Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

# Section H Update

for Hospital Pharmaceuticals

**May 2020**

Cumulative for April and May 2020

PHARMAC
TE PĀTAKA WHAIORANGA

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## Summary of decisions
**EFFECTIVE 1 MAY 2020**

- Alglucosidase alfa (Myozyme) inj 50 mg vial – amended restriction criteria
- Betaine (Cystadane) powder for oral soln – amended restriction criteria
- Bupivacaine hydrochloride (Marcain) inj 2.5 mg per ml, 20 ml ampoule sterile, inj 5 mg per ml, 10 ml and 20 ml ampoule sterile – price decrease and addition of HSS
- Calcium folinate (DBL Leucovorin Calcium) tab 15 mg – price increase
- Chlorhexidine (healthE) soln 4%, 50 ml – to be delisted 1 November 2020
- Chlorhexidine gluconate (healthE) mouthwash 0.2%, 200 ml – to be delisted 1 November 2020
- Chlorhexidine gluconate (healthE) crm 1%, 50 g and lotn 1%, 200 ml – to be delisted 1 November 2020
- Chlorhexidine with ethanol (healthE) soln 0.5% with ethanol 70%, non staining (pink) and staining (red), 100 ml & 500 ml; soln 2% with ethanol 70%, non staining (pink), 100 ml and staining (red), 100 ml & 500 ml – to be delisted 1 November 2020
- Dacarbazine (DBL Dacarbazine) inj 200 mg vial – price increase
- Dantrolene cap 25 mg (Dantrium) and inj 20 mg vial (Dantrium IV) – price increase
- Daunorubicin (Pfizer) inj 2 mg per ml, 10 ml vial – price increase
- Diazepam (Stesolid) rectal tubes 5 mg – price increase
- Dinoprostone (Prostin E2) vaginal gel 1 mg and 2 mg in 3 g – price increase
- Enteral feed 1 kcal/ml (e.g.Nutrison Low Sodium) liquid 4 g protein, 12.3 g carbohydrate and 3.9 g fat per 100 ml, 1,000 ml bottle – new listing
- Ergotamine tartrate with caffeine tab 1 mg with caffeine 100 mg – delisted 1 May 2020
- Etanercept (Enbrel) inj 25 mg vial, inj 50 mg autoinjector and syringe – price decrease
- Galsulfase (Naglazyme) inj 1 mg per ml, 5 ml vial – amended restriction criteria
- Hydrocortisone acetate (AFT) crm 1%, 14.2 g – to be delisted 1 November 2020
- Hydroxychloroquine (Plaquenil) tab 200 mg – amended restriction criteria
- Iodine with ethanol (healthE) soln 1% with ethanol 70%, 100 ml – to be delisted 1 November 2020
- Levocarnitine oral soln 1,100 mg per 15 ml – new listing
- Mitomycin C (Teva) inj 5 mg vial – price increase

**Summary of decisions – effective 1 May 2020 (continued)**

- Nintedanib (Ofev) cap 100 mg and 150 mg – amended restriction criteria
- Olopatadine (Olopatadine Teva) eye drops 0.1%, 5 ml – new listing and addition of HSS
- Olopatadine (Patanol) eye drops 0.1%, 5 ml – to be delisted 1 October 2020
- Oxytocin (Oxytocin BNM) inj 10 iu per ml, 1 ml ampoule – new Pharmacode listing
- Phenylephrine hydrochloride (Neosynephrine HCL) inj 10 mg per ml, 1 ml ampoule – price increase
- Pirfenidone (Esbriet) tab 801 mg and cap 267 mg – amended restriction criteria
- Povidone-iodine (Betadine) oint 10%, 65 g – new pack size listing and addition of HSS
- Povidone-iodine (Betadine) oint 10%, 25 g – to be delisted 1 October 2020
- Promethazine hydrochloride (Hospira) inj 25 mg per ml, 2 ml ampoule – price increase
- Rifabutin (Mycobutin) cap 150 mg – price increase
- Sapropterin dihydrochloride (Kuvan) tab soluble 100 mg – amended restriction criteria
- Sodium phenylbutyrate (Pheburane) grans 483 mg per g – amended restriction criteria
- Terbutaline sulphate (Bricanyl Turbuhaler) powder for inhalation 200 mcg per dose (equivalent to 250 mcg metered dose), breath activated, 120 dose – new listing
- Tobramycin (TOBI) solution for inhalation 60 mg per ml, 5 ml – new Pharmacode listing
- Vincristine sulphate (DBL Vincristine Sulfate) inj 1 mg per ml, 2 ml vial – price increase

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

# Section H changes to Part II

## Effective 1 May 2020

### ALIMENTARY TRACT AND METABOLISM

13 ALGLUCOSIDASE ALFA (amended restriction criteria)

➔ Inj 50 mg vial ..... 1,142.60 1 Myozyme

Restricted
Initiation
Metabolic physician
*Re-assessment required after 12 months*
All of the following:

1 The patient is aged up to 24 months at the time of initial application and has been diagnosed with infantile Pompe disease; and
2 Any of the following:
  2.1 Diagnosis confirmed by documented deficiency of acid alpha-glucosidase by prenatal diagnosis using chorionic villus biopsies and/or cultured amniotic cells; or
  2.2 Documented deficiency of acid alpha-glucosidase, and urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides; or
  2.3 Documented deficiency of acid alpha-glucosidase, and documented molecular genetic testing indicating a disease-causing mutation in the acid alpha-glucosidase gene (GAA gene); or
  2.4 Documented urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides, and molecular genetic testing indicating a disease-causing mutation in the GAA gene; and
3 Patient has not required long-term invasive ventilation for respiratory failure prior to starting enzyme replacement therapy (ERT); and
4 Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by ERT or might be reasonably expected to compromise a response to ERT; and
5 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks.

Continuation
~~Metabolic physician~~
*Re-assessment required after 12 months*
All of the following:

1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and
2 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks; and
3 Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
4 Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by ERT; and
5 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
6 There is no evidence of life threatening progression of respiratory disease as evidenced by the needed for > 14 days of invasive ventilation; and
7 There is no evidence of new or progressive cardiomyopathy.

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 May 2020 (continued)

14 BETAINE (amended restriction criteria)

➔ Powder for oral soln ..... 575.00 180 g Cystadane

Restricted
Initiation
Metabolic physician
*Re-assessment required after 12 months*
All of the following:
1 The patient has a confirmed diagnosis of homocystinuria; and
2 Any of the following:
  2.1 A cystathionine beta-synthase (CBS) deficiency; or
  2.2 A 5,10-methylene-tetrahydrofolate reductase (MTHFR) deficiency; or
  2.3 A disorder of intracellular cobalamin metabolism; and
3 An appropriate homocysteine level has not been achieved despite a sufficient trial of appropriate vitamin supplementation.

