Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

March 2020

Cumulative for December 2019, January, February and March 2020

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 MARCH 2020

- Amikacin (DBL Amikacin) inj 250 mg per ml, 2 ml vial – Pharmacode change
- Benzbromarone tab 50 mg – new listing
- Bortezomib (Bortezomib – Dr Reddy's) inj 3.5 mg vial – new listing, addition of HSS and amended restriction criteria
- Bortezomib (Velcade) inj 3.5 mg vial – to be delisted 1 August 2020
- Budesonide cap 3 mg – amended restriction criteria
- Cetomacrogol with glycerol (Boucher) crm 90% with glycerol 10%, 500 ml and 1,000 ml – addition of note
- Cilazapril with hydrochlorothiazide (Apo-Cilazapril/Hydrochlorothiazide) tab 5 mg with hydrochlorothiazide 12.5 mg – restriction added and to be delisted 1 December 2020
- Dactinomycin [actinomycin D] (Cosmegen) inj 0.5 mg vial – price increase
- Etanercept (Enbrel) inj 25 mg vial, 50 mg autoinjector and syringe – amended restriction criteria
- Fluticasone (Flixotide) aerosol inhaler 50 mcg and 250 mcg per dose – price decrease and addition of HSS
- Fluticasone (Flixotide) aerosol inhaler 125 mcg per dose – addition of HSS
- Fluticasone with salmeterol (Seretide) aerosol inhaler 50 mcg with salmeterol 25 mcg and 125 mcg with salmeterol 25 mcg – price decrease and addition of HSS
- Fluoxetine hydrochloride (Arrow-Fluoxetine) tab dispersible 20 mg, scored and cap 20 mg – delisting delayed until further notice
- Hyoscine hydrobromide (Hospira) inj 400 mcg per ml, 1 ml ampoule – to be delisted 1 September 2020
- Morphine tartrate (DBL Morphine Tartrate) inj 80 mg per ml, 1.5 ml ampoule – to be delisted 1 September 2020
- Ornidazole (Arrow-Ornidazole) tab 500 mg – price increase
- Primaquine phosphate tab 15 mg – new listing
- Ticagrelor (Brilinta) tab 90 mg – amended restriction criteria
- Rituximab (mabthera) (Mabthera) inj 10 mg per ml, 10 ml and 50 ml vial – amended restriction criteria and chemical name
- Rituximab (riximyo) (Riximyo) inj 10 mg per ml, 10 ml and 50 ml vial – new listing
- Rocuronium bromide (Hameln) inj 10 mg per ml, 5 ml ampoule – new listing and addition of HSS

Summary of decisions – effective 1 March 2020 (continued)

- Rocuronium bromide (DBL Rocuronium Bromide) inj 10 mg per ml, 5 ml ampoule – to be delisted 1 August 2020
- Ruxolitnib (Jakavi) tab 5 mg, 15 mg and 20 mg – amended restriction criteria
- Tolterodine tartrate (Arrow-Tolterodine) tab 2 mg – to be delisted 1 July 2020
- Zopiclone (Zopiclone Actavis) tab 7.5 mg – to be delisted 1 July 2020

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

Section H changes to Part II

Effective 1 March 2020

ALIMENTARY TRACT AND METABOLISM

5 BUDESONIDE (amended restriction criteria – new criteria shown only)
➔ Cap 3 mg

Restricted
Initiation - non-cirrhotic autoimmune hepatitis
Reassessment required after 6 months
All of the following:
1 Patient has autoimmune hepatitis*; and
2 Patient does not have cirrhosis; and
3 Any of the following:
3.1 Diabetes; or
3.2 Cushingoid habitus; or
3.3 Osteoporosis where there is significant risk of fracture; or
3.4 Severe acne following treatment with conventional corticosteroid therapy; or
3.5 History of severe psychiatric problems associated with corticosteroid treatment; or
3.6 History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high; or
3.7 Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated); or
3.8 Adolescents with poor linear growth (where conventional corticosteroid use may limit further growth)
Note: Indications marked with * are unapproved indications

Continuation - non-cirrhotic autoimmune hepatitis
Reassessment required after 6 months
Treatment remains appropriate and the patient is benefitting from the treatment.

BLOOD AND BLOOD FORMING ORGANS

32 TICAGRELOR (amended restriction criteria – new criteria shown only)
➔ Tab 90 mg ..... 90.00 56 Brilinta

Restricted
Initiation– thrombosis prevention post neurological stenting
Re-assessment required after 12 months
Both:
1 Patient has had a neurological stenting procedure* in the last 60 days; and
2 Either
2.1 Patient has demonstrated clopidogrel resistance using the P2Y12 (VerifyNow) assay and requires antiplatelet treatment with ticagrelor; or
2.2 Clopidogrel resistance has been demonstrated by the occurrence of a new cerebral ischemic event.

