Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

April 2021

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 APRIL 2021

- Aciclovir (ViruPOS) eye oint 3%, 4.5 g – price decrease and addition of PSS
- Bendamustine hydrochloride (Ribomustin) inj 25 mg and 100 mg vial – price decrease and addition of PSS
- Brinzolamide (Azopt) eye drops 1%, 5 ml – new listing and addition of PSS
- Cilazapril (Zapril) tab 0.5 mg, 2.5 mg and 5 mg – restriction added
- Empagliflozin (Jardiance) tab 10 mg and tab 25 mg – amended restriction criteria
- Empagliflozin with metformin hydrochloride (Jardiamet) tab 5 mg with 500 mg and 1,000 mg metformin hydrochloride and tab 12.5 mg with 500 mg and 1,000 mg metformin hydrochloride – amended restriction criteria
- Glyceryl trinitrate (Rectogesic) oint 0.2%, 30 g – addition of PSS
- Lapatinib (Tykerb) tab 250 mg – amended restriction criteria and delisting revoked
- Latanoprost with timolol (Arrow - Lattim) eye drops 0.005% with timolol 0.5% – new listing and addition of HSS
- Lithium carbonate (Priadel) tab long-acting 400 mg – new listing and addition of PSS
- Loratadine (Haylor syrup) ora liq 1 mg per ml, 100 ml – new listing and addition of HSS
- Loratadine (Lorfast syrup) ora liq 1 mg per ml, 120 ml – to be delisted 1 September 2021
- Low-GI oral feed 1 kcal/ml (Sustagen Diabetic (Vanilla)) liquid 4.5 g protein, 9.8 g carbohydrate, 4.4 g fat and 1.9 g fibre per 100 ml, can, 237 ml – to be delisted 1 October 2021
- Low-GI oral feed 1 kcal/ml (Nutren Diabetes (Vanilla)) liquid 7 g protein, 10.9 g carbohydrate, 2.7 g fat and 2 g fibre per 100 ml, bottle, 200 ml – new listing
- Mepolizumab (Nucala) inj 100 mg prefilled pen – new listing
- Mesalazine (Pentasa) suppos 1 g – new pack size listing
- Moclobemide (Aurorix) tab 150 mg – new Pharmacode listing
- Oxycodone hydrochloride (OxyNorm) oral liq 5 mg per 5 ml, 250 ml – addition of PSS
- Pegylated interferon alfa-2a (Pegasys) inj 180 mcg prefilled syringe – amended restriction criteria
- SGLT2 Inhibitors – amended therapeutic group name and addition of restriction criteria

Summary of decisions – effective 1 April 2021 (continued)

- Sodium calcium edetate inj 50 mg per ml, 10 ml ampoule – new listing
- Somatropin (Omnitrope) inj 5 mg, 10 mg and 15 mg cartridge – amended restriction criteria
- Tenoxicam (Tilcotil) tab 20 mg – new Pharmacode listing
- Timolol maleate tab 10 mg – to be delisted 1 August 2021
- Ursodeoxycholic acid (Ursosan) cap 500 mg – amended restriction criteria
- Zoledronic acid (Zoledronic acid Mylan) inj 4 mg per 5 ml, vial – amended restriction criteria

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

Section H changes to Part II

Effective 1 April 2021

ALIMENTARY TRACT AND METABOLISM

6 MESALAZINE (new pack size listing)

Suppos 1 g	50.96	28	Pentasa

Note – Pentasa suppos 1 g, 30 pack to be delisted from 1 November 2021.

7 GLYCERYL TRINITRATE (addition of PSS)

Oint 0.2% – **5% DV Sep-21 to 2024**	22.00	30 g	**Rectogesic**

10 ~~Blood Glucose Lowering Agents~~ **SGLT2 Inhibitors** (amended Therapeutic group name and addition of restriction criteria)

Restricted
Initiation
Either:
1 For continuation use; or
2 All of the following:
2.1 Patient has type 2 diabetes; and
2.2 Any of the following:
2.2.1 Patient is Maaori or any Pacific ethnicity*; or
2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
2.2.5 Patient has diabetic kidney disease (see note b)*; and
2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and
2.4 Treatment will not be used in combination with a funded GLP-1 agonist.

