP | C5962 C5968 | P5962 P5968 | 42 | 0 |  | 42 |  |  |

[285] Schedule 1, Part 1, entries for Voriconazole

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Voriconazole | Powder for oral suspension 40 mg per mL, 70 mL | Oral | Vfend | PF | MP NP | C15979 C15981 C16042 C16094 C16115 |  | 1 | 0 |  | 1 |  |  |
| Voriconazole | Tablet 50 mg | Oral | Voriconazole Sandoz | SZ | MP NP | C16115 | P16115 | 56 | 0 |  | 56 |  |  |
| Voriconazole | Tablet 50 mg | Oral | Voriconazole Sandoz | SZ | MP NP | C15979 C15981 C16042 C16094 | P15979 P15981 P16042 P16094 | 56 | 2 |  | 56 |  |  |
| Voriconazole | Tablet 50 mg | Oral | Vttack | AF | MP NP | C16115 | P16115 | 56 | 0 |  | 56 |  |  |
| Voriconazole | Tablet 50 mg | Oral | Vttack | AF | MP NP | C15979 C15981 C16042 C16094 | P15979 P15981 P16042 P16094 | 56 | 2 |  | 56 |  |  |
| Voriconazole | Tablet 50 mg | Oral | Vzole | RW | MP NP | C16115 | P16115 | 56 | 0 |  | 56 |  |  |
| Voriconazole | Tablet 50 mg | Oral | Vzole | RW | MP NP | C15979 C15981 C16042 C16094 | P15979 P15981 P16042 P16094 | 56 | 2 |  | 56 |  |  |
| Voriconazole | Tablet 200 mg | Oral | Voriconazole Sandoz | SZ | MP NP | C16115 | P16115 | 56 | 0 |  | 56 |  |  |
| Voriconazole | Tablet 200 mg | Oral | Voriconazole Sandoz | SZ | MP NP | C15979 C15981 C16042 C16094 | P15979 P15981 P16042 P16094 | 56 | 2 |  | 56 |  |  |
| Voriconazole | Tablet 200 mg | Oral | Vttack | AF | MP NP | C16115 | P16115 | 56 | 0 |  | 56 |  |  |
| Voriconazole | Tablet 200 mg | Oral | Vttack | AF | MP NP | C15979 C15981 C16042 C16094 | P15979 P15981 P16042 P16094 | 56 | 2 |  | 56 |  |  |
| Voriconazole | Tablet 200 mg | Oral | Vzole | RW | MP NP | C16115 | P16115 | 56 | 0 |  | 56 |  |  |
| Voriconazole | Tablet 200 mg | Oral | Vzole | RW | MP NP | C15979 C15981 C16042 C16094 | P15979 P15981 P16042 P16094 | 56 | 2 |  | 56 |  |  |

[286] Schedule 1, Part 1, entry for Zolmitriptan [Brand: Zomig]

omit from the column headed “Responsible Person”: AP substitute: AS

[287] Schedule 1, Part 1, entry for Zuclopenthixol decanoate

insert in the column headed “Circumstances”: C15956

[288] Schedule 1, Part 2, omit entry for Carbomer 974

[289] Schedule 1, Part 2, omit entry for Hypromellose with dextran

[290] Schedule 1, Part 2, omit entry for Mepolizumab

[291] Schedule 1, Part 2, omit entry for Risankizumab

[292] Schedule 3,

omit:

|  |  |  |
| --- | --- | --- |
| CJ | Celgene Pty Limited | 42 118 998 771 |

[293] Schedule 4, Part 1, entry for Circumstances Code “C4246”

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

[294] Schedule 4, Part 1, omit entry for Circumstances Code “C4260”

[295] Schedule 4, Part 1, entry for Circumstances Code “C4268”

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

[296] Schedule 4, Part 1, entry for Circumstances Code “C4295”

**(a)** insert in alphabetical order in the column headed “Listed Drug”: Glycomacropeptide formula with amino acids and low phenylalanine

**(b)** insert in alphabetical order in the column headed “Listed Drug”: Glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine

[297] Schedule 4, Part 1, omit entry for Circumstances Code “C4304”

[298] Schedule 4, Part 1, omit entry for Circumstances Code “C4683”

[299] Schedule 4, Part 1, omit entry for Circumstances Code “C4685”

[300] Schedule 4, Part 1, omit entry for Circumstances Code “C5083”

[301] Schedule 4, Part 1, entry for Circumstances Code “C5098”

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

[302] Schedule 4, Part 1, omit entry for Circumstances Code “C5169”

[303] Schedule 4, Part 1, omit entry for Circumstances Code “C5395”

