

**PB 55 of 2020**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 6)**

*National Health Act 1953*

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

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

Dated 29th June 2020

**THEA DANIEL**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Department of Health

1. **Name of Instrument**
2. This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 6)*.
3. This Instrument may also be cited as PB 55 of 2020.
4. **Commencement**

This Instrument commences on 1 July 2020.

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

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

Schedule 1 Amendments

1. Schedule 1, entry for Alectinib
   1. omit from the column headed “Number of Repeats”: 1 substitute: 3
2. Schedule 1, entry for Amoxicillin in the form Capsule 250 mg (as trihydrate)
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP |  | P10404 | 40 CN10404 | 0 CN10404 | 20 |  |  |

1. Schedule 1, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate) *[Maximum Quantity: 20; Number of Repeats: 0]*
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED AMOXICILLIN | VO | MP NP MW PDP |  |  | 20 | 0 | 20 |  |  |

1. Schedule 1, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate) *[Maximum Quantity: 40; Number of Repeats: 0]*
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amoxycillin Ranbaxy | RA | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED AMOXICILLIN | VO | MP NP |  | P10402 | 40 CN10402 | 0 CN10402 | 20 |  |  |

1. Schedule 1, entry for Anastrozole
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Anastrozole AN | JO | MP NP | C5464 |  | 30 | 5 | 30 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Astzol | JU | MP NP | C5464 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Aspirin
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet, dispersible, 300 mg | Oral |  | Solprin | RC | PDP | C5870 |  | 96 | 0 | 96 |  |  |
|  |  |  |  |  |  | MP NP | C5857 |  | 96 | 1 | 96 |  |  |

1. Schedule 1, entry for Atezolizumab in the form Solution concentrate for I.V. infusion 840 mg in 14 mL
   1. insert in numerical order in the column headed “Circumstances”: C10509
2. Schedule 1, entry for Atezolizumab in the form Solution concentrate for I.V. infusion 1200 mg in 20 mL
   * 1. omit from the column headed “Circumstances”: C10203
     2. insert in numerical order in the column headed “Circumstances”: C10521
3. Schedule 1, entry for Bicalutamide
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Bicalide | JU | MP NP | C5729 |  | 28 | 5 | 28 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Bicalutamide AN | JO | MP NP | C5729 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Bleomycin in the form Powder for injection containing bleomycin sulfate 15,000 I.U.
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Bleo 15K | JU | MP | C6224 C6275 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Brentuximab vedotin
   * 1. omit from the column headed “Circumstances”: C6904
     2. omit from the column headed “Circumstances”: C6941
     3. insert in numerical order in the column headed "Circumstances": C10519 C10524
2. Schedule 1, entry for Capecitabine in the form Tablet 150 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Xelocitabine | JU | MP |  |  | 60 | 2 | 60 |  |  |

1. Schedule 1, entry for Capecitabine in the form Tablet 500 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Xelocitabine | JU | MP |  |  | 120 | 2 | 120 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Carbimazole | Tablet 5 mg | Oral | a | NeoMercazole | BZ | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Neo-Mercazole | GH | MP NP |  |  | 200 | 2 | 100 |  |  |

1. Schedule 1, entry for Celecoxib in the form Capsule 100 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Celecoxib APOTEX | TY | MP NP | C4907 C4962 |  | 60 | 3 | 60 |  |  |

1. Schedule 1, entry for Celecoxib in the form Capsule 200 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Celecoxib APOTEX | TY | MP NP | C4907 C4962 |  | 30 | 3 | 30 |  |  |