Continuation
~~Metabolic physician~~
*Re-assessment required after 12 months*
The treatment remains appropriate and the patient is benefiting from treatment.

15 GALSULFASE (amended restriction criteria)

➔ Inj 1 mg per ml, 5 ml vial ..... 2,234.00 1 Naglazyme

Restricted
Initiation
Metabolic physician
*Re-assessment required after 12 months*
Both:
1 The patient has been diagnosed with mucopolysaccharidosis VI; and
2 Either:
  2.1 Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency confirmed by either enzyme activity assay in leukocytes or skin fibroblasts; or
  2.2 Detection of two disease causing mutations and patient has a sibling who is known to have mucopolysaccharidosis VI.

Continuation
~~Metabolic physician~~
*Re-assessment required after 12 months*
All of the following:
1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and
2 Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
3 Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by Enzyme Replacement Therapy (ERT); and
4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT.

16 LEVOCARNITINE (new listing)

➔ Oral soln 1,100 mg per 15 ml

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 May 2020 (continued)

16 SAPROPTERIN DIHYDROCHLORIDE (amended restriction criteria)

➔ Tab soluble 100 mg ..... 1,452.70 30 Kuvan

Restricted
Initiation
Metabolic physician
*Re-assessment required after 1 month*
All of the following:
1 Patient has phenylketonuria (PKU) and is pregnant or actively planning to become pregnant; and
2 Treatment with sapropterin is required to support management of PKU during pregnancy; and
3 Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg; and
4 Sapropterin to be used alone or in combination with PKU dietary management; and
5 Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery.

Continuation
~~Metabolic physician or any relevant practitioner on the recommendation of a metabolic physician~~
*Re-assessment required after 12 months*
All of the following:
1 Either:
  1.1 Following the initial one-month approval, the patient has demonstrated an adequate response to a 2 to 4 week trial of sapropterin with a clinically appropriate reduction in phenylalanine levels to support management of PKU during pregnancy; or
  1.2 On subsequent renewal applications, the patient has previously demonstrated response to treatment with sapropterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy; and
2 Any of the following:
  2.1 Patient continues to be pregnant and treatment with sapropterin will not continue after delivery; or
  2.2 Patient is actively planning a pregnancy and this is the first renewal for treatment with sapropterin; or
  2.3 Treatment with sapropterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy; and
3 Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg; and
4 Sapropterin to be used alone or in combination with PKU dietary management; and
5 Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery.

17 SODIUM PHENYLBUTYRATE (amended restriction criteria)

➔ Grans 483 mg per g ..... 1,920.00 174 g Pheburane

Restricted
Initiation
Metabolic physician
*Re-assessment required after 12 months*
For the chronic management of a urea cycle disorder involving a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.

Continuation
~~Metabolic physician~~
*Re-assessment required after 12 months*
The treatment remains appropriate and the patient is benefiting from treatment.

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 May 2020 (continued)

19 CHLORHEXIDINE GLUCONATE (delisting)
Mouthwash 0.2% ..... 2.57 200 ml healthE
Note – healthE mouthwash 0.2%, 200 ml to be delisted from 1 November 2020.

### CARDIOVASCULAR SYSTEM

47 PHENYLEPHRINE HYDROCHLORIDE (↑ price)
Inj 10 mg per ml, 1 ml ampoule ..... 142.07 25 Neosynephrine HCL

### DERMATOLOGICALS

55 HYDROCORTISONE ACETATE (delisting)
Crm 1%..... 2.48 14.2 g AFT
Note – AFT crm 1%, 14.2 g to be delisted from 1 November 2020.

### GENITO-URINARY SYSTEM

58 CHLORHEXIDINE GLUCONATE (delisting)
Crm 1%..... 1.21 50 g healthE
Lotn 1%, 200 ml..... 2.98 1 healthE
Note – healthE crm 1%, 50 g and lotn 1%, 200 ml to be delisted from 1 November 2020.

59 DINOPROSTONE (↑ price)
Vaginal gel 1 mg in 3 g ..... 56.86 1 Prostin E2
Vaginal gel 2 mg in 3 g ..... 69.77 1 Prostin E2

59 OXYTOCIN (Pharmacode change)
Inj 10 iu per ml, 1 ml ampoule – **1% DV Nov-18 to 2021** ..... 4.98 5 **Oxytocin BNM**
Note – this is a new Pharmacode listing, 2577046. Pharmacode 2448203 to be delisted from 1 November 2020.

### INFECTIONS

72 TOBRAMYCIN (Pharmacode change)
➔ Solution for inhalation 60 mg per ml, 5 ml ..... 2,200.00 56 dose TOBI
Note – this is a new Pharmacode listing, 2578891. Pharmacode 2465957 to be delisted 1 August 2020.

83 RIFABUTIN (↑ price)
➔ Cap 150 mg..... 299.75 30 Mycobutin


➔ Restriction
*(Brand)* indicates a brand example only. It is not a contracted product.

## Changes to Section H Part II – effective 1 May 2020 (continued)

### MUSCULOSKELETAL SYSTEM

94 HYDROXYCHLOROQUINE (amended restriction criteria)

| | | | |
|---|---|---|---|
| ➔ Tab 200 mg – **1% DV Sep-18 to 2021** | 7.98 | 100 | **Plaquenil** |

Restricted
Initiation
Any of the following:
1 Rheumatoid arthritis; or
2 Systemic or discoid lupus erythematosus; or
3 Malaria treatment or suppression; **or**
**4 Relevant dermatological conditions (cutaneous forms of lupus and lichen planus, cutaneous vasculitides and mucosal ulceration)**

100 DANTROLENE (↑ price)

| | | | |
|---|---|---|---|
| Cap 25 mg | 97.50 | 100 | Dantrium |
| Inj 20 mg vial | 888.00 | 6 | Dantrium IV |

### NERVOUS SYSTEM

105 BUPIVACAINE HYDROCHLORIDE (↓ price and addition of HSS))

| | | | |
|---|---|---|---|
| Inj 2.5 mg per ml, 20 ml ampoule sterile pack | | | |
| – **1% DV Aug-20 to 2023** | 23.36 | 5 | **Marcain** |
| Inj 5 mg per ml, 10 ml ampoule sterile pack | | | |
| – **1% DV Aug-20 to 2023** | 16.20 | 5 | **Marcain** |
| Inj 5 mg per ml, 20 ml ampoule sterile pack | | | |
| – **1% DV Aug-20 to 2023** | 16.56 | 5 | **Marcain** |