[304] Schedule 4, Part 1, omit entry for Circumstances Code “C5396”

[305] Schedule 4, Part 1, omit entry for Circumstances Code “C5464”

[306] Schedule 4, Part 1, entry for Circumstances Code “C5522”

**(a)** insert in alphabetical order in the column headed “Listed Drug”: Anastrozole

**(b)** insert in alphabetical order in the column headed “Listed Drug”: Letrozole

**(c)** insert in alphabetical order in the column headed “Listed Drug”: Tamoxifen

[307] Schedule 4, Part 1, omit entry for Circumstances Code “C5536”

[308] Schedule 4, Part 1, omit entry for Circumstances Code “C5550”

[309] Schedule 4, Part 1, omit entry for Circumstances Code “C5552”

[310] Schedule 4, Part 1, omit entry for Circumstances Code “C5584”

[311] Schedule 4, Part 1, omit entry for Circumstances Code “C5585”

[312] Schedule 4, Part 1, omit entry for Circumstances Code “C5592”

[313] Schedule 4, Part 1, omit entry for Circumstances Code “C5624”

[314] Schedule 4, Part 1, omit entry for Circumstances Code “C5639”

[315] Schedule 4, Part 1, omit entry for Circumstances Code “C5664”

[316] Schedule 4, Part 1, omit entry for Circumstances Code “C5665”

[317] Schedule 4, Part 1, omit entry for Circumstances Code “C5691”

[318] Schedule 4, Part 1, omit entry for Circumstances Code “C5692”

[319] Schedule 4, Part 1, omit entry for Circumstances Code “C5725”

[320] Schedule 4, Part 1, entry for Circumstances Code “C5729”

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

[321] Schedule 4, Part 1, omit entry for Circumstances Code “C5734”

[322] Schedule 4, Part 1, omit entry for Circumstances Code “C5748”

[323] Schedule 4, Part 1, omit entry for Circumstances Code “C5782”

[324] Schedule 4, Part 1, omit entry for Circumstances Code “C5809”

[325] Schedule 4, Part 1, omit entry for Circumstances Code “C5813”

[326] Schedule 4, Part 1, omit entry for Circumstances Code “C5814”

[327] Schedule 4, Part 1, omit entry for Circumstances Code “C5816”

[328] Schedule 4, Part 1, omit entry for Circumstances Code “C5826”

[329] Schedule 4, Part 1, omit entry for Circumstances Code “C5830”

[330] Schedule 4, Part 1, omit entry for Circumstances Code “C5842”

[331] Schedule 4, Part 1, omit entry for Circumstances Code “C5856”

[332] Schedule 4, Part 1, omit entry for Circumstances Code “C5861”

[333] Schedule 4, Part 1, omit entry for Circumstances Code “C5862”

[334] Schedule 4, Part 1, omit entry for Circumstances Code “C5868”

[335] Schedule 4, Part 1, entry for Circumstances Code “C5869”

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

[336] Schedule 4, Part 1, omit entry for Circumstances Code “C5881”

[337] Schedule 4, Part 1, omit entry for Circumstances Code “C5882”

[338] Schedule 4, Part 1, omit entry for Circumstances Code “C5890”

[339] Schedule 4, Part 1, omit entry for Circumstances Code “C5891”

[340] Schedule 4, Part 1, omit entry for Circumstances Code “C5903”

[341] Schedule 4, Part 1, omit entry for Circumstances Code “C5904”

[342] Schedule 4, Part 1, omit entry for Circumstances Code “C5915”

[343] Schedule 4, Part 1, omit entry for Circumstances Code “C5957”

[344] Schedule 4, Part 1, omit entry for Circumstances Code “C5978”

[345] Schedule 4, Part 1, omit entry for Circumstances Code “C5988”

[346] Schedule 4, Part 1, omit entry for Circumstances Code “C6002”

[347] Schedule 4, Part 1, omit entry for Circumstances Code “C6005”

[348] Schedule 4, Part 1, omit entry for Circumstances Code “C6006”

[349] Schedule 4, Part 1, omit entry for Circumstances Code “C6016”

[350] Schedule 4, Part 1, omit entry for Circumstances Code “C6022”

[351] Schedule 4, Part 1, omit entry for Circumstances Code “C6035”

[352] Schedule 4, Part 1, omit entry for Circumstances Code “C6037”

[353] Schedule 4, Part 1, omit entry for Circumstances Code “C6045”

[354] Schedule 4, Part 1, omit entry for Circumstances Code “C6057”

[355] Schedule 4, Part 1, omit entry for Circumstances Code “C6381”

[356] Schedule 4, Part 1, omit entry for Circumstances Code “C6449”

