

PB 45 of 2014

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014   
(No. 6)

*National Health Act 1953*

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 11 June 2014

**FELICITY McNEILL**

First Assistant Secretary

Pharmaceutical Benefits Division

Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 6)*.

(2) This Instrument may also be cited as PB 45 of 2014.

2 Commencement

This Instrument commences on 1 July 2014.

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

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

Schedule 1 Amendments

1. Schedule 1, entry for Acitretin in the form Capsule 10 mg

*omit from the column headed “Responsible Person” for the brand “Neotigason”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Acitretin in the form Capsule 25 mg

*omit from the column headed “Responsible Person” for the brand “Neotigason”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Atorvastatin and ezetimibe in the form Pack containing 30 tablets atorvastatin 10 mg (as calcium) and   
   30 tablets ezetemibe 10 mg

**(a)** *omit from the column headed “Form”:* **ezetemibe** *substitute:* **ezetimibe**

**(b)** *omit from the column headed “Brand”:* **10mg + 10mg**

1. Schedule 1, entry for Atorvastatin and ezetimibe in the form Pack containing 30 tablets atorvastatin 20 mg (as calcium) and   
   30 tablets ezetemibe 10 mg

**(a)** *omit from the column headed “Form”:* **ezetemibe** *substitute:* **ezetimibe**

**(b)** *omit from the column headed “Brand”:* **10mg + 20mg**

1. Schedule 1, entry for Atorvastatin and ezetimibe in the form Pack containing 30 tablets atorvastatin 40 mg (as calcium) and   
   30 tablets ezetemibe 10 mg

**(a)** *omit from the column headed “Form”:* **ezetemibe** *substitute:* **ezetimibe**

**(b)** *omit from the column headed “Brand”:* **10mg + 40mg**

1. Schedule 1, entry for Atorvastatin and ezetimibe in the form Pack containing 30 tablets atorvastatin 80 mg (as calcium) and   
   30 tablets ezetemibe 10 mg

**(a)** *omit from the column headed “Form”:* **ezetemibe** *substitute:* **ezetimibe**

**(b)** *omit from the column headed “Brand”:* **10mg + 80mg**

1. **Schedule 1, after entry for Bimatoprost with timolol in the form Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate)   
   per mL, 3 mL**

*insert in the columns in the order indicated:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30 | Application to the eye | GANfort PF 0.3/5 | AG | MP | C4572 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  | AO | C4326 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Adesan HCT 32/12.5 | AF | MP NP | C4374 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Adesan HCT 32/25 | AF | MP NP | C4374 |  | 30 | 5 | 30 |  |  |

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

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Cefepime Alphapharm | AF | MP NP | C1427 |  | 10 | 0 | 1 |  |  |

1. Schedule 1, entry for Cephalexin in the form Capsule 250 mg (anhydrous) *[Maximum Quantity: 40; Number of Repeats: 2]*
   * 1. *omit from the column headed “Circumstances” (all instances):* **C4243**
     2. *insert in the column headed “Purposes” (all instances):* **P4243**
2. Schedule 1, entry for Cinacalcet in the form Tablet 30 mg (as hydrochloride) *[Maximum Quantity: 28; Number of Repeats: 5]*
   * 1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
     2. *omit from the column headed “Purposes”:* **P3672 P3673**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | NP | C3672 C3673 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Cinacalcet in the form Tablet 60 mg (as hydrochloride) *[Maximum Quantity: 28; Number of Repeats: 5]*
   * 1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
     2. *omit from the column headed “Purposes”:* **P3672 P3673**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | NP | C3672 C3673 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Cinacalcet in the form Tablet 90 mg (as hydrochloride) *[Maximum Quantity: 28; Number of Repeats: 5]*
   * 1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
     2. *omit from the column headed “Purposes”:* **P3672 P3673**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | NP | C3672 C3673 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Ciprofloxacin in the form Tablet 250 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Cifran | RA | MP NP | C1143 C1431 C1432 C1572 C1573 |  | 14 | 0 | 14 |  |  |

1. **Schedule 1, entry for Clarithromycin in the form Tablet 250 mg *[Maximum Quantity: 14; Number of Repeats: 1]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Clarihexal | HX | MP NP |  |  | 14 | 1 | 14 |  |  |

1. **Schedule 1, entry for Clarithromycin in the form Tablet 250 mg *[Maximum Quantity: 100; Number of Repeats: 2]***