112 DIAZEPAM (↑ price)

| | | | |
|---|---|---|---|
| Rectal tubes 5 mg | 43.50 | 5 | Stesolid |

115 ERGOTAMINE TARTRATE WITH CAFFEINE (delisted)
Tab 1 mg with caffeine 100 mg
Note – ergotamine tartrate with caffeine tab 1 mg with caffeine 100 mg delisted 1 May 2020

### ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

129 DAUNORUBICIN (↑ price)

| | | | |
|---|---|---|---|
| Inj 2 mg per ml, 10 ml vial | 149.50 | 1 | Pfizer |

130 MITOMYCIN C (↑ price)

| | | | |
|---|---|---|---|
| Inj 5 mg vial | 851.37 | 1 | Arrow |

133 DACARBAZINE (↑ price)

| | | | |
|---|---|---|---|
| Inj 200 mg vial | 62.70 | 1 | DBL Dacarbazine |

143 CALCIUM FOLINATE (↑ price)

| | | | |
|---|---|---|---|
| Tab 15 mg | 114.69 | 10 | DBL Leucovorin Calcium |

| | | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|---|

## Changes to Section H Part II – effective 1 May 2020 (continued)

144 VINCRISTINE SULPHATE (↑ price)

| | | | |
|---|---|---|---|
| Inj 1 mg per ml, 2 ml vial | 102.73 | 5 | DBL Vincristine Sulfate |

147 ETANERCEPT (↓ price)

| | | | |
|---|---|---|---|
| ➔ Inj 25 mg vial – 5**% DV Sep-19 to 2024** | 690.00 | 4 | **Enbrel** |
| ➔ Inj 50 mg autoinjector – **5% DV Sep-19 to 2024** | 1,050.00 | 4 | **Enbrel** |
| ➔ Inj 50 mg syringe – **5% DV Sep-19 to 2024** | 1,050.00 | 4 | **Enbrel** |

## RESPIRATORY SYSTEM AND ALLERGIES

202 PROMETHAZINE HYDROCHLORIDE (↑ price)

| | | | |
|---|---|---|---|
| Inj 25 mg per ml, 2 ml ampoule | 17.87 | 5 | Hospira |

203 NINTEDANIB (amended restriction criteria)

| | | | |
|---|---|---|---|
| ➔ Cap 100 mg | 2,554.00 | 60 | Ofev |
| ➔ Cap 150 mg | 3,870.00 | 60 | Ofev |

Restricted
Initiation – idiopathic pulmonary fibrosis
Respiratory specialist
*Re-assessment required after 12 months*
All of the following:
1 Patient has been diagnosed with idiopathic pulmonary fibrosis ~~by a multidisciplinary team including a radiologist~~; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Nintedanib is to be discontinued at disease progression (See Note); and
4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
5 Any of the following:
  5.1 The patient has not previously received treatment with pirfenidone; or
  5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance; or
  5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

Continuation – idiopathic pulmonary fibrosis
~~Respiratory specialist~~
*Re-assessment required after 12 months*
All of the following:
1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Nintedanib is not to be used in combination with subsidised pirfenidone; and
3 Nintedanib is to be discontinued at disease progression (See Note).
Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.


➔ Restriction
*(Brand)* indicates a brand example only. It is not a contracted product.

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 May 2020 (continued)

204 PIRFENIDONE (amended restriction criteria)

| | | | |
|---|---|---|---|
| ➔ Tab 801 mg | 3,645.00 | 90 | Esbriet |
| ➔ Cap 267 mg | 3,645.00 | 270 | Esbriet |

Restricted
Initiation – idiopathic pulmonary fibrosis
Respiratory specialist
*Re-assessment required after 12 months*
All of the following:
1 Patient has been diagnosed with idiopathic pulmonary fibrosis ~~by a multidisciplinary team including a radiologist~~; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Pirfenidone is to be discontinued at disease progression (See Notes); and
4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
5 Any of the following:
  5.1 The patient has not previously received treatment with nintedanib; or
  5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
  5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Continuation – idiopathic pulmonary fibrosis
~~Respiratory specialist~~
*Re-assessment required after 12 months*
All of the following:
1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Pirfenidone is not to be used in combination with subsidised nintedanib; and
3 Pirfenidone is to be discontinued at disease progression (See Note).
Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

205 TERBUTALINE SULPHATE (new listing)

| | | | |
|---|---|---|---|
| Powder for inhalation, 200 mcg per dose (equivalent to 250 mcg metered dose), breath activated | 22.20 | 120 dose | Bricanyl Turbuhaler |

## SENSORY ORGANS

211 OLOPATADINE (brand change)

| | | | |
|---|---|---|---|
| Eye drops 0.1% – **1% DV Oct-20 to 2022** | 2.20 | 5 ml | **Olopatadine Teva** |

Note – Patanol eye drops 0.1% to be delisted from 1 October 2020.

| | | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|---|

## Changes to Section H Part II – effective 1 May 2020 (continued)

### VARIOUS

218 CHLORHEXIDINE (delisting)

| | | | |
|---|---|---|---|
| Soln 4% | 1.86 | 50 ml | healthE |

Note – healthE soln 4%, 50 ml to be delisted from 1 November 2020.

218 IODINE WITH ETHANOL (delisting)

| | | | |
|---|---|---|---|
| Soln 1% with ethanol 70%, 100 ml | 9.30 | 1 | healthE |

Note – healthE soln 1% with ethanol 70%, 100 ml to be delisted from 1 November 2020

218 CHLORHEXIDINE WITH ETHANOL (delisting)

| | | | |
|---|---|---|---|
| Soln 0.5% with ethanol 70%, non-staining (pink) 100 ml | 2.65 | 1 | healthE |
| Soln 2% with ethanol 70%, non-staining (pink) 100 ml | 3.54 | 1 | healthE |
| Soln 0.5% with ethanol 70%, staining (red) 100 ml | 2.90 | 1 | healthE |
| Soln 2% with ethanol 70%, staining (red) 100 ml | 3.86 | 1 | healthE |
| Soln 0.5% with ethanol 70%, non-staining (pink) 500 ml | 5.45 | 1 | healthE |
| Soln 0.5% with ethanol 70%, staining (red) 500 ml | 5.90 | 1 | healthE |
| Soln 2% with ethanol 70%, staining (red) 500 ml | 9.56 | 1 | healthE |

Note – healthE soln 0.5% with ethanol 70%, non staining (pink) and staining (red), 100 ml & 500 ml; soln 2% with ethanol 70%, non staining (pink), 100 ml and staining (red), 100 ml & 500 ml to be delisted from 1 November 2020.

