Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

December 2020

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 DECEMBER 2020

- Adalimumab inj 20 mg per 0.4 ml and 40 mg per 0.8 ml syringe (Humira) and inj 40 mg per 0.8 ml pen (HumiraPen) – amended restriction criteria
- Amino acid formula (without phenylalanine) (e.g. PKU Anamix Infant) powder 13.1 g protein, 50.1 g carbohydrate, 23 g fat and 5.3 g fibre per 100 g, 400 g can – new listing
- Amino acid formula (without phenylalanine) (e.g. PKU Anamix Infant) powder 13.1 g protein, 49.5 g carbohydrate, 23 g fat and 5.3 g fibre per 100 g, 400 g can – to be delisted 1 June 2021
- Bupropion hydrochloride (Zyban) tab modified-release 150 mg – addition of HSS
- Calcium carbonate (Calci-Tab 500) tab 1.25 g (500 mg elemental) – new listing and addition of HSS
- Calcium carbonate (Arrow-Calcium) tab 1.25 g (500 mg elemental) – to be delisted 1 May 2021
- Cyclizine lactate (Hameln) inj 50 mg per ml, 1 ml ampoule – new listing and addition of HSS
- Cyclizine lactate (Nausicalm) inj 50 mg per ml, 1 ml ampoule – to be delisted 1 May 2021
- Docetaxel (DBL Docetaxel) inj 10 mg per ml, 2 ml vial – to be delisted 1 June 2021
- Dornase alfa (Pulmozyme) nebuliser soln 2.5 mg per 2.5 ml ampoule – amended restriction criteria
- Emicizumab (Hemlibra) inj 30 mg in 1 ml vial, 60 mg in 0.4 ml vial, 105 mg in 0.7 ml vial and 150 mg in 1 ml vial – new listing
- Etanercept (Enbrel) inj 25 mg vial, inj 50 mg autoinjector and syringe – amended restriction criteria
- Extensively hydrolysed formula powder 1.6 g protein, 7.5 g carbohydrate and 3.1 g fat per 100 ml, 900 g can (Aptamil AllerPro SYNEO 1) and powder 1.6 g protein, 7.8 g carbohydrate and 3.2 g fat per 100 ml, 900 g can (Aptamil AllerPro SYNEO 2) – amended brand name
- Goserelin (Teva) implant 3.6 mg and 10.8 mg, syringe – new listing and addition of HSS
- Goserelin (Zoladex) implant 3.6 mg and 10.8 mg, syringe – to be delisted 1 May 2021
- Imatinib mesilate (Imatinib-Rex) cap 400 mg – new listing and addition of HSS
- Imatinib mesilate (Imatinib-AFT) cap 400 mg – to be delisted 1 June 2021
- Mitomycin C (Teva) inj 20 mg vial – new listing

Summary of decisions – effective 1 December 2020 (continued)

- Paraldehyde soln 97% – new listing
- Pegaspargase (Oncaspar LYO) inj 750 iu per ml, 5 ml vial – amended restriction criteria
- Pegylated interferon alfa-2a (Pegasys) inj 180 mcg prefilled syringe – amended restriction criteria
- Pimecrolimus (Elidel) crm 1%, 15 g – new listing
- Rifaximin (Xifaxan) tab 550 mg – addition of HSS
- Rituximab (Mabthera) inj 10 mg per ml, 10 ml and 50 ml vial – amended restriction criteria
- Tobramycin (Tobramycin BNM) solution for inhalation 60 mg per ml, 5 ml – new listing and addition of HSS
- Tobramycin (TOBI) solution for inhalation 60 mg per ml, 5 ml – to be delisted 1 May 2021
- Tocilizumab (Actemra) inj 20 mg per ml, 4 ml, 10 ml and 20 ml vial – amended restriction criteria
- Water (InterPharma) inj 5 ml and 20 ml ampoule – to be delisted 1 June 2021

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

Section H changes to Part II

Effective 1 December 2020

ALIMENTARY TRACT AND METABOLISM

9 RIFAXIMIN (addition of HSS)

➔Tab 550 mg – **1% DV Mar-21 to 2023**	625.00	56	**Xifaxan**

17 CALCIUM CARBONATE (brand change)

Tab 1.25 g (500 mg elemental) – **1% DV May-21 to 2023**	6.69	250	**Calci-Tab 500**

Note – Arrow-Calcium tab 1.25 g (500 mg elemental) to be delisted from 1 May 2021.

