Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

# Section H Update

for Hospital Pharmaceuticals

**January 2020**

Cumulative for December 2019 and January 2020

PHARMAC
TE PĀTAKA WHAIORANGA

# Contents

## Summary of decisions
### EFFECTIVE 1 JANUARY 2020

- Apomorphine hydrochloride (Movapo) inj 10 mg per ml, 2 ml ampoule – price decrease and addition of HSS
- Enalapril maleate (Acetec) tab 5 mg, 10 mg and 20 mg – new listing and addition of HSS
- Enalapril maleate (Ethics Enalapril) tab 5 mg, 10 mg and 20 mg – to be delisted 1 June 2020
- Hydrocortisone (Pharmacy Health) crm 1%, 500 g – price increase
- Isosorbide mononitrate (Ismo 40 Retard) tab long-acting 40 mg – price increase
- Lidocaine [lignocaine] hydrochloride (Instillagel Lido) gel 2%, 11 ml urethral syringe – new listing and addition of HSS
- Lidocaine [lignocaine] hydrochloride (Cathejell) gel 2%, 10 ml urethral syringe – to be delisted 1 April 2020
- Lithium carbonate (Lithicarb FC) tab 250 mg – to be delisted 1 November 2020
- Magnesium sulphate inj 100 mg per ml, 50 ml bag – new listing
- Metronidazole (Baxter) inj 5 mg per ml, 100 ml bag, 10 bag pack – new pack size listing
- Metronidazole (Baxter) inj 5 mg per ml, 100 ml bag, 48 bag pack – to be delisted 1 April 2020
- Morphine sulphate (Arrow-Morphine LA) tab long-acting 100 mg – to be delisted 1 March 2020
- Nifedipine (Nyefax Retard) tab long-acting 20 mg – price increase
- Pholcodine (AFT Pholcodine Linctus BP) oral liq 1 mg per ml, 200 ml – new listing and addition of HSS
- Retinol oral liq 666.7 mcg per 2 drops, 10 ml – new listing
- Vitamin A with Vitamins D and C (e.g. Vitadol C) soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops – new listing

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

# Section H changes to Part II

## Effective 1 January 2020

### ALIMENTARY TRACT AND METABOLISM

18 MAGNESIUM SULPHATE (new listing)
Inj 100 mg per ml, 50 ml bag

21 VITAMIN A WITH VITAMINS D AND C (new listing)
Soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops — *e.g. Vitadol C*

21 RETINOL (new listing)
Oral liq 666.7 mcg per 2 drops, 10 ml

### CARDIOVASCULAR SYSTEM

38 ENALAPRIL MALEATE (brand change)

| | | | |
|---|---|---|---|
| Tab 5 mg – **1% DV Jun-20 to 2022** | 1.82 | 100 | **Acetec** |
| Tab 10 mg – **1% DV Jun-20 to 2022** | 2.02 | 100 | **Acetec** |
| Tab 20 mg – **1% DV Jun-20 to 2022** | 2.42 | 100 | **Acetec** |

Note – Ethics Enalapril tab 5 mg, 10 mg and 20 mg to be delisted from 1 June 2020.

43 NIFEDIPINE (↑ price)

| | | | |
|---|---|---|---|
| Tab long-acting 20 mg | 17.72 | 100 | Nyefax Retard |

47 ISOSORBIDE MONONITRATE (↑ price)

| | | | |
|---|---|---|---|
| Tab long-acting 40 mg | 8.20 | 30 | Ismo 40 Retard |

### DERMATOLOGICALS

55 HYDROCORTISONE (↑ price)

| | | | |
|---|---|---|---|
| Crm 1%, 500 g | 17.15 | 500 g | Pharmacy Health |

### INFECTIONS

84 METRONIDAZOLE (pack size change)

| | | | |
|---|---|---|---|
| Inj 5 mg per ml, 100 ml bag | 55.00 | 10 | Baxter |

Note – Baxter inj 5 mg per ml, 100 ml bag, 48 bag pack to be delisted from 1 April 2020.



➔ 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 January 2020 (continued)

### NERVOUS SYSTEM

103 APOMORPHINE HYDROCHLORIDE (↓ price and addition of HSS)
Inj 10 mg per ml, 2 ml ampoule – **1% DV Jan-20 to 2023**..... 59.50 5 **Movapo**

106 LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (brand change)
Gel 2%, 11 ml urethral syringe – **1% DV Apr-20 to 2022**..... 42.00 10 **Instillagel Lido**
Note – Cathejell gel 2%, 10 ml urethral syringe to be delisted from 1 April 2020.