Continuation – thrombosis prevention post neurological stenting
Re-assessment required after 12 months
Both:
1 Patient is continuing to benefit from treatment; and
2 Treatment continues to be clinically appropriate.
Note: Indications marked with * are unapproved indications

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

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

CARDIOVASCULAR SYSTEM

38 CILAZAPRIL WITH HYDROCHLOROTHIAZIDE – **Restricted: For continuation only** (restriction added and delisting)
➔ Tab 5 mg with hydrochlorothiazide 12.5 mg ..... 10.18 100 Apo-Cilazapril/ Hydrochlorothiazide
Note – Apo-Cilazapril/Hydrochlorothiazide tab 5 mg with hydrochlorothiazide 12.5 mg to be delisted from 1 December 2020.

DERMATOLOGICALS

54 CETOMACROGOL WITH GLYCEROL (addition of note)
Crm 90% with glycerol 10% – **1% DV Mar-20 to 2022** ..... 2.35 500 ml **Boucher**
3.10 1,000 ml **Boucher**
Note: DV limit applies to the pack sizes of greater than 100 g.

GENITO-URINARY SYSTEM

61 TOLTERODINE TARTRATE (delisting)
➔ Tab 2 mg ..... 14.56 56 Arrow-Tolterodine
Note – Arrow-Tolterodine tab 2 mg to be from 1 July 2020.

INFECTIONS

72 AMIKACIN (Pharmacode change)
➔ Inj 250 mg per ml, 2 ml vial – **1% DV Aug-18 to 2021** ..... 265.00 5 **DBL Amikacin**
Note – this is a new Pharmacode listing, 2572214. Pharmacode 461571 to be delisted from 1 June 2020.

84 ORNIDAZOLE (↑ price)
Tab 500 mg ..... 32.95 10 Arrow-Ornidazole

84 PRIMAQUINE PHOSPHATE (new listing)
➔ Tab 15 mg

MUSCULOSKELETAL SYSTEM

99 BENZBROMARONE (new listing)
➔ Tab 50 mg

100 ROCURONIUM BROMIDE (brand change)
Inj 10 mg per ml, 5 ml ampoule – **1% DV Aug-20 to 2022** ..... 31.14 10 **Hameln**
Note – DBL Rocuronium Bromide inj 10 mg per ml, 1 ml vial to be delisted from 1 August 2020.

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

NERVOUS SYSTEM

116 HYOSCINE HYDROBROMIDE (delisting)
Inj 400 mcg per ml, 1 ml ampoule ..... 46.50 5 Hospira
Note – Hospira inj 400 mcg per ml, 1 ml ampoule to be delisted from 1 September 2020.

109 MORPHINE TARTRATE (delisting)
Inj 80 mg per ml, 1.5 ml ampoule ..... 42.72 5 DBL Morphine Tartrate
Note – DBL Morphine Tartrate inj 80 mg per ml, 1.5 ml ampoule to be delisted from 1 September 2020.

112 FLUOXETINE HYDROCHLORIDE (delisting delayed)
Tab dispersible 20 mg, scored..... 2.47 30 Arrow-Fluoxetine
Cap 20 mg ..... 7.49 84 Arrow-Fluoxetine
Note – Arrow-Fluoxetine tab dispersible 20 mg, scored and cap 20 mg delisting delayed until further notice.

123 ZOPICLONE (delisting)
Tab 7.5 mg ..... 0.98 30 Zopiclone Actavis
Note – Zopiclone Actavis tab 7.5 mg to be delisted from 1 July 2020.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

129 DACTINOMYCIN [ACTINOMYCIN D] (↑ price)
Inj 0.5 mg vial ..... 255.00 1 Cosmegen

132 BORTEZOMIB (brand change and amended restriction criteria)
➔ Inj 3.5 mg vial – **1% DV Aug-20 to 2022**..... 105.00 1 **Bortezomib - Dr Reddy's**

Restricted
Initiation – ~~treatment naive~~ multiple myeloma/amyloidosis
~~Limited to 15 months treatment~~
~~Both:~~
~~1~~ Either:
~~1.~~1 The patient has ~~treatment-naive~~ symptomatic multiple myeloma; or
~~1.~~2 The patient has ~~treatment-naive~~ symptomatic systemic AL amyloidosis~~; and~~
~~2. Maximum of 9 treatment cycles.~~