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Klacid | AB | MP See Note 1 |  | P1434 P3325 | 100 CN1434 CN3325 | 2 CN1434 CN3325 | 100 |  | C(100) |

1. Schedule 1, entry for Clopidogrel in the form Tablet 75 mg (as besilate)

*omit from the column headed “Responsible Person” for the brand “Clopidogrel Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Diazepam in the form Oral liquid 1 mg in 1 mL, 100 mL

*omit from the column headed “Circumstances”:* **4244** *substitute:* **C4244**

1. Schedule 1, entry for Diltiazem in the form Tablet containing diltiazem hydrochloride 60 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Coras | AF | MP NP |  |  | 90 | 5 | 90 |  |  |

1. Schedule 1, entry for Diphenoxylate with Atropine
   * 1. omit from the column headed “Responsible Person” for the brand “Lofenoxal”: **HC** substitute: **IA**
     2. omit from the column headed “Responsible Person” for the brand “Lomotil”: **BI** substitute: **IV**
2. Schedule 1, entry for Docetaxel in the form Solution concentrate for I.V. infusion 140 mg in 7 mL

*omit from the column headed “Responsible Person”:* **TA** *substitute:* **GN**

1. Schedule 1, entry for Docetaxel in the form Solution concentrate for I.V. infusion 20 mg in 1 mL
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Oncotaxel 20 | TA | MP | C3888 C3892 C3916 C3956 C4078 C4140 C4160 C4239 | See Note 3 | See Note 3 | See  Note 3 | 1 |  | D(100) |

* + 1. omit from the column headed “Purposes” for the brand “Taxotere”: **See Note 3**

1. Schedule 1, entry for Docetaxel in the form Solution concentrate for I.V. infusion 20 mg in 2 mL

*omit from the column headed “Purposes” (twice occurring):* **See Note 3**

1. Schedule 1, entry for Docetaxel in the form Solution concentrate for I.V. infusion 80 mg in 4 mL

*omit from the column headed “Responsible Person” for the brand “Oncotaxel 80”:* **TA** *substitute:* **GN**

1. **Schedule 1, entry for Doxycycline in the form Tablet 100 mg (as monohydrate)**
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxyhexal | SZ | PDP |  |  | 7 | 0 | 7 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxyhexal | SZ | MP NP |  |  | 7 | 1 | 7 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxyhexal | SZ | MP NP |  | P4485 | 21 | 0 | 7 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxyhexal | SZ | MP NP |  | P4514 | 28 | 0 | 7 |  |  |

1. Schedule 1, entry for Doxycycline in the form Tablet 50 mg (as monohydrate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxyhexal | SZ | MP NP | C4475 C4529 C4539 |  | 25 | 5 | 25 |  |  |

1. Schedule 1, entry for Eletriptan in each of the forms: Tablet 40 mg (as hydrobromide); and Tablet 80 mg (as hydrobromide)

*omit from the column headed “Circumstances”:* **C3233** *substitute:* **C4573**

1. Schedule 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL

*omit from the column headed “Responsible Person” for the brand “Epirubicin Actavis 10”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL

*omit from the column headed “Responsible Person” for the brand “Epirubicin Actavis 20”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL

*omit from the column headed “Responsible Person” for the brand “Epirubicin Actavis 50”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL

*omit from the column headed “Responsible Person” for the brand “Epirubicin Actavis 200”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Fludarabine in the form Powder for I.V. injection containing fludarabine phosphate 50 mg

*omit from the column headed “Responsible Person” for the brand “Fludarabine Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Fosinopril with Hydrochlorothiazide in each of the forms: Tablet containing fosinopril sodium 10 mg   
   with hydrochlorothiazide 12.5 mg; and Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Hyforil | RA | MP NP | C4389 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Glucose in the form I.V. infusion 278 mmol (anhydrous) per L, 1 L**
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fresenius Kabi Australia Pty Limited | PK | PDP |  |  | 5 | 0 | 1 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fresenius Kabi Australia Pty Limited | PK | MP NP |  |  | 5 | 1 | 1 |  |  |

1. Schedule 1, entry for Hydrocortisone in the form Injection 100 mg (as sodium succinate) with 2 mL solvent *[Maximum Quantity: 6; Number of Repeats: 0]*
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | PDP | C1128 |  | 6 | 0 | 1 |  |  |

1. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
2. Schedule 1, entry for Hydrocortisone in the form Injection 250 mg (as sodium succinate) with 2 mL solvent *[Maximum Quantity: 6; Number of Repeats: 0]*
3. *omit from the column headed “Authorised Prescriber”:* **MP NP** *substitute:* **MP NP PDP**
4. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | PDP | C1128 |  | 6 | 0 | 1 |  |  |

1. Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Irinotecan Actavis | TA | MP |  |  | See Note 3 | See  Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL

*omit from the column headed “Responsible Person” for the brand “Irinotecan Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL

*omit from the column headed “Responsible Person” for the brand “Irinotecan Actavis 500”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Ivermectin in the form Tablet 3 mg *[Maximum Quantity: 4; Number of Repeats: 0]*

*insert in numerical order in the column headed “Circumstances”:* **C4565 C4566**

1. Schedule 1, entry for Ivermectin in the form Tablet 3 mg *[Maximum Quantity: 8; Number of Repeats: 2]*
   * 1. *insert in numerical order in the column headed “Circumstances”:* **C4565 C4566**
     2. *insert in numerical order in the column headed “Purposes”:* **P4565 P4566**
2. **Schedule 1, entry for Lamotrigine in the form Tablet 5 mg**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Lamotrigine Aspen 5 | FM | MP NP | C1426 |  | 56 | 5 | 56 |  |  |

1. Schedule 1, entry for Lamotrigine in the form Tablet 25 mg

*omit from the column headed “Responsible Person” for the brand “Torlemo DT 25”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Lamotrigine in the form Tablet 50 mg

*omit from the column headed “Responsible Person” for the brand “Torlemo DT 50”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Lamotrigine in the form Tablet 100 mg

*omit from the column headed “Responsible Person” for the brand “Torlemo DT 100”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Lamotrigine in the form Tablet 200 mg

*omit from the column headed “Responsible Person” for the brand “Torlemo DT 200”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Lanreotide in the form Powder for suspension for injection 30 mg (as acetate) with diluent

*omit from the column headed “Circumstances”:* **C2619 C3387** *substitute:* **C4559 C4567**

1. Schedule 1, entry for Lanreotide in the form Injection 60 mg (as acetate) in single dose pre‑filled syringe
   * 1. *omit from the column headed “Circumstances”:* **C2620 C2621 C3388 C3389** *substitute:* **C4569 C4570 C4574 C4575**
     2. *omit from the column headed “Number of Repeats”:* **11** *substitute:* **5**
2. Schedule 1, entry for Lanreotide in the form Injection 90 mg (as acetate) in single dose pre‑filled syringe
   * 1. *omit from the column headed “Circumstances”:* **C2620 C2621 C3388 C3389** *substitute:* **C4569 C4570 C4574 C4575**
     2. *omit from the column headed “Number of Repeats”:* **11** *substitute:* **5**
3. Schedule 1, entry for Lanreotide in the form Injection 120 mg (as acetate) in single dose pre‑filled syringe
   * 1. *omit from the column headed “Circumstances”:* **C2620 C2621 C3388 C3389** *substitute:* **C4569 C4570 C4574 C4575**
     2. *omit from the column headed “Number of Repeats”:* **11** *substitute:* **5**
4. Schedule 1, entry for Lanthanum in the form Tablet, chewable, 500 mg (as carbonate hydrate) *[Maximum Quantity: 90; Number of Repeats: 5]*
   * 1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
     2. *omit from the column headed “Purposes”:* **P3546 P3547**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | NP | C3546 C3547 |  | 90 | 5 | 90 |  |  |

1. Schedule 1, entry for Lanthanum in the form Tablet, chewable, 750 mg (as carbonate hydrate) *[Maximum Quantity: 90; Number of Repeats: 5]*
   * 1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
     2. *omit from the column headed “Purposes”:* **P3546 P3547**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | NP | C3546 C3547 |  | 90 | 5 | 90 |  |  |

1. Schedule 1, entry for Lanthanum in the form Tablet, chewable, 1000 mg (as carbonate hydrate) *[Maximum Quantity: 90; Number of Repeats: 5]*
   * 1. *omit from the column headed “Authorised Prescriber”:* **MP** *substitute:* **MP NP**
     2. *omit from the column headed “Purposes”:* **P3546 P3547**
     3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | NP | C3546 C3547 |  | 90 | 5 | 90 |  |  |