109 MORPHINE SULPHATE (delisting)
Tab long-acting 100 mg ..... 6.10 10 Arrow-Morphine LA
Note – Arrow-Morphine LA tab long-acting 100 mg to be delisted from 1 March 2020.

118 LITHIUM CARBONATE (delisting)
Tab 250 mg ..... 34.30 500 Lithicarb FC
Note – Lithicarb FC tab 250 mg to be delisted from 1 November 2020.

### RESPIRATORY SYSTEM AND ALLERGIES

197 PHOLCODINE (new listing)
Oral liq 1 mg per ml – **1% DV Jun-20 to 2022** ..... 3.09 200 ml **AFT Pholcodine Linctus BP**

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

## Changes to Section H Part II – effective 1 December 2019

### ALIMENTARY TRACT AND METABOLISM

5 SIMETICONE (new listing)
Oral drops 40 mg per ml

20 MULTIVITAMINS (↑ price and addition of HSS)
Tab (BPC cap strength) – **1% DV Mar-20 to 2022** ..... 11.45 1,000 **Mvite**

21 ASCORBIC ACID (↑ price and addition of HSS)
Tab 100 mg – **1% DV Mar-20 to 2022** ..... 9.90 500 **Cvite**

### BLOOD AND BLOOD FORMING ORGANS

27 TRANEXAMIC ACID (brand change)
Tab 500 mg – **1% DV May-20 to 2022** ..... 9.45 60 **Mercury Pharma**
Note – Cyklokapron tab 500 mg to be delisted from 1 May 2020.

31 CLOPIDOGREL (brand change)
Tab 75 mg – **1% DV May-20 to 2022** ..... 4.60 84 **Clopidogrel Multichem**
Note – Arrow - Clopid tab 75 mg to be delisted from 1 May 2020.

### CARDIOVASCULAR SYSTEM

41 FLECAINIDE ACETATE (↑ price)
Inj 10 mg per ml, 15 ml ampoule ..... 100.00 5 Tambocor

### HORMONE PREPARATIONS

65 DANAZOL (new listing)
Cap 100 mg ..... 19.13 28 Mylan

65 DANAZOL (delisting)
Cap 100 mg ..... 68.33 100 Azol
Note – Azol cap 100 mg to be delisted from 1 June 2020.

### INFECTIONS

79 **METHENAMINE (**HEXAMINE**)** HIPPURATE (new listing and amended chemical name)
Tab 1 g ..... 40.01 100 Hiprex

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

## Changes to Section H Part II – effective 1 December 2019 (continued)

### NERVOUS SYSTEM

111 DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE (new listing)
➔ Cap 25 mg ..... 7.83 50 Dosulepin Mylan

112 FLUOXETINE HYDROCHLORIDE (HSS delayed and delisted)
Tab dispersible 20 mg, scored ~~– 1% DV Apr-20 to 2022~~ ..... 1.98 30 Fluox
Cap 20 mg ~~– 1% DV Apr-20 to 2022~~ ..... 2.91 84 Fluox
Note – Fluox tab dispersible 20 mg, scored and cap 20 mg delisted 1 December 2019 and HSS delayed until 1 August 2020.

112 FLUOXETINE HYDROCHLORIDE (delisting delayed)
Tab dispersible 20 mg, scored ..... 2.47 30 Arrow-Fluoxetine
Cap 20 mg ..... 1.99 90 Arrow-Fluoxetine
Note – delisting delayed from 1 April 2020 until 1 August 2020.

116 DROPERIDOL (brand change)
Inj 2.5 mg per ml, 1 ml ampoule – **1% DV May-20 to 2022** ..... 30.95 10 **Droleptan**
Note – Droperidol Panpharma inj 2.5 mg per ml, 1 ml ampoule to be delisted from 1 May 2020.

121 OCRELIZUMAB (new listing)
➔ Inj 30 mg per ml, 10 ml vial ..... 9,346.00 1 Ocrevus
Restricted
Initiation
Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

### ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130 MITOMYCIN C (new listing)
Inj 20 mg vial ..... 816.32 1 Omegapharm

133 COLASPASE [L-ASPARAGINASE] (delisting)
Inj 10,000 iu vial ..... 102.32 1 Leunase
Note – Leunase inj 10,000 iu vial to be delisted from 1 December 2020.

