Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

September 2022



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Summary of decisions EFFECTIVE 1 SEPTEMBER 2022

- Ambrisentan (Mylan) tab 10 mg new listing
- Ambrisentan (Ambrisentan Mylan) tab 10 mg to be delisted 1 March 2023
- Amino acid formula (without phenylalanine) powder 20 g protein, 3.8 g carbohydrate and 0.23 g fibre per 28 g sachet (e.g. PKU Lophlex Powder (neutral) and powder 36 g protein, 32 g carbohydrate and 12.5 g fat per 100 g, 36 g sachet (e.g. PKU Anamix Junior (van/choc/neutral)) amended example brand name
- Amisulpride (Sulprix) tab 400 mg Pharmacode 2500159 to be delisted 1 March 2023.
- Amoxicillin with clavulanic acid (Augmentin) grans for oral liq amoxicillin
 25 mg with clavulanic acid 6.25 mg per ml, 100 ml price increase
- Ascorbic acid (Cvite) tab 100 mg new Pharmacode listing and addition of PSS
- Ascorbic acid (Cvite) tab 100 mg Pharmacode 2439697 to be delisted
 1 February 2023
- Bendamustine hydrochloride (Ribomustin) inj 25 mg and 100 mg vial
 amended restriction criteria
- Benralizumab (Fasenra) inj 30 mg per ml, 1 ml prefilled pen new listing
- Cetomacrogol with glycerol (Evara) crm 90% with glycerol 10%, 500 ml and 1,000 ml – new listing
- Cetomacrogol with glycerol (Boucher) crm 90% with glycerol 10%, 500 ml and 1,000 ml – to be delisted 1 March 2023
- Ciprofloxacin (Viatris) inj 2 mg per ml, 100 ml bag new listing
- Codeine phosphate (Aspen) tab 30 mg new listing
- Dexamethasone phosphate (Hameln) inj 4 mg per ml, 1 ml and 2 ml ampoule
 new listing and addition of PSS
- Dexamethasone phosphate (Dexamethasone Phosphate Panpharma) inj 4 mg per ml, 1 ml and 2 ml ampoule – to be delisted 1 February 2023
- Diazepam (Stesolid) rectal tubes 5 mg price increase and addition of PSS
- Eplerenone (Inspra) tab 25 mg Pharmacode 2316129 to be delisted 1 March 2023
- Eplerenone (Inspra) tab 50 mg new Pharmacode listing
- Erlotinib (Alchemy) tab 100 mg and 150 mg new listing and addition of PSS
- Erlotinib (Tarceva) tab 100 mg and 150 mg to be delisted 1 February 2023
- Fluoxetine hydrochloride (Fluox) tab dispersible 20 mg, scored, 28 tab pack
 price increase and addition of PSS

Summary of decisions – effective 1 September 2022 (continued)

- Fluoxetine hydrochloride (Fluox) tab dispersible 20 mg, scored, 30 tab pack
 to be delisted 1 February 2023
- ullet Glycerol (Lax-suppositories Glycerol) suppos 4 g new listing and addition of PSS
- Glycerol suppos 1.27 g, 2.55 g and suppos 3.6 g (PSM) to be delisted
 1 February 2023
- Loratadine (Lorafix) tab 10 mg price increase and addition of PSS
- Macrogol 3350 with ascorbic acid, potassium chloride and sodium chloride (e.g. Glycoprep-O) powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 210 g sachet – new listing
- Macrogol 3350 with ascorbic acid, potassium chloride, sodium chloride and citric acid with magnesium oxide and sodium picosulfate (e.g. Prepkit-O) powder for oral soln 52.9 g with ascorbic acid 6 g, potassium chloride 740 mg, sodium chloride 2.6 g and sodium sulphate 5.6 g per sachet (1) and powder for oral soln citric acid 12 g with magnesium oxide 3.5 g and sodium picosulfate 10 mg per sachet (2) new listing
- Mepolizumab (Nucala) inj 100 mg prefilled pen and vial amended restriction criteria
- Methadone hydrochloride (Methadone BNM) tab 5 mg new listing and addition of PSS
- Methadone hydrochloride (Methatabs) tab 5 mg to be delisted 1 February 2023
- Methenamine (hexamine) hippurate (Hiprex) tab 1 g price decrease and addition of PSS
- Multivitamins (Mvite) tab (BPC cap strength) new Pharmacode listing and addition of PSS
- Multivitamins (Mvite) tab (BPC cap strength) Pharmacode 2439689 to be delisted 1 February 2023
- Naloxone hydrochloride (Hameln) inj 400 mcg per ml, 1 ml ampoule
 new listing and addition of PSS
- Naloxone hydrochloride (DBL Naloxone Hydrochloride) inj 400 mcg per ml,
 1 ml ampoule to be delisted 1 February 2023
- Obinutuzumab (Gazyva) inj 25 mg per ml, 40 ml vial amended restriction criteria
- Paracetamol (Avallon) oral liq 120 mg per 5 ml and oral liq 240 mg per 5 ml, 200 ml – new listing