Note: *Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.

a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.

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

Changes to Section H Part II – effective 1 April 2021 (continued)

10 EMPAGLIFLOZIN (amended restriction criteria)

➔ Tab 10 mg	58.56	30	Jardiance
➔ Tab 25 mg	58.56	30	Jardiance

~~Restricted~~
~~Initiation~~
~~Either:~~
~~1 For continuation use; or~~
~~2 All of the following:~~
~~2.1 Patient has type 2 diabetes; and~~
~~2.2 Any of the following:~~
~~2.2.1 Patient is Maaori or any Pacific ethnicity*; or~~
~~2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or~~
~~2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or~~
~~2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or~~
~~2.2.5 Patient has diabetic kidney disease (see note b)*; and~~
~~2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and~~
~~2.4 Treatment will not be used in combination with a funded GLP-1 agonist.~~
~~Note: *Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.~~
~~a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.~~
~~b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.~~

11 EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE (amended restriction criteria)

➔ Tab 5 mg with 1,000 mg metformin hydrochloride	58.56	60	Jardiamet
➔ Tab 5 mg with 500 mg metformin hydrochloride	58.56	60	Jardiamet
➔ Tab 12.5 mg with 1,000 mg metformin hydrochloride	58.56	60	Jardiamet
➔ Tab 12.5 mg with 500 mg metformin hydrochloride	58.56	60	Jardiamet

~~Restricted~~
~~Initiation~~
~~Either:~~
~~1 For continuation use; or~~
~~2 All of the following:~~
~~2.1 Patient has type 2 diabetes; and~~
~~2.2 Any of the following:~~
~~2.2.1 Patient is Maaori or any Pacific ethnicity*; or~~
~~2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or~~
~~2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or~~
~~2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or~~
~~2.2.5 Patient has diabetic kidney disease (see note b)*; and~~
~~2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and~~
~~2.4 Treatment will not be used in combination with a funded GLP-1 agonist.~~
~~Note: *Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.~~

continued...

Changes to Section H Part II – effective 1 April 2021 (continued)

continued...

~~a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.~~

~~b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m² in the presence of diabetes, without alternative cause~~.

12 URSODEOXYCHOLIC ACID (amended restriction criteria – new criteria shown only)

➔ Cap 250 mg – **1% DV Oct-20 to 2023** ..... 32.95 100 **Ursosan**

Restricted

Initiation – prevention of sinusoidal obstruction syndrome

Limited to 6 months

Both:

1 The patient is enrolled in the Children's Oncology Group AALL1732 trial; and

2 The patient has leukaemia/lymphoma and is receiving inotuzumab ozogamicin.

CARDIOVASCULAR SYSTEM

40 CILAZAPRIL – **Restricted: For continuation only** (restriction added)

Tab 0.5 mg – **1% DV Sep-19 to 2022** ..... 2.09 90 **Zapril**

Tab 2.5 mg – **1% DV Feb-20 to 2022** ..... 4.80 90 **Zapril**

Tab 5 mg – **1% DV Feb-20 to 2022** ..... 8.35 90 **Zapril**

44 TIMOLOL MALEATE (delisting)

➔ Tab 10 mg

Note – Timolol maleate tab 10 mg to be delisted from 1 August 2021.

HORMONE PREPARATIONS

65 ZOLEDRONIC ACID (amended restriction criteria)

➔ Inj 4 mg per 5 ml, vial – **1% DV May-19 to 2021** ..... 38.03 1 **Zoledronic acid Mylan**

Restricted

Initiation – bone metastases

~~Oncologist, haematologist, or palliative care specialist~~

Any of the following:

1 Patient has hypercalcaemia of malignancy; or

2 Both:

2.1 Patient has bone metastases or involvement; and

2.2 Patient has severe bone pain resistant to standard first-line treatments; or

3 Both:

3.1 Patient has bone metastases or involvement; and

3.2 Patient is at risk of skeletal-related events (pathological fracture, spinal cord compression, radiation to bone or surgery to bone).