[357] Schedule 4, Part 1, omit entry for Circumstances Code “C6897”

[358] Schedule 4, Part 1, omit entry for Circumstances Code “C6899”

[359] Schedule 4, Part 1, omit entry for Circumstances Code “C6938”

[360] Schedule 4, Part 1, omit entry for Circumstances Code “C7509”

[361] Schedule 4, Part 1, omit entry for Circumstances Code “C7532”

[362] Schedule 4, Part 1, omit entry for Circumstances Code “C7893”

[363] Schedule 4, Part 1, omit entry for Circumstances Code “C7898”

[364] Schedule 4, Part 1, omit entry for Circumstances Code “C7916”

[365] Schedule 4, Part 1, omit entry for Circumstances Code “C7934”

[366] Schedule 4, Part 1, omit entry for Circumstances Code “C7957”

[367] Schedule 4, Part 1, omit entry for Circumstances Code “C7958”

[368] Schedule 4, Part 1, omit entry for Circumstances Code “C7966”

[369] Schedule 4, Part 1, omit entry for Circumstances Code “C7990”

[370] Schedule 4, Part 1, omit entry for Circumstances Code “C7996”

[371] Schedule 4, Part 1, omit entry for Circumstances Code “C8662”

[372] Schedule 4, Part 1, omit entry for Circumstances Code “C8692”

[373] Schedule 4, Part 1, omit entry for Circumstances Code “C8947”

[374] Schedule 4, Part 1, omit entry for Circumstances Code “C10023”

[375] Schedule 4, Part 1, entry for Circumstances Code “C10075”

omit from the column headed “Listed Drug”: Lanreotide

[376] Schedule 4, Part 1, omit entry for Circumstances Code “C10745”

[377] Schedule 4, Part 1, omit entry for Circumstances Code “C10747”

[378] Schedule 4, Part 1, omit entry for Circumstances Code “C10751”

[379] Schedule 4, Part 1, omit entry for Circumstances Code “C11018”

[380] Schedule 4, Part 1, omit entry for Circumstances Code “C12004”

[381] Schedule 4, Part 1, omit entry for Circumstances Code “C12064”

[382] Schedule 4, Part 1, omit entry for Circumstances Code “C13819”

[383] Schedule 4, Part 1, omit entry for Circumstances Code “C13820”

[384] Schedule 4, Part 1, omit entry for Circumstances Code “C14189”

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

**(a)** insert in alphabetical order in the column headed “Listed Drug”: Ezetimibe

**(b)** insert in alphabetical order in the column headed “Listed Drug”: Ezetimibe and rosuvastatin

**(c)** insert in alphabetical order in the column headed “Listed Drug”: Ezetimibe with atorvastatin

**(d)** insert in alphabetical order in the column headed “Listed Drug”: Ezetimibe with simvastatin

**(e)** omit from the column headed “Listed Drug”: Penicillamine

[386] Schedule 4, Part 1, omit entry for Circumstances Code “C14249”

[387] Schedule 4, Part 1, omit entry for Circumstances Code “C14269”

[388] Schedule 4, Part 1, omit entry for Circumstances Code “C14283”

[389] Schedule 4, Part 1, omit entry for Circumstances Code “C14284”

[390] Schedule 4, Part 1, entry for Circumstances Code “C14301”

**(a)** insert in alphabetical order in the column headed “Listed Drug”: Apixaban

**(b)** insert in alphabetical order in the column headed “Listed Drug”: Dabigatran etexilate

[391] Schedule 4, Part 1, omit entry for Circumstances Code “C14302”

[392] Schedule 4, Part 1, omit entry for Circumstances Code “C14308”

[393] Schedule 4, Part 1, omit entry for Circumstances Code “C14310”

[394] Schedule 4, Part 1, entry for Circumstances Code “C14318”

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

[395] Schedule 4, Part 1, omit entry for Circumstances Code “C14348”

[396] Schedule 4, Part 1, omit entry for Circumstances Code “C14350”

[397] Schedule 4, Part 1, omit entry for Circumstances Code “C14472”

[398] Schedule 4, Part 1, entry for Circumstances Code “C14872”

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

[399] Schedule 4, Part 1, entry for Circumstances Code “C14895”

**(a)** insert in alphabetical order in the column headed “Listed Drug”: Anastrozole

**(b)** insert in alphabetical order in the column headed “Listed Drug”: Exemestane

**(c)** insert in alphabetical order in the column headed “Listed Drug”: Letrozole

[400] Schedule 4, Part 1, omit entry for Circumstances Code “C14943”

[401] Schedule 4, Part 1, omit entry for Circumstances Code “C14984”