Summary of decisions – effective 1 September 2022 (continued)

- Piperacillin with tazobactam (PipTaz-AFT) inj 4 g with tazobactam 0.5 g vial new listing and addition of PSS
- Piperacillin with tazobactam (PipTaz Sandoz and PiperTaz Sandoz) inj 4 g with tazobactam 0.5 g vial to be delisted 1 February 2023
- Secretin pentahydrochloride inj 80 u and 100 u vial new listing
- Sodium thiosulfate inj 250 mg per ml, 100 ml vial new listing

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

Section H changes to Part II

Effective 1 September 2022

ALIMENTARY TRACT AND METABOLISM

ALIM	ENTAILI IIIAOT AND INETADOLION	
14	MACROGOL 3350 WITH ASCORBIC ACID, POTASSIUM CHLORIDE AND SODIUM CHLOR Powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 210 g sachet	RIDE (new listing) e.g. Glycoprep-0
14	MACROGOL 3350 WITH ASCORBIC ACID, POTASSIUM CHLORIDE, SODIUM CHLORIDE MAGNESIUM OXIDE AND SODIUM PICOSULFATE (new listing) Powder for oral soln 52.9 g with ascorbic acid 6 g, potassium chloride 740 mg, sodium chloride 2.6 g and sodium sulphate 5.6 g per sachet (1) and powder for oral soln citric acid 12 g with magnesium oxide 3.5 g and sodium picosulfate 10 mg per sachet (2)	AND CITRIC ACID WITH e.g. Prepkit-0
15	GLYCEROL (new listing and addition of PSS) Suppos 4 g $-$ 5% DV Feb-23 to 2025	Lax-suppositories Glycerol
15	GLYCEROL (delisting) Suppos 1.27 g Suppos 2.55 g Suppos 3.6 g	PSM y 2023.
24	MULTIVITAMINS (new listing and addition of PSS) Tab (BPC cap strength) – 5% DV Feb-23 to 2025 18.50 1,000 Note – this is a new Pharmacode listing, 2642247.	Mvite
24	MULTIVITAMINS (delisting) Tab (BPC cap strength)11.45 1,000 Note – this delist applies to Pharmacode, 2439689 from 1 February 2023.	Mvite
26	ASCORBIC ACID (new listing and addition of PSS) Tab 100 mg – 5% DV Feb-23 to 2025	Cvite
26	ASCORBIC ACID (delisting) Tab 100 mg9.90 500 Note – this delisting applies to Pharmacode, 2439697 from 1 February 2023.	Cvite

	Price (ex man. Excl. G \$	ST) Per	Brand or Generic Manufacturer
Changes to Section H Part II – effective 1 Septe	ember 2022 (con	tinued)	
CARDIOVASCULAR SYSTEM			
8 EPLERENONE (delisting) → Tab 25 mg – 5% DV Jun-22 to 2024 Note – this delist applies to Pharmacode 2316129 fro		30	Inspra
8 EPLERENONE (new Pharmacode listing) → Tab 50 mg – 5% DV Jun-22 to 2024 Note – this is a new Pharmacode listing, 2619520.	25.00	30	Inspra
3 AMBRISENTAN (new listing)			

30

30

Mylan

Ambrisentan Mylan

DERMATOLOGICALS

AMBRISENTAN (delisting)

53

58	CETOMACROGOL WITH GLYCEROL (new listing)		
	Crm 90% with glycerol 10%2.35	500 ml	Evara
	3.10	1,000 ml	Evara
	Note: DV limit applies to the pack sizes of greater than 100 g.		
58	CETOMACROGOL WITH GLYCEROL (delisting)		
	Crm 90% with glycerol 10%2.35	500 ml	Boucher
	3.10	1,000 ml	Boucher
	Note: DV limit applies to the pack sizes of greater than 100 g.		
	Note – Boucher crm 90& with glycerol 10%, 500 ml and 1,000 ml delisted	d from 1 Marcl	n 2023.