218 POVIDONE-IODINE (pack size change)

| | | | |
|---|---|---|---|
| Oint 10% – **1% DV Oct-20 to 2023** | 7.40 | 65 g | **Betadine** |

Note – Betadone oint 10%, 25 g to be delisted from 1 October 2020.

### SPECIAL FOODS

240 ENTERAL FEED 1 KCAL/ML (new listing)

| | | | |
|---|---|---|---|
| Liquid 4 g protein, 12.3 g carbohydrate and 3.9 g fat per 100 ml, 1,000 ml bottle | | | *e.g. Nutrison Low Sodium* |



➔ Restriction

*(Brand)* indicates a brand example only. It is not a contracted product.

| | | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020

### ALIMENTARY TRACT AND METABOLISM

| | | | | |
|---|---|---|---|---|
| 6 | MESALAZINE (↓ price and addition of HSS) | | | |
| | Tab long-acting 500 mg – **1% DV Jul-20 to 2023** | 56.10 | 100 | **Pentasa** |
| 7 | HYOSCINE BUTYLBROMIDE (↓ price and addition of HSS) | | | |
| | Inj 20 mg, 1 ml ampoule – **1% DV Jul-20 to 2023** | 6.35 | 5 | **Buscopan** |
| 7 | MEBEVERINE HYDROCHLORIDE (↓ price and addition of HSS) | | | |
| | Tab 135 mg – **1% DV Jul-20 to 2023** | 9.20 | 90 | **Colofac** |
| 9 | GLUCAGON HYDROCHLORIDE (addition of HSS) | | | |
| | Inj 1 mg syringe kit – **1% DV Jul-20 to 2023** | 32.00 | 1 | **Glucagen Hypokit** |

### BLOOD AND BLOOD FORMING ORGANS

| | | | | |
|---|---|---|---|---|
| 31 | ENOXAPARIN SODIUM (Pharmacode change) | | | |
| | Inj 20 mg in 0.2 ml syringe | 27.93 | 10 | Clexane |
| | Inj 40 mg in 0.4 ml syringe | 37.27 | 10 | Clexane |
| | Inj 60 mg in 0.6 ml syringe | 56.18 | 10 | Clexane |
| | Inj 80 mg in 0.8 ml syringe | 74.90 | 10 | Clexane |
| | Inj 100 mg in 1 ml syringe | 93.80 | 10 | Clexane |
| | Inj 120 mg in 0.8 ml syringe | 116.55 | 10 | Clexane Forte |
| | Inj 150 mg in 1 ml syringe | 133.20 | 10 | Clexane Forte |
| | Note – these are new Pharmacode listings, current Pharmacodes: 795615, 795623, 416991, 417009, 417017, 389366 and 389390 to be delisted from 1 January 2021. | | | |
| 31 | HEPARIN SODIUM (↑ price) | | | |
| | Inj 1,000 iu per ml, 1 ml ampoule | 197.06 | 50 | Hospira |
| | Inj 5,000 iu per ml, 1 ml ampoule | 32.66 | 5 | Hospira |
| 31 | HEPARINISED SALINE (↑ price) | | | |
| | Inj 10 iu per ml, 5 ml ampoule | 65.48 | 50 | Pfizer |
| 31 | WARFARIN SODIUM (↓ price) | | | |
| | Tab 1 mg | 6.46 | 100 | Marevan |
| | Tab 3 mg | 10.03 | 100 | Marevan |
| | Tab 5 mg | 11.48 | 100 | Marevan |
| 34 | PEGFILGRASTIM (amended restriction criteria) | | | |
| | ➔ Inj 6 mg per 0.6 ml syringe | 1,080.00 | 1 | Neulastim |

Restricted
Initiation
For prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to **5** ~~20~~%*).
Note: *Febrile neutropenia risk greater than or equal to **5** ~~20~~% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

## CARDIOVASCULAR SYSTEM

39 SACUBITRIL WITH VALSARTAN (amended restriction criteria)

| | | | |
|---|---|---|---|
| ➔ Tab 24.3 mg with valsartan 25.7 mg | 190.00 | 56 | Entresto 24/26 |
| ➔ Tab 48.6 mg with valsartan 51.4 mg | 190.00 | 56 | Entresto 49/51 |
| ➔ Tab 97.2 mg with valsartan 102.8 mg | 190.00 | 56 | Entresto 97/103 |

Restricted
Initiation
*Re-assessment required after 12 months*
All of the following:
1 Patient has heart failure; and
2 Any of the following:
  2.1 Patient is in NYHA/WHO functional class II; or
  2.2 Patient is in NYHA/WHO functional class III; or
  2.3 Patient is in NYHA/WHO functional class IV; and
**3 Either**:
  3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; **or**
  **3.2 An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and**
4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

Continuation
*Re-assessment required after 12 months*
The treatment remains appropriate and the patient is benefiting from treatment.
Note: Due to the angiotensin II receptor blocking activity of sacubitril with valsartan it should not be co-administered with an ACE inhibitor or another ARB.

41 LABETALOL (brand change)

| | | | |
|---|---|---|---|
| Tab 100 mg – **1% DV Sep-20 to 2024** | 14.50 | 100 | **Trandate** |
| Tab 200 mg – **1% DV Sep-20 to 2024** | 27.00 | 100 | **Trandate** |

Note – Presolol tab 100 mg and 200 mg to be delisted from 1 September 2020.

41 LABETALOL (new listing)
Tab 50 mg

## Changes to Section H Part II – effective 1 April 2020 (continued)

49 SILDENAFIL (amended restriction criteria – affected criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Tab 25 mg – **1% DV Sep-18 to 2021** | 0.64 | 4 | **Vedafil** |
| ➔ Tab 50 mg – **1% DV Sep-18 to 2021** | 0.64 | 4 | **Vedafil** |
| ➔ Tab 100 mg – **1% DV Sep-18 to 2021** | 6.60 | 12 | **Vedafil** |

➔ Inj 0.8 mg per ml, 12.5 ml vial

Restricted
Initiation – tablets Pulmonary arterial hypertension
Any of the following:
1 All of the following:
- 1.1 Patient has pulmonary arterial hypertension (PAH); and
- 1.2 Any of the following:
  - 1.2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or
  - 1.2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications; or
  - 1.2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and
- 1.3 Any of the following:
  - 1.3.1 PAH is in NYHA/WHO functional class II; or
  - 1.3.2 PAH is in NYHA/WHO functional class III; or
  - 1.3.3 PAH is in NYHA/WHO functional class IV; and
- 1.4 Either:
  - 1.4.1 All of the following:
    - 1.4.1.1 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 1.4.1.2 Either:
      - 1.4.1.2.1 Patient has a mean pulmonary artery pressure (PAPm) > 25 mmHg; or
      - 1.4.1.2.2 Patient is peri Fontan repair; and
    - 1.4.1.3 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dyn s cm-5); or
  - 1.4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age **or health system capacity constraints**; or

2 For use in neonatal units for persistent pulmonary hypertension of the newborn (PPHN); or
3 In-hospital stabilisation in emergency situations.