~~Initiation – relapsed/refractory multiple myeloma/amyloidosis~~
~~Re-assessment required after 8 months~~
~~All of the following:~~
~~1. Either:~~
~~1.1. The patient has relapsed or refractory multiple myeloma; or~~
~~1.2. The patient has relapsed or refractory systemic AL amyloidosis; and~~
~~2. The patient has received only one prior front line chemotherapy for multiple myeloma or amyloidosis; and~~
~~3. The patient has not had prior publicly funded treatment with bortezomib; and~~
~~4. Maximum of 4 treatment cycles.~~

~~Continuation – relapsed/refractory multiple myeloma/amyloidosis~~
~~Re-assessment required after 8 months~~
~~Both:~~
~~1. The patient's disease obtained at least a partial response from treatment with bortezomib at the completion of cycle 4; and~~
~~2. Maximum of 4 further treatment cycles (making a total maximum of 8 consecutive treatment cycles).~~

continued...

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

continued...

~~Notes: Responding relapsed/refractory multiple myeloma patients should receive no more than 2 additional cycles of treatment beyond the cycle at which a confirmed complete response was first achieved. A line of therapy is considered to comprise either:~~

~~1 A known therapeutic chemotherapy regimen and supportive treatments; or~~

~~2 A transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.~~

~~Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.~~

Note – Velcade inj 3.5 mg vial to be delisted from 1 August 2020.

140 RUXOLITINIB (amended restriction criteria)

➔ Tab 5 mg	2,500.00	56	Jakavi
➔ Tab 15 mg	5,000.00	56	Jakavi
➔ Tab 20 mg	5,000.00	56	Jakavi

Restricted
Initiation
Haematologist
Reassessment required after 12 months
All of the following:

1 The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis; and

2 Either

2.1 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; ~~and~~ **or**

2.2 Both

2.2.1 A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and

2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; and

3 A maximum dose of 20 mg twice daily is to be given.

Continuation
Relevant specialist or medical practitioner on the recommendation of a relevant specialist.
Reassessment required after 12 months
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 A maximum dose of 20 mg twice daily is to be given.

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

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

146 ETANERCEPT (amended restriction criteria – new criteria shown only)

➔ Inj 25 mg vial – **5% DV Sep-19 to 2024**	799.96	4	**Enbrel**
➔ Inj 50 mg autoinjector – **5% DV Sep-19 to 2024**	1,599.96	4	**Enbrel**
➔ Inj 50 mg syringe – **5% DV Sep-19 to 2024**	1,599.96	4	**Enbrel**

Restricted

Initiation - undifferentiated spondyloarthritis

Rheumatologist

Reassessment required after 6 months

All of the following:

1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

2 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

3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose); and

4 Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose); and

5 Any of the following:

5.1 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

5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application; or

5.3 ESR and CRP 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.

Note: Indications marked with * are unapproved indications

Continuation — undifferentiated spondyloarthritis

Rheumatologist or medical practitioner on the recommendation of a rheumatologist

Reassessment required after 6 months

All of the following:

1 Either:

1.1 Applicant is a rheumatologist; or

1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and

2 Either:

2.1 Following 3 to 4 months' initial treatment, the patient has 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

2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and

3 Etanercept to be administered at doses no greater than 50 mg dose every 7 days.

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

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

173 RITUXIMAB **(MABTHERA)** (amended restriction criteria and chemical name)

➔ 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

~~Haematologist~~

~~Any of the following:~~

~~1 Patient has mild congenital haemophilia complicated by inhibitors; or~~

~~2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or~~

~~3 Patient has acquired haemophilia.~~

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

~~Both:~~

~~1 The patient has B-cell post-transplant lymphoproliferative disorder*; and~~

~~2 To be used for a maximum of 8 treatment cycles.~~

~~Note: Indications marked with * are unapproved indications.~~

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*

~~Re-assessment required after 9 months~~

~~Either:~~

~~1 Both:~~

~~1.1 The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and~~

~~1.2 To be used for a maximum of 6 treatment cycles; or~~

~~2 Both:~~

~~2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and~~

~~2.2 To be used for a maximum of 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.~~

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

continued...

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

continued...

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.