[402] Schedule 4, Part 1, omit entry for Circumstances Code “C14992”

[403] Schedule 4, Part 1, entry for Circumstances Code “C15269”

insert in alphabetical order in the column headed “Listed Drug”: Dapagliflozin with sitagliptin

[404] Schedule 4, Part 1, entry for Circumstances Code “C15270”

insert in alphabetical order in the column headed “Listed Drug”: Dapagliflozin with sitagliptin

[405] Schedule 4, Part 1, omit entry for Circumstances Code “C15355”

[406] Schedule 4, Part 1, omit entry for Circumstances Code “C15356”

[407] Schedule 4, Part 1, omit entry for Circumstances Code “C15358”

[408] Schedule 4, Part 1, omit entry for Circumstances Code “C15385”

[409] Schedule 4, Part 1, omit entry for Circumstances Code “C15439”

[410] Schedule 4, Part 1, after entry for Circumstances Code “C15952”

insert:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C15955 | P15955 | CN15955 | Lanreotide | Functional carcinoid tumour  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must be causing intractable symptoms; AND  Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND  Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND  The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.  Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 15955 |
| C15956 | P15956 | CN15956 | Auranofin  Chlorpromazine  Digoxin  Disopyramide  Isoniazid  Lidocaine  Penicillamine  Periciazine  Zuclopenthixol decanoate | For prescribing by certain health practitioners  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C15964 | P15964 | CN15964 | Cefazolin  Cefotaxime  Ceftriaxone | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C15965 | P15965 | CN15965 | Flecainide | Serious supra-ventricular cardiac arrhythmias  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C15966 | P15966 | CN15966 | Flecainide | Serious ventricular cardiac arrhythmias  The treatment must be initiated in a hospital; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C15967 | P15967 | CN15967 | Amiodarone  Sotalol | Severe cardiac arrhythmias  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C15973 | P15973 | CN15973 | Rifampicin | Leprosy  Patient must be an adult;  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C15975 | P15975 | CN15975 | Fluconazole | Cryptococcal meningitis  The treatment must be maintenance therapy; AND  Patient must be immunosuppressed; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 15975 |
| C15978 | P15978 | CN15978 | Itraconazole | Systemic sporotrichosis  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 15978 |
| C15979 | P15979 | CN15979 | Voriconazole | Serious Candida infections  Treatment and maintenance therapy  The condition must be caused by species not susceptible to fluconazole; or  The condition must be resistant to fluconazole; or  Patient must be unable to tolerate fluconazole; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C15981 | P15981 | CN15981 | Voriconazole | Serious invasive mycosis infections  Treatment and maintenance therapy  The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C15984 | P15984 | CN15984 | Fluconazole | Cryptococcal meningitis  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 15984 |
| C15994 | P15994 | CN15994 | Fentanyl  Methadone | Chronic severe disabling pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  The condition must require daily, continuous, long term opioid treatment; AND  Patient must not be opioid naive; AND  Patient must have cancer pain; or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 15994 |
| C15996 | P15996 | CN15996 | Fentanyl  Methadone | Chronic severe disabling pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  The condition must require daily, continuous, long term opioid treatment; AND  Patient must not be opioid naive; AND  Patient must have cancer pain; or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 15996 |
| C16000 | P16000 | CN16000 | Fentanyl  Methadone | Chronic severe disabling pain  Continuing PBS treatment after 1 June 2020  Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16000 |
| C16009 | P16009 | CN16009 | Buprenorphine  Buprenorphine with naloxone | Opioid dependence  The treatment must be within a framework of medical, social and psychological treatment.  The prescriber must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs. | Compliance with Authority Required procedures - Streamlined Authority Code 16009 |
| C16015 | P16015 | CN16015 | Buprenorphine | Opioid dependence  Must be treated by a health care professional; AND  The treatment must be within a framework of medical, social and psychological treatment; AND  Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.  The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs. | Compliance with Authority Required procedures - Streamlined Authority Code 16015 |
| C16018 | P16018 | CN16018 | Eptinezumab  Galcanezumab | Chronic migraine  Initial treatment  Must be treated by a neurologist; or  Must be treated by a general practitioner in consultation with a neurologist; AND  Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication; AND  Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND  Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND  Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug;  Patient must be at least 18 years of age.  Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.  Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 16018 |
| C16021 | P16021 | CN16021 | Romosozumab | Severe established osteoporosis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 November 2024; AND  Patient must not have received PBS-subsidised treatment with any of the following prior to initiating non-PBS-subsidised treatment with this drug for this condition: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab; AND  Patient must be at very high risk of fracture; AND  Patient must have had a Bone Mineral Density (BMD) T-score of -2.5 or less prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  Patient must have had a symptomatic fracture due to minimal trauma prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  Patient must have had at least 1 hip or symptomatic vertebral fracture in the 24 months prior to starting non-PBS-subsidised treatment with this drug for this condition; or  Patient must have had at least 2 fractures including 1 symptomatic new fracture in the 24 months prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy; AND  Must be treated by a consultant physician.  Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.  Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid. | Compliance with Authority Required procedures |
| C16022 | P16022 | CN16022 | Romosozumab | Severe established osteoporosis  Continuing treatment - First-line therapy  Patient must have previously received PBS-subsidised treatment with this drug for this condition as first-line therapy; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy; AND  Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner. | Compliance with Authority Required procedures |
| C16023 | P16023 | CN16023 | Romosozumab | Severe established osteoporosis  Continuing treatment - Second-line therapy  Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy; AND  The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy; AND  Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner. | Compliance with Authority Required procedures |
