Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

# **Section H Update**

for Hospital Pharmaceuticals

**April 2020** 



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## Summary of decisions EFFECTIVE 1 APRIL 2020

- Abciximab (ReoPro) inj 2 mg per ml, 5 ml vial to be delisted 1 January 2021
- Adult diphtheria and tetanus vaccine (ADT Booster) inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml syringe – to be delisted 1 October 2020
- Betamethasone dipropionate with calcipotriol (Enstilar) foam spray 500 mcg with calcipotriol 50 mcg per g, 60 g new listing
- Ceftaroline fosamil (Zinforo) inj 600 mg vial price increase
- Diazepam (Hospira) inj 5 mg per ml, 2 ml ampoule price increase
- Enoxaparin sodium inj 20 mg in 0.2 ml, 40 mg in 0.4 ml, 60 mg in 0.6 ml, 80 mg in 0.8 ml and 100 mg in 1 ml syringe (Clexane) and inj 120 mg in 0.8 ml and 150 mg in 1 ml syringe (Clexane Forte) new Pharmacode listing
- Fulvestrant (Faslodex) inj 50 mg per ml, 5 ml prefilled syringe new listing
- Gemcitabine (Gemcitabine Ebewe) inj 10 mg per ml, 100 ml vial

   addition of HSS
- Glucagon hydrochloride (Glucagen Hypokit) inj 1 mg syringe kit
   addition of HSS
- Heparin sodium (Hospira) inj 1,000 iu per ml and 5,000 iu per ml, 1 ml ampoule price increase
- Heparinised saline (Pfizer) inj 10 iu per ml, 5 ml ampoule price increase
- Hepatitis B recombinant vaccine (HBvaxPRO) inj 5 mcg in 0.5 ml, 10 mcg in 1 ml and 40 mcg per 1 ml vial – to be delisted 1 October 2020
- Hepatitis B recombinant vaccine (Engerix-B) inj 20 mcg per 1 ml prefilled syringe – addition of HSS
- Hydrocortisone (Hydrocortisone (PSM)) crm 1%, 100 g new listing and addition of HSS
- Hydrocortisone (DermAssist) crm 1%, 30 g to be delisted 1 September 2020
- Hyoscine butylbromide (Buscopan) inj 20 mg, 1 ml ampoule price decrease and addition of HSS
- Labetalol (Trandate) tab 100 mg and 200 mg new listing and addition of HSS
- Labetalol (Presolol) tab 100 mg and 200 mg to be delisted 1 September 2020
- Labetalol tab 50 mg new listing
- Lenalidomide (Revlimid) cap 5 mg, 10 mg and 15 mg new listing
- Lenalidomide (Revlimid) cap 10 mg and 15 mg price decrease
- Lenalidomide (Revlimid) cap 10 mg, 15 mg and 25 mg amended restriction criteria

#### Summary of decisions – effective 1 April 2020 (continued)

- Mebeverine hydrochloride (Colofac) tab 135 mg price decrease and addition of HSS
- Mepolizumab (Nucala) inj 100 mg vial new listing
- Mesalazine (Pentasa) tab long-acting 500 mg price decrease and addition of HSS
- Metronidazole (Trichozole) tab 200 mg and 400 mg to be delisted 1 September 2020
- Mitomycin C (Teva) inj 5 mg vial amended brand name
- Oestriol (Ovestin) tab 2 mg new listing and addition of HSS
- Paediatric oral feed 1kcal/ml ((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 – delisting revoked
- Palbociclib (Ibrance) cap 75 mg, 100 mg and 125 mg new listing
- Pholcodine (AFT Pholcodine Linctus BP) oral liq 1 mg per ml, 200 ml
   new Pharmacode listing
- Piperacillin with tazobactam (PiperTaz Sandoz) inj 4 g with tazobactam 0.5 g vial – new listing
- Povidone-iodine with ethanol (Betadine Skin Prep) soln 10% with ethanol 30%, 500 ml – to be delisted 1 June 2020
- Primaquine tab 7.5 mg and 15 mg amended chemical name
- Rituximab (mabthera) (Mabthera) inj 10 mg per ml, 10 ml and 50 ml vial
   amended restriction criteria
- Rituximab (riximyo) (Riximyo) inj 10 mg per ml, 10 ml and 50 ml vial amended restriction criteria
- Sumatriptan (Imigran) inj 12 mg per ml, 0.5 ml prefilled pen new listing and addition of HSS
- Sumatriptan (Clustran) inj 12 mg per ml, 0.5 ml prefilled pen to be delisted 1 September 2020
- Tetracycline (Accord) tab 250 mg new listing
- Tetracycline (Tetracyclin Wolff) cap 500 mg to be delisted 1 December 2020
- Vinblastine sulphate (Hospira) inj 1 mg per ml, 10 ml vial price increase
- Warfarin sodium (Marevan) tab 1 mg, 3 mg and 5 mg price decrease