Initiation – aggressive CD20 positive NHL

~~Either:~~

~~1 All of the following:~~

~~1.1 The patient has treatment naive aggressive CD20 positive NHL; and~~

~~1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and~~

~~1.3 To be used for a maximum of 8 treatment cycles; or~~

~~2 Both:~~

~~2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and~~

~~2.2 To be used for a maximum of 6 treatment cycles.~~

~~Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.~~

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

~~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 The patient is rituximab treatment naive; and~~

~~3 Either:~~

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

~~3.2 Both:~~

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

~~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~~

~~4 The patient has good performance status; and~~

~~5 The patient does not have chromosome 17p deletion CLL; and~~

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

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

~~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.~~

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:

continued...

Changes to Section H Part II – effective 1 March 2020 (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 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.

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:

continued...

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

continued...

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
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.

continued...

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

continued...

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

Initiation – warm autoimmune haemolytic anaemia (warm AIHA)
~~Haematologist~~
~~Re-assessment required after 4 weeks~~
~~Both:~~
~~1 Patient has warm autoimmune haemolytic anaemia*; and~~
~~2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin.~~
~~Note: Indications marked with * are unapproved indications.~~
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 4 weeks
Either:
1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
  2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and
  2.2 An initial response lasting at least 12 months was demonstrated; and
  2.3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – immune thrombocytopenic purpura (ITP)
~~Haematologist~~
~~Re-assessment required after 4 weeks~~
~~Both:~~
~~1 Either:~~
  ~~1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or~~
  ~~1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and~~

continued...

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

continued...

~~2 Any of the following:~~
~~2.1 Treatment with steroids and splenectomy have been ineffective; or~~
~~2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or~~
~~2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).~~

~~Note: Indications marked with * are unapproved indications.~~

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

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

Note: Indications marked with * are unapproved indications.

Initiation – thrombotic thrombocytopenic purpura (TTP)
~~Haematologist~~
~~Re-assessment required after 4 weeks~~
~~Either:~~
~~1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or~~
~~2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.~~

~~Note: Indications marked with * are unapproved indications.~~

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 4 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.

Note: Indications marked with * are unapproved indications.

Initiation – pure red cell aplasia (PRCA)
~~Haematologist~~
~~Re-assessment required after 6 weeks~~
~~Patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder.~~

~~Note: Indications marked with * are unapproved indications.~~

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.

continued...

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

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

continued...

Initiation – ANCA associated vasculitis

~~Re-assessment required after 4 weeks~~

~~All of the following:~~

~~1 Patient has been diagnosed with ANCA associated vasculitis*; and~~

~~2 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks; and~~

~~3 Any of the following:~~

~~3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or~~

~~3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or~~

~~3.3 Cyclophosphamide and methotrexate are contraindicated; or~~

~~3.4 Patient is a female of child-bearing potential; or~~

~~3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.~~

~~Note: Indications marked with * are unapproved indications.~~

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 4 weeks

All of the following:

1 Patient has been diagnosed with ANCA associated vasculitis*; and

2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and

3 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

Initiation – treatment refractory systemic lupus erythematosus (SLE)

~~Rheumatologist or nephrologist~~

~~All of the following:~~

~~1 The patient has severe, immediately life- or organ-threatening SLE*; and~~

~~2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and~~

~~3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and~~

~~4 Maximum of four 1000 mg infusions of rituximab.~~

~~Note: Indications marked with * are unapproved indications.~~

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

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

~~Nephrologist~~

~~Patient has been diagnosed with antibody-mediated renal transplant rejection*.~~

~~Note: Indications marked with * are unapproved indications.~~

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 March 2020 (continued)

continued...

Initiation – ABO-incompatible renal transplant
~~Nephrologist~~
~~Patient is to undergo an ABO-incompatible renal transplant*.~~
~~Note: Indications marked with * are unapproved indications.~~
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)
~~Nephrologist~~
~~Re-assessment required after 4 weeks~~
~~All of the following:~~
~~1 Patient is a child with SDNS* or FRNS*; and~~
~~2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and~~
~~3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and~~
~~4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and~~
~~5 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with a * are unapproved indications.~~
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 4 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)
~~Nephrologist~~
~~Re-assessment required after 4 weeks~~
~~All of the following:~~
~~1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and~~
~~2 Treatment with tacrolimus for at least 3 months has been ineffective; and~~
~~3 Genetic causes of nephrotic syndrome have been excluded; and~~
~~4 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with a * are unapproved indications.~~
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 4 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.

continued...

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

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

continued...