| C16024 | P16024 | CN16024 | Lanreotide | Acromegaly  Initial treatment  Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting; AND  The condition must be active; AND  Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND  The treatment must be after failure of other therapy including dopamine agonists; or  The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or  The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND  The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant.  In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | Compliance with Authority Required procedures - Streamlined Authority Code 16024 |
| C16029 | P16029 | CN16029 | Cefazolin  Cefotaxime  Ceftriaxone | Septicaemia, proven  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C16030 | P16030 | CN16030 | Cefazolin  Cefotaxime  Ceftriaxone | Septicaemia, suspected  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C16034 | P16034 | CN16034 | Fluconazole | Fungal infection  The condition must be serious or life-threatening; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16034 |
| C16035 | P16035 | CN16035 | Itraconazole | Systemic histoplasmosis  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16035 |
| C16037 | P16037 | CN16037 | Rifampicin | Haemophilus influenzae type B  The treatment must be for prophylaxis; AND  Patient must be in contact with people who have the disease; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C16042 | P16042 | CN16042 | Voriconazole | Definite or probable invasive aspergillosis  Treatment and maintenance therapy  Patient must be immunocompromised; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16043 | P16043 | CN16043 | Rifampicin | Mycobacterium ulcerans infection (Buruli ulcer)  The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16048 | P16048 | CN16048 | Risperidone | Severe behavioural disturbances  Continuing treatment  Patient must have autism spectrum disorder; AND  Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age; AND  The treatment must be under the supervision of a paediatrician or psychiatrist; AND  The treatment must be in combination with non-pharmacological measures;  Patient must be at least 18 years of age.  Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.  The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 16048 |
| C16050 | P16050 | CN16050 | Buprenorphine | Opioid dependence  Must be treated by a health care professional; AND  The treatment must be within a framework of medical, social and psychological treatment; AND  Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.  The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs. | Compliance with Authority Required procedures - Streamlined Authority Code 16050 |
| C16051 | P16051 | CN16051 | Buprenorphine | Opioid dependence  Must be treated by a health care professional; AND  The treatment must be within a framework of medical, social and psychological treatment.  The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs. | Compliance with Authority Required procedures - Streamlined Authority Code 16051 |
| C16053 | P16053 | CN16053 | Avelumab | Stage IV (metastatic) Merkel Cell Carcinoma  Initial treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction. or  The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 16053 |
| C16054 | P16054 | CN16054 | Chlormethine | Mycosis fungoides cutaneous T-cell lymphoma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  Patient must be treated by at least one of the following prescriber types (i) dermatologist, (ii) haematologist; AND  The treatment must be approved for 1 unit if the condition is no more than 10% of the patient's body surface area to provide 4 weeks of treatment per script. or  The treatment must be approved for 2 units if the condition is no more than 25% of the patient's body surface area to provide 4 weeks of treatment per script. | Compliance with Authority Required procedures |
| C16055 | P16055 | CN16055 | Lanreotide | Acromegaly  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must be active; AND  Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND  The treatment must be after failure of other therapy including dopamine agonists; or  The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or  The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND  The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant.  In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | Compliance with Authority Required procedures - Streamlined Authority Code 16055 |
| C16056 | P16056 | CN16056 | Lanreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)  Initial treatment  Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting; AND  The condition must be unresectable locally advanced disease or metastatic disease; AND  The condition must be World Health Organisation (WHO) grade 1 or 2; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must be at least 18 years of age.  WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.  WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 16056 |
| C16057 | P16057 | CN16057 | Lanreotide | Functional carcinoid tumour  Initial treatment  Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting; AND  The condition must be causing intractable symptoms; AND  Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND  Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND  The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.  Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 16057 |
| C16063 | P16063 | CN16063 | Tirofiban | Non-Q-wave myocardial infarction  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16063 |
| C16067 | P16067 | CN16067 | Cefepime | Febrile neutropenia  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16072 | P16072 | CN16072 | Posaconazole | Invasive aspergillosis  Patient must be unable to tolerate alternative therapy; or  Patient must have disease refractory to alternative therapy; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16073 | P16073 | CN16073 | Itraconazole | Oropharyngeal candidiasis  Patient must be immunosuppressed; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16073 |
| C16075 | P16075 | CN16075 | Rifampicin | Meningococcal disease  The treatment must be for prophylaxis; AND  Patient must be a carrier of the disease; or  Patient must be in close contact with people who have the disease; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C16078 | P16078 | CN16078 | Penicillamine | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. |  |
| C16083 | P16083 | CN16083 | Methadone | Opioid dependence  The treatment must be within a framework of medical, social and psychological treatment.  The prescriber must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs. | Compliance with Authority Required procedures - Streamlined Authority Code 16083 |
| C16085 | P16085 | CN16085 | Avelumab | Stage IV (metastatic) Merkel Cell Carcinoma  Continuing treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction. or  The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 16085 |