## Section H changes to Part II

Effective 1 April 2020

Tab 50 mg

## **ALIMENTARY TRACT AND METABOLISM**

6	MESALAZINE (↓ price and addition of HSS) Tab long-acting 500 mg – 1% DV Jul-20 to 202356.10	100	Pentasa	
7	HYOSCINE BUTYLBROMIDE (‡ price and addition of HSS) Inj 20 mg, 1 ml ampoule – 1% DV Jul-20 to 2023	5	Buscopan	
7	MEBEVERINE HYDROCHLORIDE (↓ price and addition of HSS) Tab 135 mg – 1% DV Jul-20 to 2023	90	Colofac	
9	GLUCAGON HYDROCHLORIDE (addition of HSS) Inj 1 mg syringe kit – 1% DV Jul-20 to 202332.00	1	Glucagen Hypokit	
BI	LOOD AND BLOOD FORMING ORGANS			
31	ENOXAPARIN SODIUM (Pharmacode change)  Inj 20 mg in 0.2 ml syringe	10 10 10 10 10 10 10 5, 795623, 4	Clexane Clexane Clexane Clexane Clexane Clexane Forte Clexane Forte 16991, 417009, 41701	17,
31	HEPARIN SODIUM († price) Inj 1,000 iu per ml, 1 ml ampoule	50 5	Hospira Hospira	
31	HEPARINISED SALINE († price) Inj 10 iu per ml, 5 ml ampoule	50	Pfizer	
31	WARFARIN SODIUM (4 price)  Tab 1 mg	100 100 100	Marevan Marevan Marevan	
C	ARDIOVASCULAR SYSTEM			
41	LABETALOL (brand change)  Tab 100 mg – <b>1% DV Sep-20 to 2024</b>	100 100 2020.	Trandate Trandate	
41	LABETALOL (new listing)			

Price	
(ex man. Excl. GS	ST)
\$	Per

Brand or Generic Manufacturer

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

DERMA	INT/	UCI	CVIC
PERIVIF	1 I U L	.vui	UMLO

55	HYDROCORTISONE (brand change) Crm 1%, 100 g – <b>1% DV Sep-20 to 2022</b>	100 g	Hydrocortisone (PSM)
56	BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL (new listing) Foam spray 500 mcg with calcipotriol 50 mcg per g59.95	60 g	Enstilar
HOR	MONE PREPARATIONS		
66	OESTRIOL (new listing and addition of HSS) Tab 2 mg – 1% DV Sep-20 to 2023	30	Ovestin
INFE	CTIONS		
74	CEFTAROLINE FOSAMIL (↑ price)  → Inj 600 mg vial	10	Zinforo
76	PIPERACILLIN WITH TAZOBACTAM (new listing)  → Inj 4 g with tazobactam 0.5 g vial	10	PiperTaz Sandoz
78	TETRACYCLINE (new listing) Tab 250 mg	28	Accord
78	TETRACYCLINE (delisting) Cap 500 mg	30	Tetracyclin Wolff
84	METRONIDAZOLE (delisting)       10.45         Tab 200 mg       18.15         Note – Trichozole tab 200 mg and 400 mg to be delisted from 1 September	100 100 2020.	Trichozole Trichozole
84	PRIMAQUINE <del>PHOSPHATE</del> (amended chemical name)  → Tab 7.5 mg  → Tab 15 mg		
NERV	OUS SYSTEM		
112	DIAZEPAM († price) Inj 5 mg per ml, 2 ml ampoule	5	Hospira
115	SUMATRIPTAN (brand change) Inj 12 mg per ml, 0.5 ml prefilled pen - 1% DV Sep-20 to 202234.00 Note – Clustran inj 12 mg per ml, 0.5 ml prefilled pen to be delisted from 1 S	2 September 2	<b>lmigran</b> 020.