Initiation – Neuromyelitis Optica Spectrum Disorder (NMOSD)

~~Relevant specialist or medical practitioner on the recommendation of a Relevant specialist~~

~~Re-assessment required after 6 months~~

~~Both:~~

~~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 Either:~~

~~2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or~~

~~2.2 All of the following:~~

~~2.2.1 The patient has experienced a breakthrough attack of NMOSD; and~~

~~2.2.2 The patient is receiving treatment with mycophenolate; and~~

~~2.2.3 The patients is receiving treatment with corticosteroids.~~

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

~~Neurologist or medical practitioner on the recommendation of a Neurologist~~

~~Re-assessment required after 2 years~~

~~Both:~~

~~1 One of the following dose regimens is to be used: 375 mg/m^2 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 Either:~~

~~2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or~~

~~2.2 Both:~~

~~2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and~~

~~2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.~~

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:

1 One of the following dose regimens is to be used: 375 mg/m^2 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.

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

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

173 RITUXIMAB (RIXIMYO) (new listing)

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

Restricted
Initiation – haemophilia with inhibitors
Haematologist
Any of the following:
1 Patient has mild congenital haemophilia complicated by inhibitors; or
2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
3 Patient has acquired haemophilia.

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
Both:
1 The patient has B-cell post-transplant lymphoproliferative disorder*; and
2 To be used for a maximum of 8 treatment cycles.
Note: Indications marked with * are unapproved indications.

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*
Re-assessment required after 9 months
Either:
1 Both:
  1.1 The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
  1.2 To be used for a maximum of 6 treatment cycles; or
2 Both:
  2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and
  2.2 To be used for a maximum of 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.

Continuation – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 12 months
Either:
1 All of the following:
  1.1 The patient has had a rituximab treatment-free interval of 12 months or more; and
  1.2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
  1.3 To be used for no more than 6 treatment cycles; or

continued...

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

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

continued...

2 Both:
  2.1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy, and
  2.2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m^2 every 8 weeks (maximum of 12 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.

Initiation – aggressive CD20 positive NHL
Either:
1 All of the following:
  1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  1.3 To be used for a maximum of 8 treatment cycles; or
2 Both:
  2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

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
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; or
  2.2 Either:
    2.2.1 The patient is chemotherapy treatment naive; or
    2.2.2 Both:
      2.2.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
      2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; 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 The patient has good performance status; and
4 Either:
  4.1 The patient does not have chromosome 17p deletion CLL; or
  4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

continued...

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

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

continued...

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
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 the 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 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 – severe cold haemagglutinin disease (CHAD)
Haematologist
Re-assessment required after 4 weeks
Both:
1 Patient has cold haemagglutinin disease*; and
2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms.

Note: Indications marked with * are unapproved indications.

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

Note: Indications marked with * are unapproved indications.

Initiation – warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
Re-assessment required after 4 weeks
Both:
1 Patient has warm autoimmune haemolytic anaemia*; and
2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin.

Note: Indications marked with * are unapproved indications.

continued...

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

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

continued...

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

Initiation – immune thrombocytopenic purpura (ITP)
Haematologist
Re-assessment required after 4 weeks
Both:
1 Either:
  1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
  1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
2 Any of the following:
  2.1 Treatment with steroids and splenectomy have been ineffective; or
  2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).
Note: Indications marked with * are unapproved indications.

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

Initiation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
Re-assessment required after 4 weeks
Either:
1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.
Note: Indications marked with * are unapproved indications.

Continuation – thrombotic thrombocytopenic purpura (TTP)
Haematologist
Re-assessment required after 4 weeks
All of the following:
1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and

continued...

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

continued...

2 An initial response lasting at least 12 months was demonstrated; and
3 Patient now requires repeat treatment.
Note: Indications marked with * are unapproved indications.

Initiation – pure red cell aplasia (PRCA)
Haematologist
Re-assessment required after 6 weeks
Patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder.
Note: Indications marked with * are unapproved indications.

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

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

Initiation – treatment refractory systemic lupus erythematosus (SLE)
Rheumatologist or nephrologist
All of the following:
1 The patient has severe, immediately life- or organ-threatening SLE*; and
2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
4 Maximum of four 1,000 mg infusions of rituximab.
Note: Indications marked with * are unapproved indications.

continued...

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

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

continued...

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
2 The disease has subsequently relapsed; and
3 Maximum of two 1,000 mg infusions of rituximab.
Note: Indications marked with * are unapproved indications.

Initiation – Antibody-mediated organ transplant rejection
Patient has been diagnosed with antibody-mediated organ transplant rejection*.
Note: Indications marked with * are unapproved indications.