1. Schedule 1, entry for Ceritinib
   1. omit from the column headed “Number of Repeats”: 1 substitute: 3
2. Schedule 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2;   
   Number of Repeats: 0]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
3. Schedule 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2;   
   Number of Repeats: 2]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
4. Schedule 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 2;   
   Number of Repeats: 5]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
5. Schedule 1, entry for Certolizumab pegol in the form Injection 200 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 6;   
   Number of Repeats: 0]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
     4. omit from the column headed “Purposes”: P10456
     5. omit from the column headed “Purposes”: P10480
     6. insert in numerical order in the column headed “Purposes”: P10507 P10513
6. Schedule 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2;   
   Number of Repeats: 0]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
7. Schedule 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2;   
   Number of Repeats: 2]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
8. Schedule 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 2;   
   Number of Repeats: 5]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
9. Schedule 1, entry for Certolizumab pegol in the form Solution for injection 200 mg in 1 mL pre-filled pen *[Maximum Quantity: 6;   
   Number of Repeats: 0]*
   * 1. omit from the column headed “Circumstances”: C10456
     2. omit from the column headed “Circumstances”: C10480
     3. insert in numerical order in the column headed “Circumstances”: C10507 C10513
     4. omit from the column headed “Purposes”: P10456
     5. omit from the column headed “Purposes”: P10480
     6. insert in numerical order in the column headed “Purposes”: P10507 P10513
10. Schedule 1, entry for Ciclesonide in each of the forms: Pressurised inhalation 80 micrograms per dose, 120 doses (CFC-free formulation); and Pressurised inhalation 160 micrograms per dose, 120 doses (CFC-free formulation)
    1. omit from the column headed “Responsible Person”: AP substitute: EU
11. Schedule 1, entry for Clonazepam in the form Tablet 500 micrograms
    * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rivotril | RO | MP NP | C6140 C6296 | P6140 | 100 | 3 | 100 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Rivotril | RO | MP NP | C6140 C6296 | P6296 | 200 | 2 | 100 |  |  |

1. Schedule 1, entry for Clonazepam in the form Tablet 2 mg
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 2 mg | Oral |  | Paxam 2 | AF | MP NP | C6140 C6296 | P6140 | 100 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C6140 C6296 | P6296 | 200 | 2 | 100 |  |  |

1. Schedule 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate)
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Plavix | SW | MP NP | C4165 C4166 C5436 C5459 C5508 C5517 C5524 C5525 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Crizotinib in each of the forms: Capsule 200 mg; and Capsule 250 mg
   1. omit from the column headed “Number of Repeats”: 1 substitute: 3
2. Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cyprostat | SY | MP |  |  | 100 | 5 | 50 |  |  |

1. Schedule 1, entry for Diazepam
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 10 mg in 2 mL | Injection |  | Hospira Pty Limited | PF | MP NP PDP |  |  | 5 | 0 | 5 |  |  |

1. Schedule 1, entry for Dorzolamide with timolol
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | DORZOLAMIDE/TIMOLOL AN 20/5 | JU | AO | C5038 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C4343 |  | 1 | 5 | 1 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pharmacor Gliclazide MR | CR | MP NP |  |  | 100 | 5 | 100 |  |  |

1. Schedule 1, entry for Gliclazide in the form Tablet 60 mg (modified release)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pharmacor Gliclazide MR | CR | MP NP |  |  | 60 | 5 | 60 |  |  |

1. Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 3]*
   * 1. omit from the column headed “Circumstances”: C10490 C10491
     2. insert in numerical order in the column headed “Circumstances”: C10506 C10515
     3. omit from the column headed “Purposes”: P10490 P10491
     4. insert in numerical order in the column headed “Purposes”: P10506 P10515
2. Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*
   * 1. omit from the column headed “Circumstances”: C10490 C10491
     2. insert in numerical order in the column headed “Circumstances”: C10506 C10515
3. Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 3]*
   * 1. omit from the column headed “Circumstances”: C10490 C10491
     2. insert in numerical order in the column headed “Circumstances”: C10506 C10515
     3. omit from the column headed “Purposes”: P10490 P10491
     4. insert in numerical order in the column headed “Purposes”: P10506 P10515
4. Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 5]*
   * 1. omit from the column headed “Circumstances”: C10490 C10491
     2. insert in numerical order in the column headed “Circumstances”: C10506 C10515
5. Schedule 1, entry for Granisetron in the form Tablet 2 mg (as hydrochloride) *[Maximum Quantity: 2; Number of Repeats: 0]*
   * 1. omit from the column headed “Circumstances”: C4102
     2. insert in numerical order in the column headed “Circumstances”: C10498
6. Schedule 1, entry for Granisetron in the form Tablet 2 mg (as hydrochloride) *[Maximum Quantity: 5; Number of Repeats: 1]*
   * 1. omit from the column headed “Circumstances”: C4102
     2. insert in numerical order in the column headed “Circumstances”: C10498
     3. omit from the column headed “Purposes”: P4102 *substitute:* P10498
7. Schedule 1, entry for Heparin
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 35,000 units (as sodium) in 35 mL | Injection |  | Hospira Pty Limited | PF | MP NP |  |  | 12 | 5 | 1 |  |  |