134 PEGASPARGASE (new listing)
➔ Inj 750 iu per ml, 5 ml vial ..... 3,005.00 1 Oncaspar LYO

134 PEGASPARGASE (delisting)
➔ Inj 750 iu per ml, 5 ml vial ..... 3,005.00 1 Oncaspar
Note – Oncaspar inj 750 iu per ml, 5 ml vial to be delisted from 1 May 2020.

134 TEMOZOLOMIDE (brand change)
➔ Cap 5 mg – **1% DV May-20 to 2022** ..... 9.13 5 **Temaccord**
Note – Orion Temozolomide cap 5 mg to be delisted from 1 May 2020.

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

## Changes to Section H Part II – effective 1 December 2019 (continued)

136 ALECTINIB (new listing)

| | | | |
|---|---|---|---|
| ➔ Cap 150 mg | 7,935.00 | 224 | Alecensa |

Restricted
Initiation
*Re-assessment required after 6 months*
All of the following:
1 Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer; and
2 There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test; and
3 Patient has an ECOG performance score of 0-2.

Continuation
*Re-assessment required after 6 months*
Both:
1 No evidence of progressive disease according to RECIST criteria; and
2 The patient is benefitting from and tolerating treatment.

136 VENETOCLAX (new listing)

| | | | |
|---|---|---|---|
| ➔ Tab 10 mg | 95.78 | 14 | Venclexta |
| ➔ Tab 50 mg | 239.44 | 7 | Venclexta |
| ➔ Tab 100 mg | 8,209.41 | 120 | Venclexta |
| ➔ Tab 14 x 10 mg, 7 x 50 mg, 21 x 100 mg | 1,771.86 | 42 | Venclexta |

Restricted
Initiation - relapsed/refractory chronic lymphocytic leukaemia
Haematologist
*Re-assessment required after 7 months*
All of the following:
1 Patient has chronic lymphocytic leukaemia requiring treatment; and
2 Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and
3 Patient has not previously received funded venetoclax; and
4 The patient's disease has relapsed within 36 months of previous treatment; and
5 Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
6 Patient has an ECOG performance status of 0-2.

Continuation - relapsed/refractory chronic lymphocytic leukaemia
Haematologist
*Re-assessment required after 6 months*
Both:
1 Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and
2 Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.

Initiation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Haematologist
*Re-assessment required after 6 months*
All of the following:
1 Patient has previously untreated chronic lymphocytic leukaemia; and
2 There is documentation confirming that patient has 17p deletion by FISH testing or TP53 mutation by sequencing; and
3 Patient has an ECOG performance status of 0-2.

*continued...*

## Changes to Section H Part II – effective 1 December 2019 (continued)

*continued...*

Continuation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Haematologist
*Re-assessment required after 6 months*
The treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are unapproved indications.

173 RITUXIMAB (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
Initiation – Chronic lymphocytic leukaemia
*Re-assessment required after 12 months*
All of the following:

1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and

**2 Any of the following:**

2.**1** The patient is rituximab treatment naive; ~~and~~ **or**

**2.2** ~~3~~ Either:

**2.2.1** ~~3.1~~ The patient is chemotherapy treatment naive; or

**2.2.2** ~~3.2~~ Both:

**2.2.2.1** ~~3.2.1~~ The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and

**2.2.2.2** ~~3.2.2~~ The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; ~~and~~ **or**

**2.3 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and**

**3** ~~5~~ The patient has good performance status; and

**4 Either:**

**4.1** The patient does not have chromosome 17p deletion CLL; ~~and~~ **or**

**4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and**

**5** ~~6~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide, ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles; and

**6** ~~7~~ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), ~~or~~ bendamustine **or venetoclax**.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Continuation – Chronic lymphocytic leukaemia
*Re-assessment required after 12 months*
All of the following:
**Both:**
**1 Either:**

*continued...*

## Changes to Section H Part II – effective 1 December 2019 (continued)

*continued...*

**1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or**

**1.2** All of the following:

**1.2**.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and

**1.2**.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and

**1.2**.3 The patient does not have chromosome 17p deletion CLL; and

**1.2**.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

**2** ~~5~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide, ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

188 TRASTUZUMAB EMTANSINE (new listing)

| | | | |
|---|---|---|---|
| ➔ Inj 100 mg vial | 2,320.00 | 1 | Kadcyla |
| ➔ Inj 160 mg vial | 3,712.00 | 1 | Kadcyla |