Initiation – early breast cancer

~~Oncologist~~

All of the following:

1 Treatment to be used as adjuvant therapy for early breast cancer; and

2 Patient has been amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and

3 Treatment to be administered at a minimum interval of 6-monthly for a maximum of 2 years.

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

Changes to Section H Part II – effective 1 April 2021 (continued)

68 SOMATROPIN (amended restriction criteria – affected criteria shown only)

➔ Inj 5 mg cartridge – **1% DV Oct-18 to 2021**	34.88	1	**Omnitrope**
➔ Inj 10 mg cartridge – **1% DV Oct-18 to 2021**	69.75	1	**Omnitrope**
➔ Inj 15 mg cartridge – **1% DV Oct-18 to 2021**	104.63	1	**Omnitrope**

Restricted
Continuation – adults and adolescents
Endocrinologist or paediatric endocrinologist
Re-assessment required after 12 months
~~Either~~ **Any of the following**:

1 All of the following:
- 1.1 The patient has been treated with somatropin for < 12 months; and
- 1.2 There has been an improvement in the Quality of Life Assessment defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline; and
- 1.3 Serum IGF-I levels have increased to within ±1SD of the mean of the normal range for age and sex; and
- 1.4 The dose of somatropin does not exceed 0.7 mg per day for male patients, or 1 mg per day for female patients; or

2 All of the following:
- 2.1 The patient has been treated with somatropin for more than 12 months; and
- 2.2 The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors); and
- 2.3 Serum IGF-I levels have continued to be maintained within ±1SD of the mean of the normal range for age and sex (other than for obvious external factors); and
- 2.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients or 1 mg per day for female patients; **or**

3 All of the following:
- **3.1 The patient has had a Special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication; and**
- **3.2 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses; and**
- **3.3 The patient has severe growth hormone deficiency (see notes); and**
- **3.4 The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex; and**
- **3.5 The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®).**

Note: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.
Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.
The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and
Dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.
At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

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

Changes to Section H Part II – effective 1 April 2021 (continued)

INFECTIONS

94 PEGYLATED INTERFERON ALFA-2A (amended restriction criteria – new criteria shown only)
➔Inj 180 mcg prefilled syringe ..... 500.00 4 Pegasys

Restricted
Initiation – post-allogenic bone marrow transplant
Reassessment required after 3 months
Patient has received an allogeneic bone marrow transplant* and has evidence of disease relapse

Continuation – post-allogenic bone marrow transplant
Reassessment required after 3 months
Patient is responding and ongoing treatment remains appropriate
Note: Indications marked with * are unapproved indications

MUSCULOSKELETAL SYSTEM

105 TENOXICAM (new Pharmacode listing)
Tab 20 mg – **1% DV Oct-19 to 2022** ..... 9.15 100 **Tilcotil**
Note – this is a new Pharmacode listing, 2520559. Pharmacode 729396 to be delisted from 1 September 2021.

NERVOUS SYSTEM

112 OXYCODONE HYDROCHLORIDE (addition of PSS)
Oral liq 5 mg per 5 ml – **5% DV Sep-21 to 2024** ..... 11.20 250 ml **OxyNorm**

114 MOCLOBEMIDE (new Pharmacode listing)
Tab 150 mg – **1% DV Apr-19 to 2021** ..... 6.40 60 **Aurorix**
Note – this is a new Pharmacode listing, 2602385. Pharmacode 2560429 to be delisted from 1 September 2021.