BLOOD AND BLOOD FORMING ORGANS

26 EMICIZUMAB (new listing)

➔Inj 30 mg in 1 ml vial	3,570.00	1	Hemlibra
➔Inj 60 mg in 0.4 ml vial	7,138.00	1	Hemlibra
➔Inj 105 mg in 0.7 ml vial	12,492.00	1	Hemlibra
➔Inj 150 mg in 1 ml vial	17,846.00	1	Hemlibra

Restricted
Initiation
Haematologist
Reassessment required after 6 months
All of the following:

1 Patient has severe congenital haemophilia A and history of bleeding and bypassing agent usage within the last six months; and
2 Either:
  2.1 Patient has had greater than or equal to 6 documented and treated spontaneous bleeds within the last 6 months if on an on-demand bypassing agent regimen; or
  2.2 Patient has had greater than or equal to 2 documented and treated spontaneous bleeds within the last 6 months if on a bypassing agent prophylaxis regimen; and
3 Patient has a high-titre inhibitor to Factor VIII (greater than or equal to 5 Bethesda units per ml) which has persisted for six months or more; and
4 There is no immediate plan for major surgery within the next 12 months; and
5 Either:
  5.1 Patient has failed immune tolerance induction (ITI) after an initial period of 12 months; or
  5.2 The Haemophilia Treaters Group considers the patient is not a suitable candidate for ITI; and
6 Treatment is to be administered at a maximum dose of 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly.

Continuation
Haematologist
Reassessment required after 6 months
Both:

1 Patient has had no more than two spontaneous and clinically significant treated bleeds after the end of the loading dose period (i.e. after the first four weeks of treatment until the end of the 24-week treatment period); and
2 The treatment remains appropriate and the patient is benefiting from treatment.

36 WATER (delisting)

Inj 5 ml ampoule	7.00	50	InterPharma
Inj 20 ml ampoule	7.50	30	InterPharma

Note – InterPharma inj 5 ml and 20 ml ampoule to be delisted from 1 June 2021.

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

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

DERMATOLOGICALS

56 PIMECROLIMUS (new listing)
➔ Crm 1% – **1% DV Mar-21 to 2023** ..... 28.50 15 g **Elidel**

Restricted
Initiation
Dermatologist, paediatrician or ophthalmologist
Both:
1 Patient has atopic dermatitis on the eyelid; and
2 Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy, documented allergy to topical corticosteroids, cataracts, glaucoma, or raised intraocular pressure.

HORMONE PREPARATIONS

66 GOSERELIN (brand change)
Implant 3.6 mg, syringe – **1% DV May-21 to 2023** ..... 65.68 1 **Teva**
Implant 10.8 mg, syringe – **1% DV May-21 to 2023** ..... 122.37 1 **Teva**
Note – Zoladex implant 3.6 mg and 10.8 mg, syringe to be delisted from 1 May 2021.

INFECTIONS

72 TOBRAMYCIN (brand change)
➔ Solution for inhalation 60 mg per ml, 5 ml
– **1% DV May-21 to 2023** ..... 395.00 56 dose **Tobramycin BNM**
Note – TOBI solution for inhalation 60 mg per ml, 5 ml to be delisted from 1 May 2021.

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

Restricted
Initiation - ocular surface squamous neoplasia
Ophthalmologist
Reassessment required after 12 months
Patient has ocular surface squamous neoplasia *

Continuation - ocular surface squamous neoplasia
Ophthalmologist
Reassessment required after 12 months
The treatment remains appropriate and patient is benefitting from treatment.
Note: Indications marked with * are unapproved indications

NERVOUS SYSTEM

113 PARALDEHYDE (new listing)
Soln 97%

117 CYCLIZINE LACTATE (brand change)
Inj 50 mg per ml, 1 ml ampoule – **1% DV May-21 to 2022** ..... 21.53 10 **Hameln**
Note – Nausicalm inj 50 mg per ml, 1 ml ampoule to be delisted from 1 May 2021.