## DERMATOLOGICALS

55 HYDROCORTISONE (brand change)

| | | | |
|---|---|---|---|
| Crm 1%, 100 g – **1% DV Sep-20 to 2022** | 3.70 | 100 g | **Hydrocortisone (PSM)** |

Note – DermAssist crm 1%, 30 g to be delisted from 1 September 2020.

56 BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL (new listing)

| | | | |
|---|---|---|---|
| Foam spray 500 mcg with calcipotriol 50 mcg per g | 59.95 | 60 g | Enstilar |

## HORMONE PREPARATIONS

66 OESTRIOL (new listing and addition of HSS)

| | | | |
|---|---|---|---|
| Tab 2 mg – **1% DV Sep-20 to 2023** | 7.00 | 30 | **Ovestin** |

## Changes to Section H Part II – effective 1 April 2020 (continued)

### INFECTIONS

74 CEFTAROLINE FOSAMIL (↑ price)
➔ Inj 600 mg vial ..... 1,595.00 | 10 | Zinforo

76 PIPERACILLIN WITH TAZOBACTAM (new listing)
➔ Inj 4 g with tazobactam 0.5 g vial ..... 38.00 | 10 | PiperTaz Sandoz

78 TETRACYCLINE (new listing)
Tab 250 mg ..... 21.42 | 28 | Accord

78 TETRACYCLINE (delisting)
Cap 500 mg ..... 46.00 | 30 | Tetracyclin Wolff
Note – Tetracyclin Wolff cap 500 mg to be delisted from 1 December 2020.

84 METRONIDAZOLE (delisting)
Tab 200 mg ..... 10.45 | 100 | Trichozole
Tab 400 mg ..... 18.15 | 100 | Trichozole
Note – Trichozole tab 200 mg and 400 mg to be delisted from 1 September 2020.

84 PRIMAQUINE ~~PHOSPHATE~~ (amended chemical name)
➔ Tab 7.5 mg
➔ Tab 15 mg

90 EMTRICITABINE WITH TENOFOVIR DISOPROXIL (amended restriction criteria)
➔ Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) – **1% DV Jun-19 to 2022** ..... 61.15 | 30 | **Teva**

Restricted
Initiation – Pre-exposure prophylaxis
*Re-assessment required after 3 months*
All of the following:
1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
2 Patient has undergone testing for HIV, syphilis **and** Hep B if not immune ~~and a full STI screen~~ in the previous two weeks; and
3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 3 months and is not contraindicated for treatment; and
4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and
5 Patient has tested HIV negative and is not at risk of HIV seroconversion; and
6 Either:
  6.1 All of the following:
    6.1.1 Patient is male or transgender; and
    6.1.2 Patient has sex with men; and
    6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
    6.1.4 Any of the following:
      6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
      6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or

*continued...*

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

6.1.4.3 Patient has used methamphetamine in the last three months; or

6.2 All of the following:

6.2.1 Patient has a regular partner who has HIV infection; and

6.2.2 Partner is either not on treatment or has a detectable viral load; and

6.2.3 Condoms have not been consistently used.

Continuation – Pre-exposure prophylaxis

*Re-assessment required after 3 months*

All of the following:

1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and

2 Patient has undergone testing for HIV, syphilis **and** Hep B if not immune ~~and a full STI screen~~ in the previous two weeks; and

3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months and is not contraindicated for treatment; and

4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and

5 Patient has tested HIV negative and is not at risk of HIV seroconversion; and

6 Either:

6.1 All of the following:

6.1.1 Patient is male or transgender; and

6.1.2 Patient has sex with men; and

6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and

6.1.4 Any of the following:

6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or

6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or

6.1.4.3 Patient has used methamphetamine in the last three months; or

6.2 All of the following:

6.2.1 Patient has a regular partner who has HIV infection; and

6.2.2 Partner is either not on treatment or has a detectable viral load; and

6.2.3 Condoms have not been consistently used.

## NERVOUS SYSTEM

| | | | | |
|---|---|---|---|---|
| 112 | DIAZEPAM (↑ price) | | | |
| | Inj 5 mg per ml, 2 ml ampoule | 23.66 | 5 | Hospira |

## Changes to Section H Part II – effective 1 April 2020 (continued)

114 VIGABATRIN (amended restriction criteria)
➔ Tab 500 mg
Restricted
Initiation
*Re-assessment required after 15 months*
Both:
1 Either:
1.1 Patient has infantile spasms; or
1.2 Both:
1.2.1 Patient has epilepsy; and
1.2.2 Either:
1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and
2 Either:
2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
2.2 It is impractical or impossible (due to comorbid conditions, **or health system capacity constraints**) to monitor the patient's visual fields.
Notes: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance. Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

Continuation
Both:
1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
2 Either:
2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or
2.2 It is impractical or impossible (due to comorbid conditions, **or health system capacity constraints**) to monitor the patient's visual fields.
Notes: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective. Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

115 SUMATRIPTAN (brand change)
Inj 12 mg per ml, 0.5 ml prefilled pen
– **1% DV Sep-20 to 2022** ..... 34.00 2 **Imigran**
Note – Clustran inj 12 mg per ml, 0.5 ml prefilled pen to be delisted from 1 September 2020.