1. Schedule 1, entry for Idarubicin
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule containing idarubicin hydrochloride 5 mg | Oral |  | Zavedos | PF | MP | C5812 |  | 3 | 0 | 1 |  |  |

1. Schedule 1, entry for Idarubicin in each of the forms: Solution for I.V. injection containing idarubicin hydrochloride 5 mg in 5 mL; and Solution for I.V. injection containing idarubicin hydrochloride 10 mg in 10 mL
   1. omit from the column headed “Section 100/ Prescriber Bag only”: PB(100) substitute: D(100)
2. Schedule 1, entry for Insulin glargine in the form Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | b | Lantus | SW | MP NP |  |  | 5 | 1 | 1 |  |  |
|  |  |  | a | Lantus SoloStar | AV | MP NP |  |  | 5 | 1 | 1 |  |  |

* + 1. omit from the column headed “Schedule Equivalent” for the brand “Optisulin”: b

1. Schedule 1, entry for Irinotecan in each of the forms: I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL; and   
   I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | IRINOTECAN ACT | JU | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Isotretinoin in the form Capsule 20 mg
   1. omit from the entry for the brand “Roaccutane”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | MP | C5224 |  | 60 | 3 | 60 |  |  |

1. Schedule 1, entry for Letrozole
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Letroz | JU | MP NP | C5464 |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Letrozole AN | JO | MP NP | C5464 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Levodopa with carbidopa in the form Tablet 250 mg-25 mg (as monohydrate)

*insert in the column headed “Schedule Equivalent” (all instances):* a

1. Schedule 1, entry for Levodopa with carbidopa
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 250 mg-25 mg (USP) | Oral |  | Carbidopa and Levodopa Tablets, USP | DZ | MP NP |  |  | 100 | 5 | 100 |  |  |

1. Schedule 1, entry for Meloxicam in each of the forms: Tablet 7.5 mg; and Tablet 15 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | MELOBIC | RF | MP NP | C4907 C4962 |  | 30 | 3 | 30 |  |  |

1. Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Metformin generichealth | GQ | MP NP |  |  | 100 | 5 | 100 |  |  |