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

127 BUPROPION HYDROCHLORIDE (addition of HSS)
Tab modified-release 150 mg – **1% DV Mar-21 to 2023** ..... 11.00 | 30 | **Zyban**

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

131 MITOMYCIN C (new listing)
Inj 20 mg vial ..... 3,275.00 | 1 | Teva

135 PEGASPARGASE (amended restriction criteria)
➔ Inj 750 iu per ml, 5 ml vial ..... 3,455.00 | 1 | Oncaspar LYO

Restricted
Initiation – Newly diagnosed ALL
Limited to 12 months treatment
Both ~~All of the following~~:
1 The patient has newly diagnosed acute lymphoblastic leukaemia; and.
2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; ~~and~~
~~3 Treatment is with curative intent.~~

Initiation – Relapsed ALL
Limited to 12 months treatment
Both ~~All of the following~~:
1 The patient has relapsed acute lymphoblastic leukaemia; and
2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; ~~and~~
~~3 Treatment is with curative intent.~~

Initiation – Lymphoma
Limited to 12 months treatment
Patient has lymphoma requiring L-asparaginase containing protocol (e.g. SMILE)

141 IMATINIB MESILATE (brand change)
Cap 400 mg – **1% DV Jun-21 to 2023** ..... 84.79 | 30 | **Imatinib-Rex**
Note – Imatinib-AFT cap 400 mg to be delisted from 1 June 2021.

145 DOCETAXEL (delisting)
Inj 10 mg per ml, 2 ml vial ..... 12.40 | 1 | DBL Docetaxel
Note – DBL Docetaxel inj 10 mg per ml, 2 ml vial to be delisted from 1 June 2021.

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

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

150 ETANERCEPT (amended restriction criteria – affected criteria shown only)

➔ 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**

Initiation - **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for adalimumab for **polyarticular course** juvenile idiopathic arthritis (JIA); and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from adalimumab; or
1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for **polyarticular course** JIA; or
2 All of the following:
~~2.1 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and~~
2.1~~2~~ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.2~~3~~ Patient has had ~~severe active~~ polyarticular course JIA for 6 months duration or longer; and
2.3 Any of the following:
2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.
~~2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m^2 weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~
~~2.5 Both:~~
~~2.5.1 Either:~~
~~2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or~~
~~2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~
~~2.5.2 Physician's global assessment indicating severe disease.~~

Initiation - oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA); and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from adalimumab; or
1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or

continued...

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

continued...

2 All of the following:
- **2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and**
- **2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and**
- **2.3 Any of the following:**
  - **2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or**
  - **2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or**
  - **2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.**

Continuation – **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Both:
1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Continuation – oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Both:
1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- **2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or**
- **2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.**

156 ADALIMUMAB (amended restriction criteria – affected criteria shown only)

➔ Inj 20 mg per 0.4 ml syringe	1,599.96	2	Humira
➔ Inj 40 mg per 0.8 ml pen	1,599.96	2	HumiraPen
➔ Inj 40 mg per 0.8 ml syringe	1,599.96	2	Humira

Restricted
Initiation – **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:
1 Both:
- 1.1 The patient has had an initial Special Authority approval for etanercept for **polyarticular course** juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
  - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for **polyarticular course** JIA; or

continued...

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

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

continued...

2 All of the following:

~~2.1 Patient diagnosed with JIA; and~~

2.1~~2~~ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.2~~3~~ Patient has had ~~severe active~~ polyarticular course JIA for 6 months duration or longer; and

2.3 Any of the following:

2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

~~2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~

~~2.5 Both:~~

~~2.5.1 Either:~~

~~2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or~~

~~2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~

~~2.5.2 Physician's global assessment indicating severe disease.~~

Initiation – oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from etanercept; or

1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for oligoarticular course JIA; or

2 All of the following:

2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and

2.3 Any of the following:

2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

Continuation - **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Reassessment required after 6 months
Both:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

continued...

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

continued...