| C16087 | P16087 | CN16087 | Romosozumab | Severe established osteoporosis  Initial treatment - Second-line therapy  Patient must be at very high risk of fracture; AND  Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND  Patient must have had 2 or more fractures due to minimal trauma; AND  Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy; AND  Patient must not have received treatment with PBS-subsidised teriparatide; or  Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy; AND  Must be treated by a consultant physician.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.  If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.  If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.  Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.  Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application. | Compliance with Authority Required procedures |
| C16094 | P16094 | CN16094 | Voriconazole | Serious fungal infections  Treatment and maintenance therapy  The condition must be caused by Scedosporium species; or  The condition must be caused by Fusarium species; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16096 | P16096 | CN16096 | Posaconazole | Fungal infection  The condition must be fusariosis; or  The condition must be zygomycosis; or  The condition must be coccidioidomycosis; or  The condition must be chromoblastomycosis; or  The condition must be mycetoma; AND  Patient must be unable to tolerate alternative therapy; or  Patient must have disease refractory to alternative therapy; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16099 | P16099 | CN16099 | Itraconazole | Disseminated pulmonary histoplasmosis infection  Treatment and maintenance therapy  Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS); AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16099 |
| C16101 | P16101 | CN16101 | Itraconazole | Chronic pulmonary histoplasmosis infection  Treatment and maintenance therapy  Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS); AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16101 |
| C16102 | P16102 | CN16102 | Itraconazole | Oesophageal candidiasis  Patient must be immunosuppressed; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16102 |
| C16104 | P16104 | CN16104 | Fremanezumab | Treatment-resistant migraine  Initial treatment  Must be treated by a neurologist; or  Must be treated by a general practitioner in consultation with a neurologist; AND  Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication; AND  Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND  Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND  Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug;  Patient must be at least 18 years of age.  Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.  Patient must have the number of migraine headache days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 16104 |
| C16111 | P16111 | CN16111 | Perhexiline | Angina  The condition must not be responding to other therapy; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16111 |
| C16114 | P16114 | CN16114 | Fluconazole | Fungal infection  The condition must be serious or life-threatening; AND  Patient must be unable to take a solid dose form of fluconazole; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16114 |
| C16115 | P16115 | CN16115 | Voriconazole | Prophylaxis of invasive fungal infections including both yeasts and moulds  Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; or  Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; or  Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |
| C16117 | P16117 | CN16117 | Posaconazole | Prophylaxis of invasive fungal infections including both yeasts and moulds  Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; or  Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.  Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.  Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.  No more than 6 months therapy per episode will be PBS-subsidised | Compliance with Authority Required procedures |
| C16119 | P16119 | CN16119 | Itraconazole | Systemic aspergillosis  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16119 |
| C16123 | P16123 | CN16123 | Tirofiban | High risk of unstable angina  Patient must have new transient or persistent ST-T ischaemic changes; AND  Patient must have pain lasting longer than 20 minutes; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16123 |
| C16132 | P16132 | CN16132 | Romosozumab | Severe established osteoporosis  Initial treatment - First-line therapy  Patient must not have received PBS-subsidised treatment with any of: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab; AND  Patient must be at very high risk of fracture; AND  Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND  Patient must have had a symptomatic fracture due to minimal trauma; AND  Patient must have had at least 1 hip or symptomatic vertebral fracture in the previous 24 months; or  Patient must have had at least 2 fractures including 1 symptomatic new fracture in the previous 24 months; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy; AND  Must be treated by a consultant physician.  Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.  Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid. | Compliance with Authority Required procedures |
| C16133 | P16133 | CN16133 | Lanreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must be unresectable locally advanced disease or metastatic disease; AND  The condition must be World Health Organisation (WHO) grade 1 or 2; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must be at least 18 years of age.  WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.  WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 16133 |
| C16141 | P16141 | CN16141 | Fluconazole | Cryptococcal meningitis  Patient must be unable to take a solid dose form of fluconazole; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16141 |
| C16145 | P16145 | CN16145 | Chlormethine | Mycosis fungoides cutaneous T-cell lymphoma  Initial treatment  The condition must be any of: (i) Stage IA, (ii) IIA, (iii) IB mycosis fungoides cutaneous T-cell lymphoma; AND  The condition must have been confirmed through a diagnostic lesion biopsy from an Approved Pathology Authority; AND  The condition must cover either of which: (i) no more than 10% of the patient's body surface area, (ii) no more than 25% of the patient's body surface area; AND  Patient must be treated by at least one of the following prescriber types (i) dermatologist, (ii) haematologist; AND  The treatment must be approved for 1 unit if the condition is no more than 10% of the patient's body surface area to provide 4 weeks of treatment per script; or  The treatment must be approved for 2 units if the condition is no more than 25% of the patient's body surface area to provide 4 weeks of treatment per script;  Patient must be at least 18 years of age.  Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C16147 | P16147 | CN16147 | Tirofiban | High risk of unstable angina  Patient must have new transient or persistent ST-T ischaemic changes; AND  Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16147 |
| C16148 | P16148 | CN16148 | Fluconazole | Cryptococcal meningitis  The treatment must be maintenance therapy; AND  Patient must be immunosuppressed; AND  Patient must be unable to take a solid dose form of fluconazole; AND  Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures - Streamlined Authority Code 16148 |