1. **Schedule 1, entry for Latanoprost**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Latanoprost GH | GQ | MP AO |  |  | 1 | 5 | 1 |  |  |

1. **Schedule 1, entry for Latanoprost with timolol**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | APO-Latanoprost/ Timolol 0.05/5 | TX | MP | C4343 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  | AO | C4326 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, entry for Letrozole

*omit from the column headed “Responsible Person” for the brand “Letrozole Actavis”:* **TA** *substitute:* **VN**

1. **Schedule 1, entry for Memantine in the form Tablet containing memantine hydrochloride 20 mg**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | APO-Memantine | TX | MP NP | C4214 C4218 C4221 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, entry for Mirtazapine in the form Tablet 15 mg (orally disintegrating)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Mirtazapine Sandoz ODT 15 | SZ | MP NP | C1211 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Mirtazapine in the form Tablet 30 mg (orally disintegrating)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Mirtazapine Sandoz ODT 30 | SZ | MP NP | C1211 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Mirtazapine in the form Tablet 45 mg (orally disintegrating)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Mirtazapine Sandoz ODT 45 | SZ | MP NP | C1211 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Naratriptan

*omit from the column headed “Circumstances”:* **C3280 C3281 C3282 C3283 C3284 C3285**

*substitute:* **C3281 C3282 C3283 C3284 C3285 C4562**

1. Schedule 1, entry for Nicotine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal patch 24.9 mg | Transdermal | Nicorette Patch | JT | MP NP | C4307 C4344 C4348 |  | 28 | 2 | 28 |  |  |

1. Schedule 1, entry for Octreotide in the form Injection (modified release) 10 mg (as acetate), vial and diluent syringe
   * 1. *omit from the column headed “Circumstances”:* **C2624 C2625 C3409 C3410** *substitute:* **C4560 C4561 C4563 C4564 C4568 C4571**
     2. *omit from the column headed “Maximum Quantity”:* **1** *substitute:* **2**
     3. *omit from the column headed “Number of Repeats”:* **11** *substitute:* **5**
2. Schedule 1, entry for Octreotide in the form Injection (modified release) 20 mg (as acetate), vial and diluent syringe
   * 1. *omit from the column headed “Circumstances”:* **C2624 C2625 C3409 C3410** *substitute:* **C4560 C4561 C4563 C4564 C4568 C4571**
     2. *omit from the column headed “Maximum Quantity”:* **1** *substitute:* **2**
     3. *omit from the column headed “Number of Repeats”:* **11** *substitute:* **5**
3. Schedule 1, entry for Octreotide in the form Injection (modified release) 30 mg (as acetate), vial and diluent syringe
   * 1. *omit from the column headed “Circumstances”:*  **C2624 C2625 C3409 C3410** *substitute:* **C4560 C4561 C4563 C4564 C4568 C4571**
     2. *omit from the column headed “Maximum Quantity”:* **1** *substitute:* **2**
     3. *omit from the column headed “Number of Repeats”:* **11** *substitute:* **5**
4. Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 50 mg

*omit from the column headed “Responsible Person” for the brand “Oxaliplatin Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 100 mg

*omit from the column headed “Responsible Person” for the brand “Oxaliplatin Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 30 mg in 5 mL

*omit from the column headed “Responsible Person” for the brand “Paclitaxel Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 100 mg in 16.7 mL

*omit from the column headed “Responsible Person” for the brand “Paclitaxel Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 150 mg in 25 mL

*omit from the column headed “Responsible Person” for the brand “Paclitaxel Actavis”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 300 mg in 50 mL

*omit from the column headed “Responsible Person” for the brand “Paclitaxel Actavis”:* **TA** *substitute:* **UA**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pantoprazole Actavis | GN | MP NP | C1177 C1337 C1476 C1533 | P1177 | 30 | 2 | 30 |  |  |

* + 1. *omit from the column headed “Responsible Person” for the brand “Torzole 40”:* **TA** *substitute:* **VN**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pantoprazole Actavis | GN | MP NP | C1177 C1337 C1476 C1533 | P1337 P1476 P1533 | 30 | 5 | 30 |  |  |

* + 1. *omit from the column headed “Responsible Person” for the brand “Torzole 40”:* **TA** *substitute:* **VN**

1. Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)

*omit from the column headed “Responsible Person” for the brand “Torzole 20”:* **TA** *substitute:* **VN**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 10 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