2 Either:
- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Continuation – oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Reassessment required after 6 months
Both:

1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- **2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or**
- **2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.**

179 RITUXIMAB (MABTHERA) (amended restriction criteria)

➔ 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 – haemophilia with inhibitors~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – haemophilia with inhibitors~~
~~Haematologist~~
~~All of the following:~~
~~1 Patient was previously treated with rituximab for haemophilia with inhibitors; and~~
~~2 An initial response lasting at least 12 months was demonstrated; and~~
~~3 Patient now requires repeat treatment.~~

~~Initiation – post-transplant~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – post-transplant~~
~~All of the following:~~
~~1 The patient has had a rituximab treatment-free interval of 12 months or more; and~~
~~2 The patient has B-cell post-transplant lymphoproliferative disorder*; and~~
~~3 To be used for no more than 6 treatment cycles.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – indolent, low-grade lymphomas or hairy cell leukaemia*~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – indolent, low-grade lymphomas or hairy cell leukaemia*~~
~~Re-assessment required after 9 months~~
~~All of the following:~~
~~1 The patient has had a rituximab treatment-free interval of 12 months or more; and~~
~~2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and~~
~~3 To be used for no more than 6 treatment cycles.~~
~~Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/ Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.~~

continued...

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

continued...

~~Initiation – aggressive CD20 positive NHL~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – aggressive CD20 positive NHL~~
~~All of the following:~~
~~1 The patient has had a rituximab treatment-free interval of 12 months or more; and~~
~~2 The patient has relapsed refractory/aggressive CD20 positive NHL; and~~
~~3 To be used with a multi-agent chemotherapy regimen given with curative intent; and~~
~~4 To be used for a maximum of 4 treatment cycles.~~
~~Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.~~

~~Initiation – Chronic lymphocytic leukaemia~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Chronic lymphocytic leukaemia~~
~~Re-assessment required after 12 months~~
~~Both:~~
~~1 Either:~~
~~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 bendamustin; and~~
~~2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, 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.~~

Initiation – rheumatoid arthritis - prior TNF inhibitor use
Rheumatologist
Limited to 4 months treatment
All of the following:
1 Both:
1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

continued...

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

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

continued...

Initiation – rheumatoid arthritis - TNF inhibitors contraindicated
Rheumatologist
Limited to 4 months treatment
All of the following:

1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
  5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of cyclosporin; or
  5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
6 Either:
  6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
7 Either:
  7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
8 Either:
  8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis - re-treatment in 'partial responders' to rituximab
Rheumatologist
Re-assessment required after 4 months
All of the following:

1 Any of the following:
  1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
  3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or

continued...

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

continued...

3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis - re-treatment in 'responders' to rituximab
Rheumatologist
Re-assessment required after 4 months
All of the following:

1 Either:
  1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
  3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

~~Initiation – severe cold haemagglutinin disease (CHAD)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – severe cold haemagglutinin disease (CHAD)~~
~~Haematologist~~
~~Re-assessment required after 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 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)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – warm autoimmune haemolytic anaemia (warm AIHA)~~
~~Haematologist~~
~~Re-assessment required after 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 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.~~

~~Initiation – immune thrombocytopenic purpura (ITP)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

continued...

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

continued...

~~Continuation – immune thrombocytopenic purpura (ITP)~~
~~Haematologist~~
~~Re-assessment required after 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)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – thrombotic thrombocytopenic purpura (TTP)~~
~~Haematologist~~
~~Re-assessment required after 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.~~

~~Initiation – pure red cell aplasia (PRCA)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – pure red cell aplasia (PRCA)~~
~~Haematologist~~
~~Re-assessment required after 6 weeks~~
~~Patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – ANCA associated vasculitis~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – ANCA associated vasculitis~~
~~Re-assessment required after 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/m² of body-surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – treatment refractory systemic lupus erythematosus (SLE)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – treatment refractory systemic lupus erythematosus (SLE)~~
~~Rheumatologist or nephrologist~~
~~All of the following:~~
~~1 Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and~~

continued...

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

continued...