Initiation – ABO-incompatible organ transplant
Patient is to undergo an ABO-incompatible solid organ transplant*.
Note: Indications marked with * are unapproved indications.

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

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Nephrologist
Re-assessment required after 4 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)
Nephrologist
Re-assessment required after 4 weeks
All of the following:
1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
2 Treatment with tacrolimus for at least 3 months has been ineffective; and
3 Genetic causes of nephrotic syndrome have been excluded; and
4 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.
Note: Indications marked with a * are unapproved indications.

continued...

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

continued...

Continuation – Steroid resistant nephrotic syndrome (SRNS)
Nephrologist
Re-assessment required after 4 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)
Re-assessment required after 6 months
Both:
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 Either:
  2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or
  2.2 All of the following:
    2.2.1 The patient has experienced a breakthrough attack of NMOSD; and
    2.2.2 The patient is receiving treatment with mycophenolate; and
    2.2.3 The patient is receiving treatment with corticosteroids.

Continuation – Neuromyelitis Optica Spectrum Disorder (NMOSD)
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 patient 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
Neurologist
Re-assessment required after 2 years
Both:
1 One of the following dose regimens is to be used: 375 mg/m^2 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 Either:
  2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
  2.2 Both:
    2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
    2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Continuation – Severe Refractory Myasthenia Gravis
Neurologist
Re-assessment required after 2 years
All of the following:
1 One of the following dose regimens is to be used: 375 mg/m^2 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

continued...

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

continued...

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.

Initiation – severe antisynthetase syndrome.
Re-assessment required after 12 months
All of the following:
1 Patient has confirmed antisynthetase syndrome; and
2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and
3 Either:
- 3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease; or
- 3.2 Rapid treatment is required due to life threatening complications; and

4 Maximum of four 1,000 mg infusions of rituximab.

Continuation - severe antisynthetase syndrome
Re-assessment required after 12 months
All of the following:
1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and
2 The patient has not received rituximab in the previous 6 months; and
3 Maximum of two cycles of 2 x 1,000 mg infusions of rituximab given two weeks apart.

Initiation – graft versus host disease
All of the following:
1 Patient has refractory graft versus host disease following transplant; and
2 Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease; 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.

Initiation – severe chronic inflammatory demyelinating polyneuropathy
Neurologist
Re-assessment required after 6 months
All of the following
1 Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
2 Either
- 2.1 Both
  - 2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
  - 2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
- 2.2 Rapid treatment is required due to life threatening complications; and

3 One of the following dose regimens is to be used: 375 mg/m^2 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.

Continuation - severe chronic inflammatory demyelinating polyneuropathy
Neurologist or medical practitioner on the recommendation of a neurologist
Re-assessment required after 6 months

continued...

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

continued...

All of the following:

1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline; and
2 The patient has not received rituximab in the previous 6 months; and
3 One of the following dose regimens is to be used: 375 mg/m^2 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.

Initiation – anti-NMDA receptor autoimmune encephalitis
Neurologist
Re-assessment required after 6 months
All of the following

1 Patient has severe anti-NMDA receptor autoimmune encephalitis; and
2 Either
  2.1 Both
    2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
    2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
  2.2 Rapid treatment is required due to life threatening complications; and
3 One of the following dose regimens is to be used: 375 mg/m^2 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.

Continuation – anti-NMDA receptor autoimmune encephalitis
Neurologist
Re-assessment required after 6 months
All of the following:

1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function; and
2 The patient has not received rituximab in the previous 6 months; and
3 The patient has experienced a relapse and now requires further treatment; and
4 One of the following dose regimens is to be used: 375 mg/m^2 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.

RESPIRATORY SYSTEM AND ALLERGIES

198 FLUTICASONE (↓ price and addition of HSS)

Aerosol inhaler 50 mcg per dose – **1% DV Sep-20 to 2023**	7.19	120 dose	**Flixotide**
Aerosol inhaler 250 mcg per dose – **1% DV Sep-20 to 2023**	24.62	120 dose	**Flixotide**

Note – Floair aerosol inhaler 50 mcg and 250 mcg per dose to be delisted from 1 September 2020.

198 FLUTICASONE (addition of HSS)

Aerosol inhaler 125 mcg per dose – **1% DV Sep-20 to 2023**	13.60	120 dose	**Flixotide**

Note – Floair aerosol inhaler 125 mcg per dose to be delisted from 1 September 2020.