[411] Schedule 4, Part 2, omit entry for Variation Code "V10745"

[412] Schedule 4, Part 2, omit entry for Variation Code "V10747"

[413] Schedule 4, Part 2, omit entry for Variation Code "V10751"

[414] Schedule 4, Part 2, after entry for Variation Code "V15457"

insert:

|  |  |  |
| --- | --- | --- |
| V15457 | Nivolumab | An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly. |

[415] Schedule 4, Part 2, omit second entry for Variation Code "V15818"

[416] Schedule 4, Part 2, after entry for Variation Code "V15832"

insert:

|  |  |  |
| --- | --- | --- |
| V15994 | Fentanyl  Methadone | Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment: (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| V15996 | Fentanyl  Methadone | Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.  Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| V16000 | Fentanyl  Methadone | Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment: (i) is less than 12 months; or (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |

[417] Schedule 5, entry for Amiodarone in the form Tablet containing amiodarone hydrochloride 200 mg

omit from the column headed "Brand": APO-Amiodarone

[418] Schedule 5, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 25 mg

omit from the column headed "Brand": APO-Amitriptyline 25

[419] Schedule 5, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 10 mg

omit from the column headed "Brand": APO-Amitriptyline 10

[420] Schedule 5, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 50 mg

omit from the column headed "Brand": APO-Amitriptyline 50

[421] Schedule 5, entry for Atenolol

omit from the column headed "Brand": APO-Atenolol

[422] Schedule 5, entry for Bosentan in each of the forms: Tablet 125 mg (as monohydrate); and Tablet 62.5 mg (as monohydrate)

omit from the column headed "Brand": BOSLEER

[423] Schedule 5, entry for Calcitriol

**(a)** omit from the column headed "Brand": APO-Calcitriol

**(b)** omit from the column headed "Brand": Kosteo

[424] Schedule 5, after entry for Celecoxib in the form Capsule 200 mg *[GRP-19623]*

insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Choriogonadotropin alfa | GRP-29227 | Solution for injection 250 micrograms in 0.5 mL pre-filled pen | Injection | Ovidrel |
| Choriogonadotropin alfa | GRP-29227 | Solution for injection 250 micrograms in 0.5 mL pre-filled syringe (S19A) | Injection | Ovidrel (USA) |