1. Schedule 1, entry for Mirtazapine in the form Tablet 30 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mirtazapine GH | GQ | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Montelukast Mylan | AF | MP NP | C6666 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Montelukast Mylan | AF | MP NP | C6674 C7781 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Naloxone in the form Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Junalox | JO | MP NP PDP |  |  | 5 | 0 | 5 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ondansetron | Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL | Oral |  | Zofran syrup 50 mL | AS | MP NP | C4102 C5721 | P5721 | 1 | 0 | 1 |  |  |
|  |  |  |  | MP | C5778 |  | 1 | 0 | 1 |  | C(100) |
|  |  |  |  | MP NP | C4102 C5721 | P4102 | 1 | 1 | 1 |  |  |
|  | Tablet (orally disintegrating) 4 mg | Oral |  | APO-Ondansetron ODT | TX | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron Mylan ODT | AF | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron ODT-DRLA | RZ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron SZ ODT | HX | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | APO-Ondansetron ODT | TX | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | Ondansetron Mylan ODT | AF | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | Ondansetron ODT-DRLA | RZ | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | Ondansetron SZ ODT | HX | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | Zilfojim ODT 4 | DO | MP NP | C10498 |  | 10 | 1 | 10 |  |  |
|  | Tablet 4 mg (as hydrochloride dihydrate) | Oral | a | APO-Ondansetron | TX | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron APOTEX | GX | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron Mylan Tablets | AF | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron SZ | HX | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron-DRLA | RZ | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Zofran | AS | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | a | APO-Ondansetron | TX | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron APOTEX | GX | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron Mylan Tablets | AF | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron SZ | HX | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron-DRLA | RZ | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Zofran | AS | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  | Tablet (orally disintegrating) 8 mg | Oral |  | APO-Ondansetron ODT | TX | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron Mylan ODT | AF | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron ODT-DRLA | RZ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | Ondansetron SZ ODT | HX | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  |  | APO-Ondansetron ODT | TX | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  |  | Ondansetron Mylan ODT | AF | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  |  | Ondansetron ODT GH | GQ | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  |  | Ondansetron ODT-DRLA | RZ | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  |  | Ondansetron SZ ODT | HX | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  |  | Zilfojim ODT 8 | DO | MP NP | C10498 |  | 10 | 1 | 10 |  |  |
|  | Tablet 8 mg (as hydrochloride dihydrate) | Oral | a | APO-Ondansetron | TX | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron APOTEX | GX | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron Mylan Tablets | AF | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron SZ | HX | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Ondansetron-DRLA | RZ | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  | a | Zofran | AS | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  | a | APO-Ondansetron | TX | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron APOTEX | GX | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron Mylan Tablets | AF | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron SZ | HX | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Ondansetron-DRLA | RZ | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  |  |  | a | Zofran | AS | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  | Wafer 4 mg | Oral |  | Zofran Zydis | AS | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  |  |  |  | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |
|  | Wafer 8 mg | Oral |  | Zofran Zydis | AS | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |
|  |  |  |  |  |  | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. Schedule 1, entry for Paclitaxel in each of the forms: Solution concentrate for I.V. infusion 30 mg in 5 mL; Solution concentrate for I.V. infusion 100 mg in 16.7 mL; Solution concentrate for I.V. infusion 150 mg in 25 mL; and Solution concentrate for I.V. infusion 300 mg in 50 mL
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Paclitaxel ACT | JU | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED PANTOPRAZOLE | VO | MP NP | C5444 C5512 C5529 |  | 30 | 5 | 30 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED PANTOPRAZOLE | VO | MP NP | C8774 C8775 C8776 C8780 C8866 | P8774 P8775 | 30 | 1 | 30 |  |  |

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”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED PANTOPRAZOLE | VO | MP NP | C8774 C8775 C8776 C8780 C8866 | P8776 P8780 P8866 | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Phenelzine
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 15 mg (as sulfate) (USP) | Oral |  | Nardil | LM | MP | C6236 |  | 100 | 1 | 60 |  |  |

1. Schedule 1, omit entry for Prasugrel
2. Schedule 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 2]*
   1. insert after entry for the brand “Risperdal”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C5903 C6898 C6899 C10020 C10021 C10052 | P6898 P6899 P10020 P10021 P10052 | 60 | 2 | 60 |  |  |

1. Schedule 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
   1. insert after entry for the brand “Risperdal”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C5903 C6898 C6899 C10020 C10021 C10052 | P5903 | 60 | 5 | 60 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C4246 C5907 C6898 C6899 C10020 C10021 C10052 | P6898 P6899 P10020 P10021 P10052 | 60 | 2 | 60 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C4246 C5907 C6898 C6899 C10020 C10021 C10052 | P4246 P5907 | 60 | 5 | 60 |  |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C4246 C5907 C6897 C6938 | P6897 P6938 | 60 | 2 | 60 |  |  |

1. Schedule 1, entry for Risperidone in the form Tablet 2 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C4246 C5907 C6897 C6938 | P4246 P5907 | 60 | 5 | 60 |  |  |