Price		Brand or
(ex man. Excl. GS	ST)	Generic
\$	Per	Manufacturer

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

#### ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130	MITOMYCIN C (amended brand name) Inj 5 mg vial204.08	1	Arrow Teva
131	GEMCITABINE (addition of HSS) Inj 10 mg per ml, 100 ml vial – <b>1% DV Jul-20 to 2023</b> 15.89	1	Gemcitabine Ebewe
133	LENALIDOMIDE (new listing)		
	→ Cap 5 mg	28	Revlimid
	→ Cap 10 mg6,207.00	28	Revlimid
	→ Cap 15 mg	28	Revlimid
133	LENALIDOMIDE (amended restriction criteria)		
	→ Cap 10 mg (↓ price)	21	Revlimid
	→ Cap 15 mg (↓ price)	21	Revlimid
	→ Cap 25 mg	21	Revlimid
	1 22 22 23 24 24 24 24 24 24 24 24 24 24 24 24 24		

#### Initiation – (Relapsed/refractory disease)

Haematologist

Re-assessment required after 6 months

All of the following:

- 1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
- 2 Patient has not previously been treated with lenalidomide; and 32 Either

- 3.1 2.1 Lenalidomide to be used as third line\* treatment for multiple myeloma; or
- 3.2 2.2 Both:
  - 3.2.1 2.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
  - 3.2.2 2.2.2 The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments: and
- 43 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

#### Continuation - (Relapsed/refractory disease)

Haematologist

Re-assessment required after 6 months

Both:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment.

#### Initiation - (Maintenance following first-line autologous stem cell transplant (SCT))

#### Haematologist

#### Reassessment required after 6 months

All of the following:

- 1 Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation; and
- 2 Patient has at least a stable disease response in the first 100 days after transplantation; and
- 3 Lenalidomide maintenance is to be commenced within 6 months of transplantation; and
- 4 The patient has ECOG performance score of 0-1: and
- 5 Lenalidomide to be administered at a maximum dose of 15 mg/day.

Brand or Generic Manufacturer

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

Continuation – (Maintenance following first line autologous SCT)

Haematologist

Reassessment required after 6 months

Roth

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment.

Note: Indication marked with \* is an unapproved indication. A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments. Prescriptions must be written by a registered prescriber in the lenalidomide risk management programme operated by the supplier.

#### 140 PALBOCICLIB (new listing)

<b>→</b>	Cap 75 mg	4,000.00	21	Ibrance
<b>→</b>	Cap 100 mg	4,000.00	21	Ibrance
<b>→</b>	Cap 125 mg	4,000.00	21	Ibrance

#### Initiation

Medical oncologist

Reassessment required after 6 months

All of the following:

- 1 Patient has unresectable locally advanced or metastatic breast cancer; and
- 2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 Fither:

second or subsequent line setting

- 4.1 Disease has relapsed or progressed during prior endocrine therapy; or
- 4.2 Both:

first line setting

- 4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
- 4.2.2 Either:
  - 4.2.2.1 Patient has not received prior systemic endocrine treatment for metastatic disease; or
  - 4.2.2.2 All of the following:
    - 4.2.2.2.1 Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and
    - 4.2.2.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease: and
    - 4.2.2.2.3 There is no evidence of progressive disease; and
- 5 Treatment must be used in combination with an endocrine partner.