*omit from the column headed “Responsible Person” for the brand “Pravastatin Actavis 10”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 10 mg *[Maximum Quantity: 30; Number of Repeats: 11]*

*omit from the column headed “Responsible Person” for the brand “Pravastatin Actavis 10”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

*omit from the column headed “Responsible Person” for the brand “Pravastatin Actavis 20”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 20 mg *[Maximum Quantity: 30; Number of Repeats: 11]*

*omit from the column headed “Responsible Person” for the brand “Pravastatin Actavis 20”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

*omit from the column headed “Responsible Person” for the brand “Pravastatin Actavis 40”:* **TA** *substitute:* **UA**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg *[Maximum Quantity: 30; Number of Repeats: 11]*

*omit from the column headed “Responsible Person” for the brand “Pravastatin Actavis 40”:* **TA** *substitute:* **UA**

1. **Schedule 1, entry for Quetiapine in the form Tablet 25 mg (as fumarate)**
   * 1. *omit from the column headed “Responsible Person” for the brand “Quetiapine Actavis 25”:* **TA** *substitute:* **VN**
     2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Quipine | VN | MP NP | C4385 C4391 C4396 |  | 60 | 0 | 60 |  |  |

1. **Schedule 1, entry for Quetiapine in the form Tablet 100 mg (as fumarate)**
   * 1. *omit from the column headed “Responsible Person” for the brand “Quetiapine Actavis 100”:* **TA** *substitute:* **VN**
     2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Quipine | VN | MP NP | C1589 C2044 C2765 |  | 90 | 5 | 90 |  |  |

1. **Schedule 1, entry for Quetiapine in the form Tablet 200 mg (as fumarate)**
   * 1. *omit from the column headed “Responsible Person” for the brand “Quetiapine Actavis 200”:* **TA** *substitute:* **VN**
     2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Quipine | VN | MP NP | C1589 C2044 C2765 |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, entry for Quetiapine in the form Tablet 300 mg (as fumarate)**
   * 1. *omit from the column headed “Responsible Person” for the brand “Quetiapine Actavis 300”:* **TA** *substitute:* **VN**
     2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Quipine | VN | MP NP | C1589 C2044 C2765 |  | 60 | 5 | 60 |  |  |

1. Schedule 1, entry for Reteplase

*omit from the column headed “Responsible Person”:* **TA** *substitute:* **GN**

1. Schedule 1, entry for Rizatriptan

*omit from the column headed “Circumstances”:* **C3233** *substitute:* **C4573**

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4228 C4238 C4248 | P4228 P4248 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C4228 C4248 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4228 C4238 C4248 | P4225 P4238 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4228 C4238 C4248 | P4228 P4248 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C4228 C4248 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4228 C4238 C4248 | P4225 P4238 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4227 C4238 C4259 | P4227 P4259 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C4227 C4259 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4227 C4238 C4259 | P4225 P4238 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4226 C4238 C4263 | P4226 P4263 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C4226 C4263 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 11]***

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rosuvastatin-DRLA | RI | MP | C4225 C4226 C4238 C4263 | P4225 P4238 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Simvastatin in the form Tablet 10 mg**
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 10 | ZP | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 10 | ZP | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Simvastatin in the form Tablet 20 mg**
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 20 | ZP | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 20 | ZP | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Simvastatin in the form Tablet 40 mg**
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 40 | ZP | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 40 | ZP | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 80 | ZP | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin‑Spirit 80 | ZP | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |  |  |

1. **Schedule 1, entry for Sodium Chloride in the form I.V. infusion 154 mmol per L. 1 L**
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fresenius Kabi Australia Pty Limited | PK | PDP |  |  | 5 | 0 | 1 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fresenius Kabi Australia Pty Limited | PK | MP NP |  |  | 5 | 1 | 1 |  |  |

1. Schedule 1, entry for Sodium Lactate Compound in the form I.V. infusion containing approximately 131 mmol sodium (as lactate and chloride), 5 mmol potassium (as chloride), 2 mmol calcium (as chloride), 29 mmol bicarbonate (as lactate) and 111 mmol chloride   
   per L, 1 L

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fresenius Kabi Australia Pty Limited | PK | MP NP |  |  | 5 | 1 | 1 |  |  |

1. Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate)

*omit from the column headed “Circumstances” (all instances):* **C3233** *substitute:* **C4558**

1. Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) *[Maximum Quantity: 4; Number of Repeats: 5; Pack Quantity: 2]*

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sumatran | QA | MP NP | C4558 |  | 4 | 5 | 2 |  |  |

1. Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) *[Maximum Quantity: 4; Number of Repeats: 5; Pack Quantity: 4]*

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sumatran | QA | MP NP | C4558 |  | 4 | 5 | 4 |  |  |

1. Schedule 1, entry for Sumatriptan in each of the forms: Tablet (fast disintegrating) 50 mg (as succinate); and Nasal spray 20 mg in 0.1 mL single dose unit

*omit from the column headed “Circumstances”:* **C3233** *substitute:* **C4558**

1. Schedule 1, entry for Telmisartan with amlodipine in each of the forms: Tablet 40 mg‑5 mg (as besylate); Tablet 40 mg‑10 mg (as besylate); Tablet 80 mg‑5 mg (as besylate); and Tablet 80 mg‑10 mg (as besylate)

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pritor/Amlodipine | FI | MP NP | C4373 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Tramadol in the form Capsule containing tramadol hydrochloride 50 mg
   * 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Lodam 50 | ZP | MP NP | C1497 C1615 | P1497 | 20 | 0 | 20 |  |  |
|  |  |  |  |  | PDP | C1497 C1615 |  | 20 | 0 | 20 |  |  |

* + 1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Lodam 50 | ZP | MP NP | C1497 C1615 | P1615 | 20 | 2 | 20 |  |  |

1. Schedule 1, entry for Zolmitriptan

*omit from the column headed “Circumstances” (twice occurring):* **C3280** *substitute:* **C4573**

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| BI | Biotech Pharmaceuticals Pty Ltd | 91 009 701 517 |

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| HC | Biotech Pharmaceuticals Pty Ltd | 91 009 701 517 |

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

insert:

|  |  |  |
| --- | --- | --- |
| IV | iNova Pharmaceuticals (Australia) Pty Limited | 88 000 222 408 |

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| TA | Actavis Australia Pty Ltd | 43 122 896 468 |

1. Schedule 4, Part 1, entry for Bimatoprost with timolol

insert in numerical order following existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C4572 |  |  | Elevated intra-ocular pressure  The condition must have been inadequately controlled with monotherapy; AND  Patient must have open-angle glaucoma; OR  Patient must have ocular hypertension |  |

1. Schedule 4, Part 1, entry for Cephalexin
   * 1. omit from the column headed “Circumstances Code”: **C4243**
     2. insert in the column headed “Purposes Code”: **P4243**
2. Schedule 4, Part 1, entry for Cinacalcet

omit from the column headed “Purposes Code”: **P3672 P3673**

1. Schedule 4, Part 1, entry for Eletriptan

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Eletriptan | C4573 |  |  | Migraine attack  The condition must have usually failed to respond to analgesics in the past | Compliance with Authority Required procedures - Streamlined Authority Code 4573 |

1. Schedule 4, Part 1, entry for Hydrocortisone

omit from the column headed “Circumstances Code”: **C1128**

1. Schedule 4, Part 1, entry for Ivermectin

insert in numerical order following existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C4565 | P4565 |  | Crusted (Norwegian) scabies  The condition must be established by clinical and/or parasitological examination; AND  Patient must be undergoing topical therapy for this condition; OR  Patient must have a contraindication to topical treatment  Patient must weigh 15 kg or over; AND  Patient must be 5 years of age or older | Compliance with Authority Required procedures - Streamlined Authority Code 4565 |
|  | C4566 | P4566 |  | Human sarcoptic scabies  The condition must be established by clinical and/or parasitological examination; AND  Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR  Patient must have a contraindication to topical treatment  Patient must weigh 15 kg or over; AND  Patient must be 5 years of age or older | Compliance with Authority Required procedures - Streamlined Authority Code 4566 |