199 FLUTICASONE WITH SALMETEROL (↓ price and addition of HSS)

Aerosol inhaler 50 mcg with salmeterol 25 mcg			
– **1% DV Sep-20 to 2023**	25.79	120 dose	**Seretide**
Aerosol inhaler 125 mcg with salmeterol 25 mcg			
– **1% DV Sep-20 to 2023**	32.60	120 dose	**Seretide**

Note – RexAir aerosol inhaler 50 mcg with salmeterol 25 mcg and 125 mcg with salmeterol 25 mcg to be delisted from 1 September 2020.

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

Changes to Section H Part II – effective 1 February 2020

ALIMENTARY TRACT AND METABOLISM

7 FAMOTIDINE (new listing)
Inj 10 mg per ml, 2 ml vial

21 VITAMIN A WITH VITAMINS D AND C (addition of note and delisting)
Note: that funding of vitamin A oral liquid can be applied for through the Exceptional Circumstances process; the application form can be found on the PHARMAC website https://pharmac.govt.nz/assets/form-alphatocopherylacetate-and-vitaminA.pdf
Soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops *e.g. Vitadol C*
Note – Vitadol C soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops to be delisted from 1 July 2020.

CARDIOVASCULAR SYSTEM

43	NIMODIPINE (new listing)			
	Tab 30 mg – **1% DV Jul-20 to 2022**	350.00	100	**Nimotop**
	Inj 200 mcg per ml, 50 ml vial – **1% DV Jul-20 to 2022**	67.50	1	**Nimotop**
44	VERAPAMIL HYDROCHLORIDE (brand change)			
	Tab long-acting 240 mg	15.12	30	Isoptin SR
	Note – Verpamil SR tab long-acting 240 mg to be delisted from 1 September 2020.			
47	ADRENALINE (↑ price)			
	Inj 1 in 1,000, 1 ml ampoule	10.76	5	DBL Adrenaline

GENITO-URINARY SYSTEM

59	LEVONORGESTREL (new listing)			
	Tab 30 mcg – **1% DV May-20 to 2022**	16.50	84	**Microlut**

HORMONE PREPARATIONS

63	DEXAMETHASONE PHOSPHATE (brand change)			
	Inj 4 mg per ml, 1 ml ampoule – **1% DV Jul-20 to 2022**	9.25	10	**Dexamethasone Phosphate Panpharma**
	Inj 4 mg per ml, 2 ml ampoule – **1% DV Jul-20 to 2022**	16.37	10	**Dexamethasone Phosphate Panpharma**
	Note – Max Health inj 4 mg per ml, 1 ml and 2 ml ampoule to be delisted from 1 July 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 February 2020 (continued)

INFECTIONS

78 AZTREONAM (pack size change)
➔ Inj 1 g vial ..... 364.92 10 Azactam
Note – Azactam inj 1 g vial, 5 vial pack to be delisted from 1 August 2020.

84 METRONIDAZOLE (new listing)
Inj 5 mg per ml, 100 ml bottle ..... 34.80 20 Colpocin-T

MUSCULOSKELETAL SYSTEM

100 ROCURONIUM BROMIDE (↑ price)
Inj 10 mg per ml, 5 ml vial ..... 48.01 10 DBL Rocuronium Bromide

101 IBUPROFEN (brand change)
Tab long-acting 800 mg – **1% DV Apr-20 to 2021** ..... 5.99 30 **Ibuprofen SR BNM**
Note – Brufen SR tab long-acting 800 mg to be delisted from 1 April 2020.

NERVOUS SYSTEM

103 APOMORPHINE HYDROCHLORIDE (new listing)
Inj 10 mg per ml, 5 ml ampoule – **1% DV Feb-20 to 2023** ..... 121.84 5 **Movapo**

104 TOLCAPONE (↑ price)
Tab 100 mg ..... 152.38 100 Tasmar

125 RIVASTIGMINE (brand change)
➔ Patch 4.6 mg per 24 hour – **1% DV Apr-20 to 2021** ..... 48.75 30 **Generic Partners**
➔ Patch 9.5 mg per 24 hour – **1% DV Apr-20 to 2021** ..... 48.75 30 **Generic Partners**
Note – Exelon patch 4.6 mg and 9.5 mg per 24 hour to be delisted from 1 April 2020.

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130 CAPECITABINE (brand change)

Tab 150 mg – **1% DV Jul-20 to 2022**	10.00	60	**Capercit**
Tab 500 mg – **1% DV Jul-20 to 2022**	49.00	120	**Capercit**

Note – Brinov tab 150 mg and 500 mg to be delisted from 1 July 2020.