Note – Ambrisentan Mylan tab 10 mg to be delisted from 1 March 2023.

HORMONE PREPARATIONS

69	DEXAMETHASONE PHOSPHATE (new listing and addition of PSS)		
	Inj 4 mg per ml, 1 ml ampoule - 5% DV Feb-23 to 2025	10	Hameln
	Inj 4 mg per ml, 2 ml ampoule – 5% DV Feb-23 to 2025 13.10	10	Hameln
	Note – Dexamethasone Phosphate Panpharma inj 4 mg per ml, 1 ml and 2 i	ml ampoule	to be delisted from
	1 February 2023.		

INFECTIONS

82	AMOXICILLIN WITH CLAVULANIC ACID († price) Grans for oral liq 25 mg with clavulanic acid 6.25 mg per ml6.50	100 ml	Augmentin
82	PIPERACILLIN WITH TAZOBACTAM (new listing and addition of PSS) → Inj 4 q with tazobactam 0.5 q vial – 5% DV Feb-23 to 20253.59	1	PipTaz-AFT

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

Changes to Section H Part II – effective 1 September 2022 (continued)

82	PIPERACILLIN WITH TAZOBACTAM (delisting) → Inj 4 g with tazobactam 0.5 g vial	10 vial to be delis	PipTaz Sandoz PiperTaz Sandoz ted from 1 February
83	CIPROFLOXACIN (new listing) Inj 2 mg per ml, 100 ml bag	10	Viatris
85	METHENAMINE (HEXAMINE) HIPPURATE (\downarrow price and addition of PSS) Tab 1 g - 5% DV Feb-23 to 2025 19.95	100	Hiprex
NERV	OUS SYSTEM		
115	PARACETAMOL (new listing) Oral liq 120 mg per 5 ml	200 ml 200 ml	Avallon Avallon
115	CODEINE PHOSPHATE (new listing) Tab 30 mg32.80	100	Aspen
116	METHADONE HYDROCHLORIDE (new listing and addition of PSS) Tab 5 mg – 5% DV Feb-23 to 2025	10	Methadone BNM
119	FLUOXETINE HYDROCHLORIDE († price and addition of PSS) Tab dispersible 20 mg, scored – 5% DV Feb-23 to 2025 2.50	28	Fluox
119	FLUOXETINE HYDROCHLORIDE (delisting) Tab dispersible 20 mg, scored	30	Fluox
119	DIAZEPAM († price and addition of PSS) Rectal tubes 5 mg – 5% DV Feb-23 to 2025	5	Stesolid
124	AMISULPRIDE (delisting) Tab 400 mg29.78 Note – this delist applies to Pharmacode 2500159 from 1 March 2023.	60	Sulprix

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

Changes to Section H Part II – effective 1 September 2022 (continued)

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

135 BENDAMUSTINE HYDROCHLORIDE (amended restriction criteria – affected criteria shown only)

→ Inj 25 mg vial – 5% DV Sep-21 to 2024	77.00	1	Ribomustin
→ Ini 100 mg vial – 5% DV Sep-21 to 2024	308.00	1	Ribomustin

Restricted

Initiation - Indolent, Low-grade lymphomas

Reassessment required after 9 months

All of the following:

- 1 The patient has indolent low grade NHL requiring treatment; and
- 2 Patient has a WHO performance status of 0-2; and
- 3 Either Any of the following:
 - 3.1 Both:
 - 3.1.1 Patient is treatment naive; and
 - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
 - 3.2 All of the following Both:
 - 3.2.1—Patient has relapsed disease following prior chemotherapy Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen: and
 - 3.2.2—The patient has not received prior bendamustine therapy Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
 - 3.2.3 Either
 - 3.3 3.2.3.1 Both All of the following:
 - **3.3.1** 3.2.2 The patient has not received prior bendamustine therapy; and
 - **3.3.2** 3.2.3.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - **3.3.3** 3.2.3.1.2 Patient has had a rituximab treatment-free interval of 12 months or more: or
 - **3.4** 3.2.3.2 Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Continuation - Indolent, Low-grade lymphomas

Reassessment required after 9 months

Both Either:

- 1 Both:
 - 1.1 Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine; and
 - 1.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
- 2 Both:
 - 2.1 Patients have not received a bendamustine regimen within the last 12 months; and
 - 2.2 Either:
 - 2.2.1 Both:
 - **2.**2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 2.2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or
 - **2.2.2** Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.