~~2 The disease has subsequently relapsed; and~~
~~3 Maximum of two 1000 mg infusions of rituximab.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – Antibody-mediated renal transplant rejection~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Initiation – ABO-incompatible renal transplant~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Initiation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)~~
~~Nephrologist~~
~~Re-assessment required after 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.~~

~~Initiation – Steroid resistant nephrotic syndrome (SRNS)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Steroid resistant nephrotic syndrome (SRNS)~~
~~Nephrologist~~
~~Re-assessment required after 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.~~

~~Initiation – Neuromyelitis Optica Spectrum Disorder (NMOSD)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Neuromyelitis Optica Spectrum Disorder (NMOSD)~~
~~Relevant specialist or medical practitioner on the recommendation of a Relevant specialist~~
~~Re-assessment required after 2 years~~
~~All of the following:~~
~~1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m^2 administered weekly for four weeks; and~~
~~2 The patients has responded to the most recent course of rituximab; and~~
~~3 The patient has not received rituximab in the previous 6 months.~~

~~Initiation – Severe Refractory Myasthenia Gravis~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Severe Refractory Myasthenia Gravis~~
~~Neurologist or medical practitioner on the recommendation of a Neurologist~~
~~Re-assessment required after 2 years~~
~~All of the following:~~

continued...

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

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

continued...

~~1 One of the following dose regimens is to be used: 375 mg/m² of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and~~
~~2 An initial response lasting at least 12 months was demonstrated; and~~
~~3 Either:~~
~~3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or~~
~~3.2 Both:~~
~~3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and~~
~~3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.~~

195 TOCILIZUMAB (amended restriction criteria – affected criteria shown only)

➔ Inj 20 mg per ml, 4 ml vial	220.00	1	Actemra
➔ Inj 20 mg per ml, 10 ml vial	550.00	1	Actemra
➔ Inj 20 mg per ml, 20 ml vial	1,100.00	1	Actemra

Initiation – polyarticular juvenile idiopathic arthritis
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 4 months
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for **polyarticular course** juvenile idiopathic arthritis (JIA); and
1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or
2 All of the following:
2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
2.2 Patient has had ~~severe active~~ polyarticular course JIA for 6 months duration or longer; and
~~2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~
2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.4 Any of the following:
2.4.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.4.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.4.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.
~~2.5 Both:~~
~~2.5.1 Either:~~
~~2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or~~
~~2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~
~~2.5.2 Physician's global assessment indicating severe disease~~

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

RESPIRATORY SYSTEM AND ALLERGIES

212 DORNASE ALFA (amended restriction criteria – affected criteria shown only)
➔ Nebuliser soln 2.5 mg per 2.5 ml ampoule ..... 250.00 6 Pulmozyme

Restricted
Initiation - cystic fibrosis
~~1 The patient has cystic fibrosis and has been approved by the Cystic Fibrosis Panel~~
Respiratory physician or paediatrician
Reassessment required after 12 months
All of the following:
1 Patient has a confirmed diagnosis of cystic fibrosis; and
2 Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline; and
3 Any of the following:
3.1 Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period; or
3.2 Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in in the previous 12 month period; or
3.3 Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a Brasfield score of <22/25; or
3.4 Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA).

Continuation - cystic fibrosis
Respiratory physician or paediatrician
The treatment remains appropriate and the patient continues to benefit from treatment.

SPECIAL FOODS

236 AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (new listing)
➔ Powder 13.1 g protein, 50.1 g carbohydrate,
23 g fat and 5.3 g fibre per 100 g, 400 g can *e.g. PKU Anamix Infant*

236 AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (delisting)
➔ Powder 13.1 g protein, 49.5 g carbohydrate, 23 g fat
and 5.3 g fibre per 100 g, 400 g can *e.g. PKU Anamix Infant*
Note – PKU Anamix Infant powder 13.1 g protein, 49.5 g carbohydrate, 23 g fat and 5.3 g fibre per 100 g, 400 g can to be delisted from 1 June 2021.

242 EXTENSIVELY HYDROLYSED FORMULA (amended brand name)
➔ Powder 1.6 g protein, 7.5 g carbohydrate and
3.1 g fat per 100 ml, 900 g can ..... 30.42 900 g **Aptamil** AllerPro **SYNEO** 1

➔ Powder 1.6 g protein, 7.8 g carbohydrate and
3.2 g fat per 100 ml, 900 g can ..... 30.42 900 g **Aptamil** AllerPro **SYNEO** 2

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