133 OLAPARIB (new listing)

➔ Cap 50 mg	7,402.00	448	Lynparza
➔ Tab 100 mg	3,701.00	56	Lynparza
➔ Tab 150 mg	3,701.00	56	Lynparza

Restriction
Initiation
Medical Oncologist
Re-assessment required after 12 months
All of the following:
1 Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
3 Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and
4 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and
5 Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and
6 Patient's disease has not progressed following prior treatment with olaparib; and
7 Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
8 Treatment to be administered as maintenance treatment; and
9 Treatment not to be administered in combination with other chemotherapy.

Continuation
Medical Oncologist
Re-assessment required after 12 months
All of the following:
1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
2 No evidence of progressive disease; and
3 Treatment to be administered as maintenance treatment; and
4 Treatment not to be administered in combination with other chemotherapy.

*Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component

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

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

SENSORY ORGANS

203 PREDNISOLONE ACETATE (↑ price)
Eye drops 1% ..... 5.93 — 10 ml — Prednisolone- AFT

VARIOUS

213 PATENT BLUE V (new listing)
Inj 2.5%, 5 ml prefilled syringe ..... 420.00 — 5 — InterPharma

SPECIAL FOODS

230 PAEDIATRIC ORAL FEED 1 KCAL/ML (delisting)
➔ Liquid 4.2 g protein, 16.7 g carbohydrate and 7.5 g fat per 100 ml, bottle ..... 1.07 — 200 ml — Pediasure (Chocolate), Pediasure (Strawberry), Pediasure (Vanilla)
Note – Pediasure (Chocolate, Strawberry and Vanilla) liquid 4.2 g protein, 16.7 g carbohydrate and 7.5 g fat per 100 ml, bottle, 200 ml to be delisted from 1 September 2020.

231 LOW CARBOHYDRATE ORAL FEED 1.5 KCAL/ML (delisting)
➔ Liquid 6.2 g protein, 10.5 g carbohydrate and 9.32 g fat per 100 ml, bottle ..... 1.66 — 237 ml — Pulmocare (Vanilla)
Note – Pulmocare (Vanilla) liquid 6.2 g protein, 10.5 g carbohydrate and 9.32 g fat per 100 ml, bottle, 237 ml to be delisted from 1 October 2020.

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

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

VACCINES

240 INFLUENZA VACCINE (new listing)

➔ Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) ..... 9.00 1 Afluria Quad Junior (2020 Formulation)

Restricted

Initiation – cardiovascular disease for patients aged 6 months to 35 months

Any of the following:

1 Ischaemic heart disease; or
2 Congestive heart failure; or
3 Rheumatic heart disease; or
4 Congenital heart disease; or
5 Cerebro-vascular disease.

Note: hypertension and/or dyslipidaemia without evidence of end-organ disease is excluded from funding.

Initiation – chronic respiratory disease for patients aged 6 months to 35 months

Either:

1 Asthma, if on a regular preventative therapy; or
2 Other chronic respiratory disease with impaired lung function.

Note: asthma not requiring regular preventative therapy is excluded from funding.

Initiation – Other conditions for patients aged 6 months to 35 months

Any of the following:

1 Diabetes; or
2 Chronic renal disease; or
3 Any cancer, excluding basal and squamous skin cancers if not invasive; or
4 Autoimmune disease; or
5 Immune suppression or immune deficiency; or
6 HIV; or
7 Transplant recipient; or
8 Neuromuscular and CNS diseases/ disorders; or
9 Haemoglobinopathies; or
10 Is a child on long term aspirin; or
11 Has a cochlear implant; or
12 Errors of metabolism at risk of major metabolic decompensation; or
13 Pre and post splenectomy; or
14 Down syndrome; or
15 Child who has been hospitalised for respiratory illness or has a history of significant respiratory illness.

240 INFLUENZA VACCINE (delisted)

➔ Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) .... 9.00 1 Fluarix Tetra

Note – Fluarix Tetra inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) delisted 1 February 2020.

240 INFLUENZA VACCINE (brand change)

➔ Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) ..... 90.00 10 Afluria Quad (2020 Formulation)

Note – Influvac Tetra inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) delisted 1 February 2020.

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

Changes to Section H 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%, 30 g	3.42	30 g	DermAssist
Crm 1%, 500 g	17.15	500 g	Pharmacy Health

Note: DV limit applies to the pack sizes of less than or equal to 100 g.

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.

		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.

112 FLUOXETINE HYDROCHLORIDE (↑ price)
Cap 20 mg ..... 7.49 90 Arrow-Fluoxetine

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**

➔ 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 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.

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

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.

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

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