Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

# Section H Update

for Hospital Pharmaceuticals

**March 2024**

PHARMAC
TE PĀTAKA WHAIORANGA

# Contents

## Summary of decisions
**EFFECTIVE 1 MARCH 2024**

- Atomoxetine (APO-Atomoxetine) cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg – price increase and addition of PSS
- Atomoxetine (Generic Partners) cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg – to be delisted 1 August 2024
- Chlorhexidine with cetrimide irrigation soln 0.015% with cetrimide 0.15%, 100 ml bottle – new listing
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.015% with cetrimide 0.15%, 100 ml bottle – to be delisted 1 March 2024
- Clomipramine hydrochloride (Clomipramine Teva) cap 10 mg – new listing
- Fluorouracil (Fluorouracil Accord) inj 50 mg per ml, 50 ml vial – new listing
- Glycomacropeptide and amino acid contains some phenylalanine (PKU GMPro Ultra Lemonade) powder 20 g protein, 4.9 g carbohydrate per 33.4 g sachet – moved chemical to new therapeutic group and revoked delisting
- Goserelin (Teva) implant 3.6 mg, syringe and 10.8 mg, syringe – price increase
- Hyoscine hydrobromide (Scopoderm TTS) patch 1 mg per 72 hours – amended presentation description
- Hyoscine hydrobromide (Scopolamine - Mylan) patch 1 mg per 72 hours – new listing
- Lapatinib tab 250 mg – new listing
- Lidocaine [Lignocaine] hydrochloride inj 10%, 5 ml ampoule – new listing
- Meningococcal b multicomponent vaccine (Bexsero) inj 175 mcg per 0.5 ml prefilled syringe, 10 inj pack – new listing
- Methyldopa (Methyldopa Mylan) tab 250 mg, Pharmacode 2500167 and 2603934 – to be delisted 1 September 2024
- Nivolumab (Opdivo) inj 10 mg per ml, 4 ml vial and 10 ml vial – amended restriction criteria
- Olanzapine (Zypine) tab 2.5 mg, 5 mg and 10 mg, 30 tab pack – new listing and addition of PSS
- Olanzapine (Zypine) tab 2.5 mg, 5 mg and 10 mg, 28 tab pack – to be delisted from 1 August 2024
- Paclitaxel (Anzatax) inj 6 mg per ml, 16.7 ml vial and 50 ml vial – new listing and addition of PSS
- Paclitaxel (Paclitaxel Ebewe) inj 6 mg per ml, 5 ml vial, 16.7 ml vial, 25 ml vial and 50 ml vial to be delisted 1 August 2024
- Paracetamol (Paracetamol Kabi) inj 10 mg per ml, 100 ml vial – price increase
- Pembrolizumab (Keytruda) inj 25 mg per ml, 4 ml vial – amended restriction criteria

**Summary of decisions – effective 1 March 2024** (continued)

- Phenobarbitone (Noumed Phenobarbitone) tab 15 mg – new listing and addition of PSS
- Phenobarbitone (PSM) tab 15 mg – to be delisted 1 August 2024
- Pralidoxime chloride inj 1 g vial – new listing
- Sacubitril with valsartan tab 24.3 mg with valsartan 25.7 mg (Entresto 24/26), tab 48.6 mg with valsartan 51.4 mg (Entresto 49/51) and tab 97.2 mg with valsartan 102.8 mg (Entresto 97/103) – amended restriction criteria
- Simvastatin (Simvastatin Mylan) tab 80 mg – to be delisted 1 September 2024
- Timolol eye drops 0.5%, gel forming – new listing
- Varicella zoster vaccine [shingles vaccine] (Shingrix) inj 50 mcg per 0.5 ml vial plus vial, 10 inj pack – new listing
- Vincristine sulphate (DBL Vincristine Sulfate) inj 1 mg per ml, 1 ml vial – price decrease

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

# Section H changes to Part II

## Effective 1 March 2024

### CARDIOVASCULAR SYSTEM

45 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 |

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.~~

50 METHYLDOPA (delisting)

| | | | |
|---|---|---|---|
| Tab 250 mg | 15.10 | 100 | Methyldopa Mylan |

Note – Methyldopa Mylan tab 250 mg, Pharmacode 2500167 and 2603934, to be delisted from 1 September 2024

53 SIMVASTATIN (delisting)

| | | | |
|---|---|---|---|
| Tab 80 mg – **5% DV Mar-24 to 2026** | 8.81 | 90 | Simvastatin Mylan |