Continuation

Medical oncologist

Reassessment required after 12 months

All of the following:

- 1 Treatment must be used in combination with an endocrine partner; and
- 2 No evidence of progressive disease; and
- 3 The treatment remains appropriate and the patient is benefitting from treatment.

#### 144 VINBLASTINE SULPHATE († price)

Brand or Generic Manufacturer

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

#### 145 FULVESTRANT (new listing)

#### Initiation

Medical Oncologist

Re-assessment required after 6 months

All of the following:

- 1 Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
- 2 Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease: and
- 3 Treatment to be given at a dose of 500 mg monthly following loading doses: and
- 4 Treatment to be discontinued at disease progression.

#### Continuation

Medical Oncologist

Re-assessment required after 6 months

All of the following:

- 1 Treatment remains appropriate and patient is benefitting from treatment; and
- 2 Treatment to be given at a dose of 500 mg monthly; and
- 3 No evidence of disease progression.

#### 154 ABCIXIMAB (delisting)

Note – ReoPro inj 2 mg per ml, 5 ml vial to be delisted from 1 January 2021.

#### 172 MEPOLIZUMAB (new listing)

#### Restricted

Initiation - (Severe eosinophilic asthma)

Respiratory physician or clinical immunologist

Re-assessment required after 12 months

All of the following

- 1 Patient must be aged 12 years or older; and
- 2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
- 3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
- 4 Patient has a blood eosinophil count of greater than 0.5 x 10 ^ 9 cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated; and
- 6 Either:
  - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
- 7 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment.

Brand or Generic Manufacturer

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

continued

Continuation – (Severe eosinophilic asthma)

Respiratory physician or clinical immunologist

Re-assessment required after 2 years

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 Fither
  - 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or
  - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

#### 175 RITUXIMAB (MABTHERA) (amended restriction criteria – affected criteria shown only)

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→ 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

Continuation – severe cold haemagglutinin disease (CHAD)

Haematologist

Re-assessment required after-4 8 weeks

- 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<sup>2</sup> 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

Note: Indications marked with \* are unapproved indications.

2.3 Patient now requires repeat treatment.

Continuation – warm autoimmune haemolytic anaemia (warm AIHA)

Haematologist

Re-assessment required after-4 8 weeks

Fither:

- 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<sup>2</sup> 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.

Continuation – immune thrombocytopenic purpura (ITP)

Haematologist

Re-assessment required after-4 8 weeks

- 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<sup>2</sup> 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.

Brand or Generic Manufacturer

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

continued...

Continuation – thrombotic thrombocytopenic purpura (TTP)

Haematologist

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

Continuation - ANCA associated vasculitis

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*: and
- 2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m² of body-surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

Nephrologist

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome\*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks

Note: Indications marked with a \* are unapproved indications.

Continuation – Steroid resistant nephrotic syndrome (SRNS)

Nephrologist

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome\*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks

Note: Indications marked with a \* are unapproved indications.

Price	
(ex man. Excl. GST)	
\$	Pe

Brand or Generic Manufacturer

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

181 RITUXIMAB (RIXIMYO) (amended restriction criteria – affected criteria shown only)

→ 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 - severe cold haemagglutinin disease (CHAD)

Haematologist

Re-assessment required after-4 8 weeks

#### All of the following 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; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Continuation – severe cold haemagglutinin disease (CHAD)

Haematologist

Re-assessment required after-4 8 weeks

Fither:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
- 2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease\*; and
- 2.2 An initial response lasting at least 12 months was demonstrated; and
- 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

Initiation - warm autoimmune haemolytic anaemia (warm AIHA)

Haematologist

Re-assessment required after-4 8 weeks

#### All of the following 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: and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Continuation – warm autoimmune haemolytic anaemia (warm AIHA)

Haematologist

Re-assessment required after-4 8 weeks

Either

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia\*; and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

Brand or Generic Manufacturer

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

continued...