1. Schedule 1, entry for Risperidone in each of the forms: Tablet 3 mg; and Tablet 4 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | NOUMED RISPERIDONE | VO | MP NP | C4246 C5907 |  | 60 | 5 | 60 |  |  |

1. Schedule 1, after entry for Selegiline
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Semaglutide | Solution for injection 2 mg in 1.5 mL pre-filled pen | Injection |  | Ozempic | NO | MP NP | C5478 C5500 |  | 1 | 5 | 1 |  |  |
|  | Solution for injection 4 mg in 3 mL pre-filled pen | Injection |  | Ozempic | NO | MP NP | C5478 C5500 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, entry for Temozolomide in the form Capsule 20 mg
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Temozolomide Amneal | JO | MP |  |  | 5 | 5 | 5 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Temozolomide Amneal | JO | MP |  | P4897 | 15 | 2 | 5 |  |  |

1. Schedule 1, entry for Temozolomide in the form Capsule 140 mg
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Temozolomide Amneal | JO | MP |  |  | 5 | 5 | 5 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Temozolomide Amneal | JO | MP |  | P4897 | 15 | 2 | 5 |  |  |

1. Schedule 1, entry for Tetracosactide
   1. omit from the column headed “Responsible Person”: LM substitute: IX
2. Schedule 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Tobramycin AN | JU | MP | C5520 |  | 56 | 2 | 56 |  |  |

1. Schedule 1, entry for Trastuzumab emtansine in each of the forms: Powder for I.V. infusion 100 mg; and Powder for I.V. infusion 160 mg
   * 1. omit from the column headed “Circumstances”: C9599
     2. insert in numerical order in the column headed “Circumstances”: C10510
2. Schedule 1, entry for Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sachets containing oral powder 100 g, 10 (RenaStart) | Oral |  | RenaStart | VF | MP NP | C6190 |  | 9 | 5 | 1 |  |  |

1. Schedule 3
   1. omit:

|  |  |  |
| --- | --- | --- |
| RC | Reckitt Benckiser (Australia) Pty Limited | 17 003 274 655 |

1. Schedule 4, Part 1, entry for Aspirin
   1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C5857 |  |  | For treatment of a patient identifying as Aboriginal or Torres Strait Islander |  |
|  | C5870 |  |  | For treatment of a patient identifying as Aboriginal or Torres Strait Islander |  |

1. Schedule 4, Part 1, entry for Atezolizumab
   * 1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10203 |  |  | Extensive-stage small cell lung cancer Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10203 |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10509 |  |  | Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10509 |
|  | C10521 |  |  | Extensive-stage small cell lung cancer Continuing treatment - 3 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10521 |

1. Schedule 4, Part 1, entry for Botulinum toxin type A purified neurotoxin complex
   1. omit entry for circumstances code “C5262” and substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C5262 |  |  | Chronic migraine Must be treated by a neurologist. 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 botulinum toxin type A neurotoxin; 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 botulinum toxin type A neurotoxin; AND Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment; AND Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin. Patient must be aged 18 years or older. Prophylactic migraine medications are propranolol, amitriptyline, methysergide, pizotifen, cyproheptadine or topiramate. | Compliance with Authority Required procedures - Streamlined Authority Code 5262 |

1. Schedule 4, Part 1, entry for Brentuximab vedotin
   * 1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C6904 |  |  | Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) The treatment must not exceed a total of 16 cycles in a lifetime | Compliance with Authority Required procedures |

* + 1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C6941 |  |  | Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) The treatment must not exceed a total of 16 cycles in a lifetime | Compliance with Authority Required procedures |

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

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|  | C10519 |  |  | Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles in a lifetime | Compliance with Authority Required procedures |
|  | C10524 |  |  | Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles in a lifetime | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Certolizumab pegol
   * 1. omit:

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|  | C10456 | P10456 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If the application is not made through the online system, the authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis change or recommencement of treatment PBS Authority Application - Supporting Information Form which seeks: (i) the BASDAI score confirming a reduction of 2 or more units from baseline and the C-reactive protein (CPR) level if the patient has had an adequate response to the most recent course of biological medicine; or (ii) confirmation that the patient has failed to achieve an adequate response with the most recent supply of biological medicine; or (iii) confirmation that an intolerance to the most recent supply of biological medicine had occurred; and (iv) an updated BASDAI score and CRP level if new baseline measurements are to be used for future assessments of response | Compliance with Written Authority Required procedures |

* + 1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10480 | P10480 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be stated in this application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. | Compliance with Written Authority Required procedures |

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

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|  | C10507 | P10507 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. | Compliance with Written Authority Required procedures |
|  | C10513 | P10513 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Golimumab
   * 1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10490 | P10490 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks duration under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be stated in this application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C10491 | P10491 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If the application is not made through the online system, the authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis change or recommencement of treatment PBS Authority Application - Supporting Information Form which seeks: (i) the BASDAI score confirming a reduction of 2 or more units from baseline and the C-reactive protein (CPR) level if the patient has had an adequate response to the most recent course of biological medicine; or (ii) confirmation that the patient has failed to achieve an adequate response with the most recent supply of biological medicine; or (iii) confirmation that an intolerance to the most recent supply of biological medicine had occurred; and (iv) an updated BASDAI score and CRP level if new baseline measurements are to be used for future assessments of response | Compliance with Written Authority Required procedures |

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

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|  | C10506 | P10506 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records: (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. | Compliance with Written Authority Required procedures |
|  | C10515 | P10515 |  | Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks duration under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Granisetron
   * 1. omit:

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|  | C4102 | P4102 |  | Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 4102 |

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

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|  | C10498 | P10498 |  | Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy; OR The condition must be associated with oral chemotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 10498 |

1. Schedule 4, Part 1, entry for Idarubicin
   1. omit:

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|  | C5812 |  |  | Acute myelogenous leukaemia (AML) |  |

1. Schedule 4, Part 1, entry for Ondansetron
   * 1. omit:

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|  | C4077 |  |  | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. |  |
|  | C4092 |  |  | Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 4092 |

* + 1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C5749 |  |  | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. |  |
|  | C5777 | P5777 |  | Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 5777 |

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

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| --- | --- | --- | --- | --- | --- |
|  | C10498 | P10498 |  | Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy; OR The condition must be associated with oral chemotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 10498 |

1. Schedule 4, Part 1, omit entry for Prasugrel
2. Schedule 4, Part 1, after entry for Selegiline
   1. insert:

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| --- | --- | --- | --- | --- | --- |
| Semaglutide | C5478 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5478 |
|  | C5500 |  |  | Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR Patient must not have tolerated a combination of metformin and a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5500 |

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

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|  | C9599 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be as monotherapy; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease; (ii) dates of treatment with trastuzumab and pertuzumab; and (iii) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab; or (iv) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | Compliance with Written Authority Required procedures |

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

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|  | C10510 |  |  | Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be as monotherapy; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease; (ii) dates of treatment with trastuzumab and pertuzumab; and (iii) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (iv) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | Compliance with Written Authority Required procedures |

1. Schedule 5, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[GRP-15475]*
   1. omit from the column headed “Brand”: Plavix
2. Schedule 5, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate) *[GRP-17110]*
   1. omit from the column headed “Brand”: Plavix
3. Schedule 5, entry for Levodopa with carbidopa
   1. omit:

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|  | GRP-22958 | Tablet 250 mg-25 mg (as monohydrate) | Oral | APO-Levodopa/Carbidopa SINADOPA 250/25 Sinemet |
|  |  | Tablet 250 mg-25 mg (USP) | Oral | Carbidopa and Levodopa Tablets, USP |

1. Schedule 5, entry for Meloxicam in the form Tablet 15 mg *[GRP-15468]*
   1. insert in alphabetical order in the column headed “Brand”: MELOBIC
2. Schedule 5, entry for Meloxicam in the form Tablet 7.5 mg *[GRP-15658]*
   1. insert in alphabetical order in the column headed “Brand”: MELOBIC
3. Schedule 5, omit entry for Phenelzine