[425] Schedule 5, entry for Ciprofloxacin in each of the forms: Tablet 750 mg (as hydrochloride); Tablet 500 mg (as hydrochloride); and Tablet 250 mg (as hydrochloride)

omit from the column headed "Brand": APX-Ciprofloxacin

[426] Schedule 5, entry for Citalopram in each of the forms: Tablet 40 mg (as hydrobromide); Tablet 20 mg (as hydrobromide); and Tablet 10 mg (as hydrobromide)

insert in alphabetical order in the column headed "Brand": CITALOPRAM-WGR

[427] Schedule 5, entry for Diazepam in each of the forms: Tablet 5 mg; and Tablet 2 mg

omit from the column headed "Brand": APO-Diazepam

[428] Schedule 5, entry for Diclofenac in each of the forms: Tablet (enteric coated) containing diclofenac sodium 50 mg; and Tablet (enteric coated) containing diclofenac sodium 25 mg

omit from the column headed "Brand": APO-Diclofenac

[429] Schedule 5, entry for Entecavir in each of the forms: Tablet 0.5 mg (as monohydrate); and Tablet 1 mg (as monohydrate)

omit from the column headed "Brand": ENTECLUDE

[430] Schedule 5, entry for Fluconazole in the form Capsule 200 mg

insert in alphabetical order in the column headed "Brand": FLUCONAZOLE-WGR

[431] Schedule 5, entry for Fulvestrant

insert in alphabetical order in the column headed "Brand": FULVESTRANT-AFT

[432] Schedule 5, entry for Gliclazide in the form Tablet 80 mg

**(a)** omit from the column headed "Brand": APO-Gliclazide

**(b)** omit from the column headed "Brand": Glyade

[433] Schedule 5, entry for Ibuprofen

omit from the column headed "Brand": MEDICHOICE Ibuprofen 400 mg

[434] Schedule 5, entry for Imatinib in the form Capsule 400 mg (as mesilate)

insert in alphabetical order in the column headed "Brand": ARX-IMATINIB

[435] Schedule 5, entry for Irbesartan in the form Tablet 75 mg

omit from the column headed "Brand": Karvea

[436] Schedule 5, entry for Itraconazole

omit from the column headed "Brand": APO-Itraconazole

[437] Schedule 5, entry for Macrogol 3350

omit from the column headed "Brand": Movicol

[438] Schedule 5, entries for Naloxone

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Naloxone | GRP-27818 | Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 | Nasal | Nyxoid |
| Naloxone | GRP-27818 | Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A) | Nasal | Nyxoid (UK) |

[439] Schedule 5, omit entries Nifedipine

[440] Schedule 5, entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)

insert in alphabetical order in the column headed "Brand": APX-PANTOPRAZOLE

[441] Schedule 5, entry for Pioglitazone in the form Tablet 45 mg (as hydrochloride)

**(a)** omit from the column headed "Brand": Acpio 45

**(b)** omit from the column headed "Brand": Actaze

[442] Schedule 5, entry for Pioglitazone in the form Tablet 15 mg (as hydrochloride)

**(a)** omit from the column headed "Brand": Acpio 15

**(b)** omit from the column headed "Brand": Actaze

[443] Schedule 5, entry for Pioglitazone in the form Tablet 30 mg (as hydrochloride)

**(a)** omit from the column headed "Brand": Acpio 30

**(b)** omit from the column headed "Brand": Actaze

**(c)** insert in alphabetical order in the column headed "Brand": ARX-PIOGLITAZONE

[444] Schedule 5, entry for Quetiapine in each of the forms: Tablet 300 mg (as fumarate); Tablet 200 mg (as fumarate); Tablet 100 mg (as fumarate); and Tablet 25 mg (as fumarate)

insert in alphabetical order in the column headed "Brand": QUETIAPINE-WGR

[445] Schedule 5, entry for Quinapril in the form Tablet 20 mg (as hydrochloride)

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quinapril | GRP-19716 | Tablet 20 mg (as hydrochloride) | Oral | Accupril ACQUIN APO-Quinapril |

[446] Schedule 5, entry for Quinapril in the form Tablet 10 mg (as hydrochloride)

omit:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quinapril | GRP-19902 | Tablet 10 mg (as hydrochloride) | Oral | Accupril ACQUIN APO-Quinapril |

[447] Schedule 5, entry for Riluzole

omit from the column headed "Brand": APO-Riluzole

[448] Schedule 5, entries for Timolol

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Timolol | GRP-29229 | Eye drops 5 mg (as maleate) per mL, 5 mL | Application to the eye | Timoptol |
| Timolol | GRP-29229 | Eye drops 5 mg (as maleate) per mL, 5 mL (S19A) | Application to the eye | Timolol (Brown & Burk, UK) |
| Timolol | GRP-28880 | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL | Application to the eye | Timoptol XE |
| Timolol | GRP-28880 | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A) | Application to the eye | Timoptol XE 0.50% (South Africa) |
| Timolol | GRP-28880 | Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL - (Timoptol-LA) (S19A) | Application to the eye | Timoptol-LA 0.5 % (Santen Oy, Finland) |

[449] Schedule 5, entry for Valaciclovir

omit from the column headed "Brand": Valaciclovir generichealth