Initiation - immune thrombocytopenic purpura (ITP)

Haematologist

Re-assessment required after-4 8 weeks

#### All of the following 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); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Continuation – immune thrombocytopenic purpura (ITP)

Haematologist

Re-assessment required after-4 8 weeks

Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura\*: and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

Initiation – thrombotic thrombocytopenic purpura (TTP)

Haematologist

Re-assessment required after-4 8 weeks

#### Roth:

- 1 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks; and
- 2 Fither
  - 2.1 Patient has thrombotic thrombocytopenic purpura\* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
  - 2.2 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 8 weeks

All of the following:

- 1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment: and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

## Changes to Section H Part II - effective 1 April 2020 (continued)

continued...

Initiation - ANCA associated vasculitis

Re-assessment required after-4 8 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/m² 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 8 weeks

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*; and
- 2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m² of body-surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Initiation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS) Nephrologist

Re-assessment required after-4 8 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a  $\ ^{\star}$  are unapproved indications.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS) Nephrologist

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome\*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Brand or Generic Manufacturer

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

continued...

Initiation – Steroid resistant nephrotic syndrome (SRNS)

Nephrologist

Re-assessment required after-4 8 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a \* are unapproved indications.

Continuation - Steroid resistant nephrotic syndrome (SRNS)

Nephrologist

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome\*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a \* are unapproved indications.

#### RESPIRATORY SYSTEM AND ALLERGIES

205	PHOLCODINE (Pharmacode change)			
	Oral liq 1 mg per ml – 1% DV Jun-20 to 2022	3.09	200 ml	AFT Pholcodine
				Linctus BP
	Note – this is a new Pharmacode listing 2586932, 2142252 to b	e delisted	from 1 Septe	mber 2020.

#### **VARIOUS**

218	POVIDONE-IODINE WITH ETHANOL (delisting)			
	Soln 10% with ethanol 30%	10.00	500 ml	Betadine Skin Prep
	Note – Betadine Skin Prep soln 10% with ethanol 30% to be delisted from 1 June 2020.			

#### **SPECIAL FOODS**

238 PAEDIATRIC ORAL FEED 1 KCAL/ML (delisting revoked)

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 will no longer be delisted from 1 September 2020.

Price					
(ex man. Excl. GST)					
\$	Per				

30

Arrow-Fluoxetine

Brand or Generic Manufacturer

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

## **VACCINES**

VAC	CINES			
242	ADULT DIPHTHERIA AND TETANUS VACCINE (delisting)  → Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml syringe – 0% DV Jul-17 to 2020  Note – ADT Booster inj 2 IU diphtheria toxoid with 20 IU tetanus to 1 October 2020.			
247	HEPATITIS B RECOMBINANT VACCINE (delisting)  → Inj 5 mcg in 0.5 ml vial – 0% DV Jul-17 to 2020  → Inj 10 mcg in 1 ml vial  → Inj 40 mcg per 1 ml vial – 0% DV Jul-17 to 2020  Note – HBvaxPRO inj 5 mcg in 0.5 ml vial, 10 mcg in 1 ml vial an 1 October 2020.	0.00 0.00	1	HBvaxPRO HBvaxPRO HBvaxPRO al to be delisted from
247	HEPATITIS B RECOMBINANT VACCINE (addition of HSS)  → Inj 20 mcg per 1 ml prefilled syringe  - 0% DV Oct-20 to 2024	0.00	1	Engerix-B
Effec	ctive 13 March 2020			
NERV	VOUS SYSTEM			
111	FLUOXETINE HYDROCHLORIDE († price)	0.00	00	A The section

Tab dispersible 20 mg, scored.......9.93

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New Zealand Permit No. 478



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