Note – Simvastatin Mylan tab 80 mg to be delisted from 1 September 2024

### HORMONE PREPARATIONS

83 GOSERELIN (↑ price)

| | | | |
|---|---|---|---|
| Implant 3.6 mg, syringe | 91.50 | 1 | Teva |
| Implant 10.8 mg, syringe | 197.50 | 1 | Teva |

### NERVOUS SYSTEM

122 LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (new listing)

Inj 10%, 5 ml ampoule

124 PARACETAMOL (↑ price)

| | | | |
|---|---|---|---|
| ➔Inj 10 mg per ml, 100 ml vial | 15.00 | 10 | Paracetamol Kabi |

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

## Changes to Section H Part II – effective 1 March 2024 (continued)

127 CLOMIPRAMINE HYDROCHLORIDE (new listing)

| | | | |
|---|---|---|---|
| Cap 10 mg | 9.49 | 28 | Clomipramine Teva |

129 PHENOBARBITONE (new listing and addition of PSS)

| | | | |
|---|---|---|---|
| Tab 15 mg – **5% DV Aug-24 to 2025** | 248.50 | 500 | **Noumed Phenobarbitone** |

Note – PSM tab 15 mg to be delisted from 1 August 2024

132 HYOSCINE HYDROBROMIDE (amended presentation description)

| | | | |
|---|---|---|---|
| ➔ Patch ~~1.5 mg~~ **1 mg per 72 hours** | 17.70 | 2 | Scopoderm TTS |

132 HYOSCINE HYDROBROMIDE (new listing)

| | | | |
|---|---|---|---|
| ➔ Patch 1 mg per 72 hours | 88.50 | 10 | Scopolamine - Mylan |

134 OLANZAPINE (new listing and addition of PSS)

| | | | |
|---|---|---|---|
| Tab 2.5 mg – **5% DV Aug-24 to 2026** | 1.40 | 30 | **Zypine** |
| Tab 5 mg – **5% DV Aug-24 to 2026** | 1.93 | 30 | **Zypine** |
| Tab 10 mg – **5% DV Aug-24 to 2026** | 1.93 | 30 | **Zypine** |

Note – Zypine tab 2.5 mg, 5 mg and 10 mg, 28 tab pack – to be delisted from 1 August 2024

141 ATOMOXETINE (↑ price and addition of PSS)

| | | | |
|---|---|---|---|
| Cap 10 mg – **5% DV Aug-24 to 2026** | 43.02 | 28 | **APO-Atomoxetine** |
| Cap 18 mg – **5% DV Aug-24 to 2026** | 45.57 | 28 | **APO-Atomoxetine** |
| Cap 25 mg – **5% DV Aug-24 to 2026** | 44.30 | 28 | **APO-Atomoxetine** |
| Cap 40 mg – **5% DV Aug-24 to 2026** | 46.21 | 28 | **APO-Atomoxetine** |
| Cap 60 mg – **5% DV Aug-24 to 2026** | 51.31 | 28 | **APO-Atomoxetine** |
| Cap 80 mg – **5% DV Aug-24 to 2026** | 65.20 | 28 | **APO-Atomoxetine** |
| Cap 100 mg – **5% DV Aug-24 to 2026** | 65.71 | 28 | **APO-Atomoxetine** |

Note – Generic Partners, cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg to be delisted from 1 August 2024

## ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

150 FLUOROURACIL (new listing)

| | | | |
|---|---|---|---|
| Inj 50 mg per ml, 50 ml vial | 14.72 | 1 | Fluorouracil Accord |

159 LAPATINIB (new listing)

➔ Tab 250 mg

164 VINCRISTINE SULPHATE (↓ price)

| | | | |
|---|---|---|---|
| Inj 1 mg per ml, 1 ml vial | 51.37 | 5 | DBL Vincristine Sulfate |

167 PACLITAXEL (new listing and addition of PSS)

| | | | |
|---|---|---|---|
| Inj 6 mg per ml, 16.7 ml vial – **5% DV Aug-24 to 2026** | 19.59 | 1 | **Anzatax** |
| Inj 6 mg per ml, 50 ml vial – **5% DV Aug-24 to 2026** | 37.89 | 1 | **Anzatax** |

Note – Paclitaxel Ebewe inj 6 mg per ml, 5 ml vial, 16.7 ml vial, 25 ml vial and 50 ml vial to be delisted from 1 August 2024

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

## Changes to Section H Part II – effective 1 March 2024 (continued)

236 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 |

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 **Baseline measurement of overall tumour burden is documented clinically and radiologically** ~~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 Baseline measurement of overall tumour burden is documented (see Note); and~~
**5** ~~6~~ Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses.