120 LITHIUM CARBONATE (new listing and addition of PSS)
Tab long-acting 400 mg – **5% DV Sep-21 to 2024**..... 72.00 100 **Priadel**

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130 BENDAMUSTINE HYDROCHLORIDE (↓ price and addition of PSS)
➔Inj 25 mg vial – **5% DV Sep-21 to 2024**..... 77.00 1 **Ribomustin**
➔inj 100 mg vial – **5% DV Sep-21 to 2024**..... 308.00 1 **Ribomustin**

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

Changes to Section H Part II – effective 1 April 2021 (continued)

142 LAPATINIB (amended restriction criteria and delisting revoked)

➔ Tab 250 mg ..... 1,899.00 70 Tykerb

Restricted
Initiation
For continuation use only
~~Re-assessment required after 12 months~~
~~Either:~~
~~1 All of the following:~~
~~1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and~~
~~1.2 The patient has not previously received trastuzumab treatment for HER 2 positive metastatic breast cancer; and~~
~~1.3 Lapatinib not to be given in combination with trastuzumab; and~~
~~1.4 Lapatinib to be discontinued at disease progression; or~~
~~2 All of the following:~~
~~2.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and~~
~~2.2 The patient started trastuzumab for metastatic breast cancer but discontinued trastuzumab within 3 months of starting treatment due to intolerance; and~~
~~2.3 The cancer did not progress whilst on trastuzumab; and~~
~~2.4 Lapatinib not to be given in combination with trastuzumab; and~~
~~2.5 Lapatinib to be discontinued at disease progression.~~

Continuation
Re-assessment required after 12 months
All of the following:
1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
3 Lapatinib not to be given in combination with trastuzumab; and
4 Lapatinib to be discontinued at disease progression.
Note – Tykerb tab 250 mg delisting revoked.

177 MEPOLIZUMAB (new listing)

➔ Inj 100 mg prefilled pen ..... 1,638.00 1 Nucala

RESPIRATORY SYSTEM AND ALLERGIES

207 LORATADINE (brand change)

Oral liq 1 mg per ml – **1% DV Sep-21 to 2022** ..... 1.43 100 ml **Haylor syrup**

Note – Lorfast oral liq 1 mg per ml to be delisted from 1 September 2021.

SENSORY ORGANS

215 ACICLOVIR (↓ price and addition of PSS)

Eye oint 3% – **5% DV Sep-21 to 2024** ..... 14.88 4.5 g **ViruPOS**

219 BRINZOLAMIDE (new listing and addition of PSS)

Eye drops 1% – **5% DV Sep-21 to 2024** ..... 7.30 5 ml **Azopt**

➔ 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 2021 (continued)

219 LATANOPROST WITH TIMOLOL (new listing and addition of HSS)
Eye drops 0.005% with timolol 0.5%
– **1% DV Sep-21 to 2023** ..... 2.49 2.5 ml **Arrow - Lattim**

VARIOUS

224 SODIUM CALCIUM EDETATE (new listing)
Inj 50 mg per ml, 10 ml ampoule

SPECIAL FOODS

239 LOW-GI ORAL FEED 1 KCAL/ML (delisting)
➔ Liquid 4.5 g protein, 9.8 g carbohydrate, 4.4 g fat and 1.9 g fibre per 100 ml, can ..... 2.10 237 ml Sustagen Diabetic (Vanilla)

Note – Sustagen Diabetic (Vanilla) liquid 4.5 g protein, 9.8 g carbohydrate, 4.4 g fat and 1.9 g fibre per 100 ml, can to be delisted from 1 October 2021.

239 LOW-GI ORAL FEED 1 KCAL/ML (new listing)
➔ Liquid 7 g protein, 10.9 g carbohydrate, 2.7 g fat and 2 g fibre per 100 ml, bottle ..... 2.10 200 ml Nutren Diabetes (Vanilla)

Index
Pharmaceuticals and brands

New Zealand
Permit No. 478

Permit

Pharmaceutical Management Agency
Level 9, 40 Mercer Street, PO Box 10254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz
Email: enquiry@pharmac.govt.nz

ISSN 1172-3694 (Print)
ISSN 1179-3708 (Online)

Te Kāwanatanga o Aotearoa New Zealand Government

If Undelivered, Return To: PO Box 10254, Wellington 6143, New Zealand