## Changes to Section H Part II – effective 1 April 2020 (continued)

### ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130 MITOMYCIN C (amended brand name)
Inj 5 mg vial ..... 204.08 1 ~~Arrow~~ **Teva**

131 GEMCITABINE (addition of HSS)
Inj 10 mg per ml, 100 ml vial – **1% DV Jul-20 to 2023** ..... 15.89 1 **Gemcitabine Ebewe**

133 LENALIDOMIDE (new listing)
➔ Cap 5 mg..... 5,122.76 28 Revlimid
➔ Cap 10 mg..... 6,207.00 28 Revlimid
➔ Cap 15 mg..... 7,239.18 28 Revlimid

133 LENALIDOMIDE (amended restriction criteria)
➔ Cap 10 mg (↓ price)..... 4,655.25 21 Revlimid
➔ Cap 15 mg (↓ price)..... 5,429.39 21 Revlimid
➔ Cap 25 mg..... 7,627.00 21 Revlimid

Initiation – (**Relapsed/refractory disease)**
Haematologist
*Re-assessment required after 6 months*
All of the following:
1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
**2 Patient has not previously been treated with lenalidomide**; and
**3** ~~2~~ Either
**3.1** ~~2.1~~ Lenalidomide to be used as third line* treatment for multiple myeloma; or
**3.2** ~~2.2~~ Both:
**3.2.1** ~~2.2.1~~ Lenalidomide to be used as second line treatment for multiple myeloma; and
**3.2.2** ~~2.2.2~~ The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
**4** ~~3~~ Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

Continuation - **(Relapsed/refractory disease)**
Haematologist
*Re-assessment required after 6 months*
Both:
1 No evidence of disease progression; and
2 The treatment remains appropriate and patient is benefitting from treatment.

**Initiation - (Maintenance following first-line autologous stem cell transplant (SCT))**
**Haematologist**
***Reassessment required after 6 months***
**All of the following:**
**1 Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation; and**
**2 Patient has at least a stable disease response in the first 100 days after transplantation; and**
**3 Lenalidomide maintenance is to be commenced within 6 months of transplantation; and**
**4 The patient has ECOG performance score of 0-1; and**
**5 Lenalidomide to be administered at a maximum dose of 15 mg/day.**

*continued...*

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

**Continuation – (Maintenance following first line autologous SCT)**
**Haematologist**
***Reassessment required after 6 months***
**Both:**
**1 No evidence of disease progression; and**
**2 The treatment remains appropriate and patient is benefitting from treatment.**
Note: Indication marked with * is an unapproved indication. A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments. Prescriptions must be written by a registered prescriber in the lenalidomide risk management programme operated by the supplier.

138 ERLOTINIB (amended restriction criteria – new criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Tab 100 mg | 764.00 | 30 | Tarceva |
| ➔ Tab 150 mg | 1,146.00 | 30 | Tarceva |

**Restricted**
**Continuation – pandemic circumstances**
***Re-assessment required after 6 months***
**All of the following:**
**1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and**
**2 Erlotinib to be discontinued at progression; and**
**3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.**

139 GEFITINIB (amended restriction criteria – new criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Tab 250 mg | 1,700.00 | 30 | Iressa |

**Restricted**
**Continuation – pandemic circumstances**
***Re-assessment required after 6 months***
**All of the following:**
**1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and**
**2 Gefitinib to be discontinued at progression; and**
**3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.**

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

140 PALBOCICLIB (new listing)

| | | | |
|---|---|---|---|
| ➔ Cap 75 mg | 4,000.00 | 21 | Ibrance |
| ➔ Cap 100 mg | 4,000.00 | 21 | Ibrance |
| ➔ Cap 125 mg | 4,000.00 | 21 | Ibrance |

Initiation
Medical oncologist
*Reassessment required after 6 months*
All of the following:
1 Patient has unresectable locally advanced or metastatic breast cancer; and
2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3 Patient has an ECOG performance score of 0-2; and
4 Either:
second or subsequent line setting
4.1 Disease has relapsed or progressed during prior endocrine therapy; or
4.2 Both:
first line setting
4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
4.2.2 Either:
4.2.2.1 Patient has not received prior systemic endocrine treatment for metastatic disease; or
4.2.2.2 All of the following:
4.2.2.2.1 Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and
4.2.2.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; and
4.2.2.2.3 There is no evidence of progressive disease; and
5 Treatment must be used in combination with an endocrine partner.

Continuation
Medical oncologist
*Reassessment required after 12 months*
All of the following:
1 Treatment must be used in combination with an endocrine partner; and
2 No evidence of progressive disease; and
3 The treatment remains appropriate and the patient is benefitting from treatment.

142 SUNITINIB (amended restriction criteria – new criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Cap 12.5 mg | 2,315.38 | 28 | Sutent |
| ➔ Cap 25 mg | 4,630.77 | 28 | Sutent |
| ➔ Cap 50 mg | 9,261.54 | 28 | Sutent |

**Restricted**
**Continuation – GIST pandemic circumstances**
***Re-assessment required after 6 months***
**All of the following:**
**1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and**
**2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and**
**3 Sunitinib is to be discontinued at progression; and**
**4 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.**

| | | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

144 ABIRATERONE ACETATE (amended restriction criteria)

➔ Tab 250 mg ..... 4,276.19 120 Zytiga

Restricted
Initiation
Medical oncologist, radiation oncologist or urologist
*Re-assessment required after 6 months*
All of the following:
1 Patient has prostate cancer; and
2 Patient has metastases; and
3 Patient's disease is castration resistant; and
4 Either:
  4.1 All of the following:
    4.1.1 Patient is symptomatic; and
    4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
    4.1.3 Patient has ECOG performance score of 0-1; and
    4.1.4 Patient has not had prior treatment with taxane chemotherapy; or
  4.2 All of the following:
    4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and
    4.2.2 Patient has ECOG performance score of 0-2; and
    4.2.3 Patient has not had prior treatment with abiraterone.

Continuation
Medical oncologist, radiation oncologist or urologist
*Re-assessment required after 6 months*
All of the following:
~~1 Significant decrease in serum PSA from baseline; and~~
**1** 2 No evidence of clinical disease progression; and
**2** 3 No initiation of taxane chemotherapy with abiraterone; and
**3** 4 The treatment remains appropriate and the patient is benefiting from treatment.

144 VINBLASTINE SULPHATE (↑ price)

Inj 1 mg per ml, 10 ml vial ..... 270.37 5 Hospira

145 FULVESTRANT (new listing)

➔ Inj 50 mg per ml, 5 ml prefilled syringe ..... 1,068.00 2 Faslodex

Initiation
Medical Oncologist
*Re-assessment required after 6 months*
All of the following:
1 Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
2 Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and
3 Treatment to be given at a dose of 500 mg monthly following loading doses; and
4 Treatment to be discontinued at disease progression.

Continuation
Medical Oncologist
*Re-assessment required after 6 months*
All of the following:
1 Treatment remains appropriate and patient is benefitting from treatment; and
2 Treatment to be given at a dose of 500 mg monthly; and
3 No evidence of disease progression.

| | | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

145 OCTREOTIDE (amended restriction criteria – new criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Inj 10 mg vial | 1,772.50 | 1 | Sandostatin LAR |
| ➔ Inj 20 mg vial | 2,358.75 | 1 | Sandostatin LAR |
| ➔ Inj 30 mg vial | 2,951.25 | 1 | Sandostatin LAR |

**Restricted**
**Continuation – Acromegaly - pandemic circumstances**
***Re-assessment required after 6 months***
**All of the following:**
**1 Patient has acromegaly; and**
**2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and**
**3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.**

154 ABCIXIMAB (delisting)

| | | | |
|---|---|---|---|
| ➔ Inj 2 mg per ml, 5 ml vial | 579.53 | 1 | ReoPro |

Note – ReoPro inj 2 mg per ml, 5 ml vial to be delisted from 1 January 2021.