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

Changes to Section H Part II - effective 1 September 2022 (continued)

146 ERLOTINIB (new listing and addition of PSS)

 → Tab 100 mg − 5% DV Feb-23 to 2023
 329.70
 30
 Alchemy

 → Tab 150 mg − 5% DV Feb-23 to 2023
 569.70
 30
 Alchemy

Note - Tarceva tab 100 mg and 150 mg to be delisted from 1 February 2023.

178 BENRALIZUMAB (new listing)

Restriction

Initiation – Severe eosinophilic asthma

Respiratory physician or clinical immunologist

Reassessment 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 $0.5 \times 10^{\circ}$ 9cells/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 anti-inflammatory reliever therapy plus maintenance 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 Treatment is not to be used in combination with subsidised mepolizumab; and
- 8 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; and
- 9 Either:
 - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
 - 9.2 Both
 - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
 - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Continuation - Severe eosinophilic asthma

Respiratory physician or clinical immunologist

Reassessment required after 2 years

Both:

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

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

Changes to Section H Part II - effective 1 September 2022 (continued)

188 MEPOLIZUMAB (amended restriction criteria – affected criteria shown only)

→ Inj 100 mg prefilled pen	1,638.00	1	Nucala
→ Inj 100 mg vial	1,638.00	1	Nucala

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 × 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 Treatment is not to be used in combination with subsidised benralizumab; and
- 8 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; and
- 9 Either
 - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
 - 9.2 Both:
 - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
 - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

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

Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 September 2022 (continued)

188 OBINUTUZUMAB (amended restriction criteria – new criteria shown only)

Restricted

Initiation – follicular / marginal zone lymphoma

Re-assessment required after 9 months

All of the following:

- 1 Either:
 - 1.1 Patient has follicular lymphoma: or
 - 1.2 Patient has marginal zone lymphoma; and
- 2 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemoimmunotherapy regimen*; and
- 3 Patient has an ECOG performance status of 0-2; and
- 4 Patient has been previously treated with no more than four chemotherapy regimens; and
- 5 Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy*

Note: *includes unapproved indications.

Continuation - follicular / marginal zone lymphoma

Re-assessment required after 24 months

All of the following:

- 1 Patient has no evidence of disease progression following obinutuzumab induction therapy; and
- 2 Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years; and
- 3 Obinutuzumab to be discontinued at disease progression.

RESPIRATORY SYSTEM AND ALLERGIES

222 LORATADINE († price and addition of PSS)

VARIOUS

236 NALOXONE HYDROCHLORIDE (new listing and addition of PSS)

Inj 400 mcg per ml, 1 ml ampoule – **5% DV Feb-23 to 2024**...35.26 10 **Hameln**

Note – DBL Naloxone Hydrochloride inj 400 mcg per ml, 1 ml ampoule to be delisted from 1 February 2023.

236 SODIUM THIOSULFATE (new listing)

Ini 250 mg per ml. 100 ml vial

241 SECRETIN PENTAHYDROCHLORIDE (new listing)

Ini 80 u vial

lnj 100 u vial

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

Changes to Section H Part II - effective 1 September 2022 (continued)

SPECIAL FOODS

- AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (amended example brand name)
 - → Powder 20 g protein, 3.8 g carbohydrate and 0.23 g fibre per 28 g sachet

e.g. PKU Lophlex Powder (unflavoured neutral)

→ Powder 36 g protein, 32 g carbohydrate and 12.5 g fat per 100 g, 36 g sachet

e.g. PKU Anamix Junior (van/choc/unfl **neutral**)

Effective 1 August 2022

VACCINES

274	VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (new listing) → Inj 50 mcg per 0.5 ml vial plus vial	1	Shingrix
274	VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (amended restriction → Inj 50 mcg per 0.5 ml vial plus vial	criteria) 1	Shingrix
	vaccine [shingles vaccine]	1	Zostavax
		10	7nstavay

Restricted

Initiation – people aged 65 years (Zostavax)

Therapy limited to 1 dose

One dose for all people aged 65 years.

Initiation - people aged 65 years (Shingrix)

Therapy limited to 2 doses

Two doses for all people aged 65 years.

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•	

Macrogol 3350 with ascorbic acid,
potassium chloride, sodium chloride and
citric acid with magnesium oxide and
sodium picosulfate
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Methadone BNM 8
Methadone hydrochloride
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Mvite
N
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New Zealand Permit No. 478



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Te Kāwanatanga o Aotearoa New Zealand Government

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