1. Schedule 4, Part 1, entry for Lanreotide

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Lanreotide | C4559 |  |  | Where the patient is receiving treatment at/from a private hospital  Acromegaly 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 (6 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment 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 Written or Telephone Authority Required procedures |
|  | C4567 |  |  | Where the patient is receiving treatment at/from a public hospital  Acromegaly  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 (6 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment 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 Written or Telephone Authority Required procedures - Streamlined Authority Code 4567 |
|  | C4569 |  |  | Where the patient is receiving treatment at/from a private hospital  Functional carcinoid tumour  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 Written or Telephone Authority Required procedures |
|  | C4570 |  |  | Where the patient is receiving treatment at/from a public hospital  Acromegaly  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  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 Written or Telephone Authority Required procedures - Streamlined Authority Code 4570 |
|  | C4574 |  |  | Where the patient is receiving treatment at/from a private hospital  Acromegaly  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  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 Written or Telephone Authority Required procedures |
|  | C4575 |  |  | Where the patient is receiving treatment at/from a public hospital  Functional carcinoid tumour  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 Written or Telephone Authority Required procedures - Streamlined Authority Code 4575 |

1. Schedule 4, Part 1, entry for Lanthanum
   * 1. omit from the column headed “Purposes Code”: **P3546 P3547**
2. Schedule 4, Part 1, entry for Naratriptan
   * 1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C3280 |  |  | Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics | Compliance with Authority Required procedures |

* + 1. insert in numerical order following existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C4562 |  |  | Migraine attack  The condition must have usually failed to respond to analgesics in the past | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Octreotide
   * 1. omit

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C2624 |  |  | Where the patient is receiving treatment at/from a private hospital  Acromegaly  Acromegaly in a patient controlled on Sandostatin subcutaneous injections  In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission  Treatment must cease if IGF1 is not lower after 3 months of treatment | Compliance with Written or Telephone Authority Required procedures |
|  | C2625 |  |  | Where the patient is receiving treatment at/from a private hospital  Functional carcinoid tumour or VIPoma  Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections  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 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. 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 Written or Telephone Authority Required procedures |

* + 1. omit

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C3409 |  |  | Where the patient is receiving treatment at/from a public hospital  Acromegaly  Acromegaly in a patient controlled on Sandostatin subcutaneous injections  In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission Treatment must cease if IGF1 is not lower after 3 months of treatment | Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3409 |
|  | C3410 |  |  | Where the patient is receiving treatment at/from a public hospital  Functional carcinoid tumour or VIPoma  Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections  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 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. 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 Written or Telephone Authority Required procedures - Streamlined Authority Code 3410 |

* + 1. insert in numerical order following existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C4560 |  |  | Where the patient is receiving treatment at/from a private hospital  Vasoactive intestinal peptide secreting tumour (VIPoma)  Patient must have achieved symptom control on octreotide immediate release injections; 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections  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 Written or Telephone Authority Required procedures |
|  | C4561 |  |  | Where the patient is receiving treatment at/from a public hospital  Functional carcinoid tumour  Patient must have achieved symptom control on octreotide immediate release injections; 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections  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 Written or Telephone Authority Required procedures - Streamlined Authority Code 4561 |
|  | C4563 |  |  | Where the patient is receiving treatment at/from a public hospital  Acromegaly  The condition must be controlled with octreotide immediate release injections; AND  The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide 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;  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4563 |
|  | C4564 |  |  | Where the patient is receiving treatment at/from a public hospital  Vasoactive intestinal peptide secreting tumour (VIPoma)  Patient must have achieved symptom control on octreotide immediate release injections; 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections  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 Written or Telephone Authority Required procedures - Streamlined Authority Code 4564 |
|  | C4568 |  |  | Where the patient is receiving treatment at/from a private hospital  Functional carcinoid tumour  Patient must have achieved symptom control on octreotide immediate release injections; 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections  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 Written or Telephone Authority Required procedures |
|  | C4571 |  |  | Where the patient is receiving treatment at/from a private hospital  Acromegaly  The condition must be controlled with octreotide immediate release injections; AND  The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide 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;  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Written or Telephone Authority Required procedures |

1. Schedule 4, Part 1, entry for Rizatriptan

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Rizatriptan | C4573 |  |  | Migraine attack  The condition must have usually failed to respond to analgesics in the past | Compliance with Authority Required procedures - Streamlined Authority Code 4573 |

1. Schedule 4, Part 1, entry for Sumatriptan

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sumatriptan | C4558 |  |  | Migraine attack  The condition must have usually failed to respond to analgesics in the past | Compliance with Authority Required procedures - Streamlined Authority Code 4558 |

1. Schedule 4, Part 1, entry for Zolmitriptan

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Zolmitriptan | C4573 |  |  | Migraine attack  The condition must have usually failed to respond to analgesics in the past | Compliance with Authority Required procedures - Streamlined Authority Code 4573 |