172 MEPOLIZUMAB (new listing)

| | | | |
|---|---|---|---|
| ➔ Inj 100 mg vial | 1,638.00 | 1 | Nucala |

Restricted
Initiation – (Severe eosinophilic asthma)
Respiratory physician or clinical immunologist
*Re-assessment required after 12 months*
All of the following
1 Patient must be aged 12 years or older; and
2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
4 Patient has a blood eosinophil count of greater than 0.5 x 10 ^ 9 cells/L in the last 12 months; and
5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated; and
6 Either:
  6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
7 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment.

Continuation – (Severe eosinophilic asthma)
Respiratory physician or clinical immunologist
*Re-assessment required after 2 years*
Both:
1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
2 Either:
  2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or
  2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

175 RITUXIMAB (MABTHERA) (amended restriction criteria – affected criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Inj 10 mg per ml, 10 ml vial | 1,075.50 | 2 | Mabthera |
| ➔ Inj 10 mg per ml, 50 ml vial | 2,688.30 | 1 | Mabthera |

Restricted
Continuation – severe cold haemagglutinin disease (CHAD)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m$^2$ weekly for 4 weeks) is now planned; or
2 All of the following:
  2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and
  2.2 An initial response lasting at least 12 months was demonstrated; and
  2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Continuation – warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m$^2$ weekly for 4 weeks) is now planned; or
2 All of the following:
  2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and
  2.2 An initial response lasting at least 12 months was demonstrated; and
  2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Continuation – immune thrombocytopenic purpura (ITP)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m$^2$ weekly for 4 weeks) is now planned; or
2 All of the following:
  2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
  2.2 An initial response lasting at least 12 months was demonstrated; and
  2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Continuation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Patient now requires repeat treatment; **and**
**4 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks**

Note: Indications marked with * are unapproved indications.

*continued...*

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

Continuation – ANCA associated vasculitis
*Re-assessment required after-4 **8** weeks*
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m$^2$ of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Nephrologist
*Re-assessment required after-4 **8** weeks*
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

Continuation – Steroid resistant nephrotic syndrome (SRNS)
Nephrologist
*Re-assessment required after-4 **8** weeks*
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

181 RITUXIMAB (RIXIMYO) (amended restriction criteria – affected criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Inj 10 mg per ml, 10 ml vial | 275.33 | 2 | Riximyo |
| ➔ Inj 10 mg per ml, 50 ml vial | 688.20 | 1 | Riximyo |

Restricted
Initiation – severe cold haemagglutinin disease (CHAD)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
**All of the following** ~~Both~~:
1 Patient has cold haemagglutinin disease*; and
2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms; **and**
**3 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.**
Note: Indications marked with * are unapproved indications.

Continuation – severe cold haemagglutinin disease (CHAD)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m$^2$ weekly for 4 weeks) is now planned; or
2 All of the following:
2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and
2.2 An initial response lasting at least 12 months was demonstrated; and
2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
**All of the following** ~~Both~~:
1 Patient has warm autoimmune haemolytic anaemia*; and
2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; **and**
**3 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.**
Note: Indications marked with * are unapproved indications.

Continuation – warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
*Re-assessment required after ~~4~~ **8** weeks*
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m$^2$ weekly for 4 weeks) is now planned; or
2 All of the following:
2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and
2.2 An initial response lasting at least 12 months was demonstrated; and
2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

*continued...*

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

Initiation – immune thrombocytopenic purpura (ITP)
Haematologist
*Re-assessment required after-4 **8** weeks*
**All of the following** ~~Both~~:
1 Either:
  1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
  1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
2 Any of the following:
  2.1 Treatment with steroids and splenectomy have been ineffective; or
  2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); **and**
**3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.**
Note: Indications marked with * are unapproved indications.

Continuation – immune thrombocytopenic purpura (ITP)
Haematologist
*Re-assessment required after-4 **8** weeks*
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
2 All of the following:
  2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
  2.2 An initial response lasting at least 12 months was demonstrated; and
  2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
*Re-assessment required after-4 **8** weeks*
**Both**:
**1 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks; and**
**2** Either:
  **2**.1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
  **2.**2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.
Note: Indications marked with * are unapproved indications.

Continuation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
*Re-assessment required after-4 **8** weeks*
All of the following:
1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Patient now requires repeat treatment; **and**
**4 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.**
Note: Indications marked with * are unapproved indications.

*continued...*

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

Initiation – ANCA associated vasculitis
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 The total rituximab dose would not exceed the equivalent of 375 mg/m$^2$ of body-surface area per week for a total of 4 weeks; and
3 Any of the following:
  3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
  3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
  3.3 Cyclophosphamide and methotrexate are contraindicated; or
  3.4 Patient is a female of child-bearing potential; or
  3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with * are unapproved indications.

Continuation – ANCA associated vasculitis
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m$^2$ of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

Initiation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Nephrologist
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient is a child with SDNS* or FRNS*; and
2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
5 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Nephrologist
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

*continued...*

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

Initiation – Steroid resistant nephrotic syndrome (SRNS)
Nephrologist
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
2 Treatment with tacrolimus for at least 3 months has been ineffective; and
3 Genetic causes of nephrotic syndrome have been excluded; and
4 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

Continuation – Steroid resistant nephrotic syndrome (SRNS)
Nephrologist
*Re-assessment required after ~~4~~ **8** weeks*
All of the following:
1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m$^2$ of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

197 NIVOLUMAB (amended restriction criteria)

| | | | |
|---|---|---|---|
| ➔ Inj 10 mg per ml, 4 ml vial | 1,051.98 | 1 | Opdivo |
| ➔ Inj 10 mg per ml, 10 ml vial | 2,629.96 | 1 | Opdivo |

Restricted
Initiation
Medical oncologist
*Re-assessment required after 4 months*
All of the following:
1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
2 Patient has measurable disease as defined by RECIST version 1.1; and
3 The patient has ECOG performance score of 0-2; and
4 Either:
  4.1 Patient has not received funded pembrolizumab; or
  4.2 Both:
    4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
    4.2.2 The cancer did not progress while the patient was on pembrolizumab; and
~~5 Nivolumab is to be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; and~~
**5** ~~6~~ Baseline measurement of overall tumour burden is documented (see Note); and
**6** ~~7~~ Documentation confirming that the patient has been informed and acknowledges that ~~the initial~~ funded treatment ~~period of~~ **with** nivolumab will not be continued ~~beyond 12 weeks (6 cycles)~~ if their disease progresses ~~during this time~~.