Restricted

Initiation

*Re-assessment required after 6 months*

All of the following:

1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and

2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and

3 Either

3.1 The patient has received prior therapy for metastatic disease*; or

3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and

4 Patient has a good performance status (ECOG 0-1); and

5 Either:

5.1 Patient does not have symptomatic brain metastases; or

5.2 Patient has brain metastases and has received prior local CNS therapy; and

6 Treatment to be discontinued at disease progression.

Continuation

Re-assessment required after 6 months

Both:

1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and

2 Treatment to be discontinued at disease progression.

*Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

## Changes to Section H Part II – effective 1 December 2019 (continued)

188 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** ~~the presence of at least one CT or MRI measurable lesion~~; 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 ~~for a maximum of 12 weeks (6 cycles)~~; 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 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:
    **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** 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; ~~and~~ **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
  **1.**5 Nivolumab will be used at a maximum dose of **no greater than the equivalent of** 3 mg/kg every 2 weeks**; or** ~~for a maximum of 12 weeks (6 cycles)~~.
**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**

*continued...*

## Changes to Section H Part II – effective 1 December 2019 (continued)

*continued...*

**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 d~~D~~isease 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 ~~CT or MRI imaging with~~ 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.

189 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** ~~the presence of at least one CT or MRI measurable lesion~~; 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 ~~for a maximum of 12 weeks (4 cycles)~~; 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 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:

*continued...*

## Changes to Section H Part II – effective 1 December 2019 (continued)

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

**1**.5 Pembrolizumab will be used at a maximum dose of **no greater than the equivalent of** 2 mg/kg every 3 weeks**; or** ~~for a maximum of 12 weeks (4 cycles)~~.

**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.**

Notes: **Baseline assessment and d**~~D~~isease 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 ~~CT or MRI imaging with~~ 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.

## RESPIRATORY SYSTEM AND ALLERGIES

| | | | | |
|---|---|---|---|---|
| 196 | PIRFENIDONE (new listing) | | | |
| | ➔ Tab 801 mg | 3,645.00 | 90 | Esbriet |

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

## Changes to Section H Part II – effective 1 December 2019 (continued)

196 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 ~~80~~ **90**% predicted; and
3 Pirfenidone is to be discontinued at disease progression (See Note); 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 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.

## SENSORY ORGANS

201 CHLORAMPHENICOL (brand change)

Eye oint 1% – **1% DV May-20 to 2022** ..... 1.55 5 g **Devatis**

Note – Chlorsig eye oint 1% to be delisted from 1 May 2020.

## SPECIAL FOODS

232 ENTERAL FEED WITH FIBRE 0.83 KCAL/ML (Pharmacode change and amended presentation description)

➔ Liquid 5.5 g protein, 8.8 g carbohydrate,
2.5 g fat and 1.5 g fibre per 100 ml, **bottle** ~~bag~~ ..... 5.29 1,000 ml Nutrison 800 Complete Multi Fibre

Note – this is a new Pharmacode listing, 2572982. Pharmacode 2510774 to be delisted from 1 June 2020.



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

## Changes to Section H Part II – effective 1 December 2019 (continued)

## VACCINES

236 MENINGOCOCCAL (A, C, Y AND W-135) CONJUGATE VACCINE (amended restriction criteria)

Inj 4 mcg or each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial – **0% DV Jul-17 to 2020** ..... 0.00 | 1 | **Menactra**

Restricted
Initiation
**Either:**
1 Any of the following:
- 1 Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant; or
- 2 One dose for close contacts of meningococcal cases; or
- 3 A maximum of two doses for bone marrow transplant patients; or
- 4 A maximum of two doses for patients following immunosuppression***; or**

**2 Both:**
- **1 Person is aged between 13 and 25 years, inclusive; and**
- **2 Either**
  - **2.1 One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons; or**
  - **2.2 One dose for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons, from 1 December 2019 to 30 November 2020.**

Notes: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.
*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

243 VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (amended restriction criteria)

➔ Varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine] ..... 0.00 | 1 | Zostavax
10 | Zostavax

Restricted
Initiation – people aged between 66 and 80 years
*Therapy limited to 1 dose*
One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 ~~March~~ **December** 2020.

# Index

Pharmaceuticals and brands

New Zealand
Permit No. 478

Permit

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