Continuation **(less than 24 months on treatment)**
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 **Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period** ~~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
  **1.3** ~~1.4~~ The treatment remains clinically appropriate and the patient is benefitting from the treatment; 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.

**Continuation (more than 24 months on treatment)**
**Medical oncologist**
***Re-assessment required after 4 months***
**Both:**
**1 Patient has been on treatment for more than 24 months; and**
**2 Either:**
  **2.1 All of the following:**
    **2.1.1 Any of the following:**
      **2.1.1.1 Patient's disease has had a complete response to treatment; or**
      **2.1.1.2 Patient's disease has had a partial response to treatment; or**
      **2.1.1.3 Patient has stable disease; and**

*continued...*

## Changes to Section H Part II – effective 1 March 2024 (continued)

*continued...*

**2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; and**

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

**2.2 All of the following:**

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

**2.2.2 Patient has signs of disease progression; and**

**2.2.3 Disease has not progressed during previous treatment with nivolumab.**

~~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.~~

237 PEMBROLIZUMAB (amended restriction criteria – amended criteria shown only)

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

Initiation — **unresectable or metastatic melanoma**

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~~ **Baseline measurement of overall tumour burden is documented clinically and radiologically**; 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 Baseline measurement of overall tumour burden is documented (see Note); and~~

**5** ~~6~~ Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses.

*continued...*

## Changes to Section H Part II – effective 1 March 2024 (continued)

*continued...*

Continuation — **unresectable or metastatic melanoma, less than 24 months on treatment**
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 **Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period** ~~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
  **1.3** ~~1.4~~ The treatment remains clinically appropriate and the patient is benefitting from the treatment; 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
  1.3 Patient has signs of disease progression; and
  2.3 Disease has not progressed during previous treatment with pembrolizumab.

**Continuation — unresectable or metastatic melanoma, more than 24 months on treatment**
**Medical oncologist**
***Re-assessment required after 4 months***
**Both:**
**1 Patient has been on treatment for more than 24 months; and**
**2 Either:**
  **2.1 All of the following:**
    **2.1.1 Any of the following:**
      **2.1.1.1 Patient's disease has had a complete response to treatment; or**
      **2.1.1.2 Patient's disease has had a partial response to treatment; or**
      **2.1.1.3 Patient has stable disease; and**
    **2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; and**
    **2.1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or**
  **2.2 All of the following:**
    **2.2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and**
    **2.2.2 Patient has signs of disease progression; and**
    **2.2.3 Disease has not progressed during previous treatment with pembrolizumab.**

~~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.~~

*continued...*

## Changes to Section H Part II – effective 1 March 2024 (continued)

*continued...*

- ~~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.~~

### SENSORY ORGANS

256 TIMOLOL (new listing)
➔ Eye drops 0.5%, gel forming – Restricted: For continuation only

### VARIOUS

260 PRALIDOXIME CHLORIDE (new listing)
Inj 1 g vial

266 CHLORHEXIDINE WITH CETRIMIDE (new listing)
Irrigation soln 0.015% with cetrimide 0.15%, 100 ml bottle
Baxter irrigation soln 0.015% with cetrimide 0.15%, 100 ml bottle to be delisted from 1 March 2024. Note – this is a brand only delist

### SPECIAL FOODS

289 **Supplements for Phenylketonuria**
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOME PHENYLALANINE (moved chemical to new therapeutic group and revoked delisting)

| | | | |
|---|---|---|---|
| ➔ Powder 20 g protein, 4.9 g carbohydrate per 33.4 g sachet | 936.00 | 30 | PKU GMPro Ultra Lemonade |

~~Note – PKU GMPro Ultra Lemonade Powder 20 g protein, 4.9 g carbohydrate per 33.4 g sachet to be delisted 1 March 2024~~

### VACCINES

292 MENINGOCOCCAL B MULTICOMPONENT VACCINE (new listing)

| | | | |
|---|---|---|---|
| ➔ Inj 175 mcg per 0.5 ml prefilled syringe | 0.00 | 10 | Bexsero |

299 VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (new listing)

| | | | |
|---|---|---|---|
| ➔ Inj 50 mcg per 0.5 ml vial plus vial | 0.00 | 10 | Shingrix |

# Index
Pharmaceuticals and brands

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