Continuation
Medical oncologist
*Re-assessment required after 4 months*
Either:
1 All of the following:
  1.1 Any of the following:

*continued...*

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or

1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or

1.1.3 Patient has stable disease according to RECIST criteria (see Note); and

~~1.2 Either:~~

~~1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or~~

~~1.2.2 Both:~~

~~1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and~~

1.2.~~2~~.2 Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and

1.3 No evidence of progressive disease according to RECIST criteria (see Note); and

1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; ~~and~~ **or**

~~1.5 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; or~~

2 All of the following:

2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and

2.2 Patient has signs of disease progression; and

2.3 Disease has not progressed during previous treatment with nivolumab; ~~and~~

~~2.4 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks.~~

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam. Target lesion measurements should be assessed using the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks.

Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

| | Price (ex man. Excl. GST) $ | Per | Brand or Generic Manufacturer |
|---|---|---|---|

## Changes to Section H Part II – effective 1 April 2020 (continued)

198 PEMBROLIZUMAB (amended restriction criteria)

➔ Inj 25 mg per ml, 4 ml vial ..... 4,680.00 1 Keytruda

Restricted
Initiation
Medical oncologist
*Re-assessment required after 4 months*
All of the following:
1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
2 Patient has measurable disease as defined by RECIST version 1.1; and
3 The patient has ECOG performance score of 0-2; and
4 Either:
  4.1 Patient has not received funded nivolumab; or
  4.2 Both:
    4.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
    4.2.2 The cancer did not progress while the patient was on nivolumab; and
~~5 Pembrolizumab is to be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks; and~~
6 Baseline measurement of overall tumour burden is documented (see Note); and
7 Documentation confirming that the patient has been informed and acknowledges that ~~the initial~~ funded treatment ~~period of~~ **with** pembrolizumab will not be continued ~~beyond 12 weeks (4 cycles)~~ if their disease progresses ~~during this time~~.

Continuation
Medical oncologist
*Re-assessment required after 4 months*
Either:
1 All of the following:
  1.1 Any of the following:
    1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
    1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
    1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
  ~~1.2 Either:~~
    ~~1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or~~
    ~~1.2.2 Both:~~
      ~~1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and~~
      1.2~~.2.2~~ Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and
  1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
  1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; ~~and~~ **or**
  ~~1.5 Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks; or~~
2 All of the following:
  2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
  2.2 Patient has signs of disease progression; and
  2.3 Disease has not progressed during previous treatment with pembrolizumab; ~~and~~
  ~~2.4 Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks.~~

*continued...*

## Changes to Section H Part II – effective 1 April 2020 (continued)

*continued...*

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam. Target lesion measurements should be assessed using the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks.

Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

200 EVEROLIMUS (amended restriction criteria – new criteria shown only)

| | | | |
|---|---|---|---|
| ➔ Tab 5 mg | 4,555.76 | 30 | Afinitor |
| ➔ Tab 10 mg | 6,512.29 | 30 | Afinitor |

**Restricted**
**Continuation – pandemic circumstances**
***Re-assessment required after 6 months***
**All of the following:**
**1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and**
**2 Everolimus to be discontinued at progression of SEGAs; and**
**3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.**
**Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.**

## RESPIRATORY SYSTEM AND ALLERGIES

205 PHOLCODINE (Pharmacode change)

| | | | |
|---|---|---|---|
| Oral liq 1 mg per ml – **1% DV Jun-20 to 2022** | 3.09 | 200 ml | **AFT Pholcodine Linctus BP** |

Note – this is a new Pharmacode listing 2586932. 2142252 to be delisted from 1 September 2020.

## VARIOUS

218 POVIDONE-IODINE WITH ETHANOL (delisting)

| | | | |
|---|---|---|---|
| Soln 10% with ethanol 30% | 10.00 | 500 ml | Betadine Skin Prep |

Note – Betadine Skin Prep soln 10% with ethanol 30% to be delisted from 1 June 2020.

## Changes to Section H Part II – effective 1 April 2020 (continued)

### SPECIAL FOODS

238 ~~PAEDIATRIC ORAL FEED 1 KCAL/ML~~ (delisting revoked)
➔ ~~Liquid 4.2 g protein, 16.7 g carbohydrate and 7.5 g fat per 100 ml, bottle~~ ~~1.07~~ ~~200 ml~~ ~~Pediasure (Chocolate)~~ ~~Pediasure (Strawberry)~~ ~~Pediasure (Vanilla)~~

Note – Pediasure (Chocolate, Strawberry and Vanilla) Liquid 4.2 g protein, 16.7 g carbohydrate and 7.5 g fat per 100 ml, bottle, 200 ml will no longer be delisted from 1 September 2020.

### VACCINES

242 ADULT DIPHTHERIA AND TETANUS VACCINE (delisting)
➔ Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml syringe – **0% DV Jul-17 to 2020** 0.00 5 **ADT Booster**

Note – ADT Booster inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml syringe to be delisted from 1 October 2020.

247 HEPATITIS B RECOMBINANT VACCINE (delisting)
➔ Inj 5 mcg in 0.5 ml vial – **0% DV Jul-17 to 2020** 0.00 1 **HBvaxPRO**
➔ Inj 10 mcg in 1 ml vial 0.00 1 HBvaxPRO
➔ Inj 40 mcg per 1 ml vial – **0% DV Jul-17 to 2020** 0.00 1 **HBvaxPRO**

Note – HBvaxPRO inj 5 mcg in 0.5 ml vial, 10 mcg in 1 ml vial and 40 mcg per 1 ml vial to be delisted from 1 October 2020.

247 HEPATITIS B RECOMBINANT VACCINE (addition of HSS)
➔ Inj 20 mcg per 1 ml prefilled syringe – **0% DV Oct-20 to 2024** 0.00 1 **Engerix-B**

249 INFLUENZA VACCINE (new listing)
➔ Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) 9.00 1 Influvac Tetra (2020 Formulation)

## Effective 13 March 2020

### NERVOUS SYSTEM

111 FLUOXETINE HYDROCHLORIDE (↑ price)
Tab dispersible 20 mg, scored 9.93 30 Arrow-Fluoxetine

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