Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

May 2021



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Summary of decisions EFFECTIVE 1 MAY 2021

- Adalimumab inj 20 mg per 0.4 ml syringe and 40 mg per 0.8 ml syringe (Humira) and 40 mg per 0.8 ml pen (HumiraPen) – amended restriction criteria
- Arginine tab 100 mg and cap 500 mg new listing
- Bendamustine hydrochloride (Ribomustin) inj 25 mg and 100 mg vial
 addition of new restriction criteria
- Bupivacaine hydrochloride with fentanyl (Bupafen NRFit) inj 1.25mg with fentanyl 2mcg per ml, 15 ml syringe new listing
- Carglumic acid tab disp 200 mg new listing
- Clonazepam (Rivotril) inj 1 mg per ml, 1 ml ampoule to be delisted 1 October 2021
- Coenzyme Q10 cap 120 mg and 160 mg new listing
- Escitalopram (Escitalopram-Apotex) tab 10 mg and 20 mg to be delisted
 1 October 2021
- Escitalopram (Escitalopram (Ethics)) tab 10 mg and 20 mg new listing and addition of HSS
- Etanercept (Enbrel) inj 25 mg autoinjector, 25 mg vial, 50 mg autoinjector, 50 mg syringe amended restriction criteria
- Fluconazole (Fluconazole-Baxter) inj 2 mg per ml, 100 ml vial new listing and addition of HSS
- Fluconazole (Fluconazole-Claris) inj 2 mg per ml, 100 ml vial to be delisted
 1 November 2021
- Hypromellose (Methopt) eye drops 0.5 % increase price
- Infliximab (Remicade) inj 100 mg amended restriction criteria
- Ketamine (Ketamine-Baxter) inj 100 mg per ml, 2 ml ampoule to be delisted 1 September 2021
- Lenalidomide (Revlimid) cap 5 mg, 10 mg, 15 mg and 25 mg
 amended restriction criteria
- Levocarnitine tab 500 mg, cap 250 mg and oral liquid 500 mg per 10 ml
 new listing
- Mixed salt solution for eye irrigation (e.g. Balanced Salt Solution) eye irrigation solution calcium chloride 0.048% with magnesium chloride 0.03%, potassium chloride 0.075%, sodium acetate 0.39%, sodium chloride 0.64% and sodium citrate 0.17%, 500 ml bag – new listing
- Norethisterone (Primolut N) tab 5 mg, 30 tab new listing

Summary of decisions – effective 1 May 2021 (continued)

- Norethisterone (Primolut N) tab 5 mg, 100 tab to be delisted 1 February 2022
- Omeprazole tab dispersible 10 mg new listing
- Riboflavin tab 100 mg and cap 100 mg new listing
- Secukinumab (Cosentyx) inj 150 mg per ml, 1 ml prefilled syringe new pack size listing and amended restriction criteria
- Sodium cromoglicate aerosol inhaler 5 mcg per dose delisting delayed until 1 November 2021
- Taurine cap 1,000 mg and powder new listing
- Terazosin (Apo-Terazosin) tab 2 mg and 5 mg to be delisted 1 August 2021

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

Section H changes to Part II

Effective 1 May 2021

ALIMENTARY TRACT AND METABOLISM

- 8 OMEPRAZOLE (new listing)
 - → Tab dispersible 10 mg
- 15 CARGLUMIC ACID (new listing)
 - → Tab disp 200 mg

Restricted

Initiation

Metabolic physician

For the acute in-patient treatment of organic acidaemias as an alternative to haemofiltration.

- 16 COENZYME Q10 (new listing)
 - → Cap 120 mg
 - → Cap 160 mg

Restricted

Initiation

Metabolic physician

Re-assessment required after 6 months

The patient has a suspected inborn error of metabolism that may respond to coenzyme Q10 supplementation.

Continuation

Metabolic physician

Re-assessment required after 24 months

Both:

- The patient has a confirmed diagnosis of an inborn error of metabolism that responds to coenzyme Q10 supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.
- 16 LEVOCARNITINE (new listing)
 - → Tab 500 mg
 - → Cap 250 mg
 - → Oral lig 500 mg per 10 ml
- 16 RIBOFLAVIN (new listing)
 - → Tab 100 mg
 - → Cap 100 mg

Restricted

Initiation

Metabolic physician or neurologist

Re-assessment required after 6 months

The patient has a suspected inborn error of metabolism that may respond to riboflavin supplementation.

Continuation

Metabolic physician or neurologist

Re-assessment required after 24 months

Both

- The patient has a confirmed diagnosis of an inborn error of metabolism that responds to riboflavin supplementation; and
- 2. The treatment remains appropriate and the patient is benefiting from treatment.

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

Brand or Generic Manufacturer

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

16 ARGININE (new listing)

Tab 1,000 mg Cap 500 mg

- 16 TAURINE (new listing)
 - → Cap 1,000 mg
 - → Powder

Restricted

Initiation

Metabolic physician

Re-assessment required after 6 months

The patient has a suspected specific mitochondrial disorder that may respond taurine supplementation.

Continuation

Metabolic physician

Re-assessment required after 24 months

Both:

- 1 The patient has a confirmed diagnosis of a specific mitochondrial disorder which responds to taurine supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

CARDIOVASCULAR SYSTEM

42	TERAZOSIN (delisting)			
	→ Tab 2 mg	7.50	500	Apo-Terazosin
	→ Tab 5 mg	10.90	500	Apo-Terazosin
	Note – Ano-Terazosin tab 2 mg and 5 mg to be delisted from	1 August 2021		

HORMONE PREPARATIONS

68	NORETHISTERONE (pack size change)			
	Tab 5 mg – 1% DV Dec-19 to 2021	5.49	30	Primolut N
	Note – Primolut N tab 5 mg, 100 pack to be delisted from 1 F	ebruary 2022.		

INFECTIONS

82 FLUCONAZOLE (brand change)

→ Inj 2 mg per ml, 100 ml vial – 1% DV Oct-19 to 20223.45 1

Note – Fluconazole-Claris inj 2 mg per ml, 100 ml vial to be delisted 1 November 2021.

NERVOUS SYSTEM

107	KETAMINE (delisting)			
	Inj 100 mg per ml, 2 ml ampoule	155.60	5	Ketamine-Baxter
	Note – Ketamine-Baxter inj 100 mg per ml, 2 ml ampoule	to be delisted from	1 Septem	nber 2021.
108	BUPIVACAINE HYDROCHLORIDE WITH FENTANYL (new Ini 1.25 mg with fentanyl 2 mcg per ml. 15 ml syringe	0,	5	Bupafen NRFit

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

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

114	ESCITALOPRAM	(brand change and addition of HSS)
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Tab 10 mg - 1% DV Oct-21 to 2023	1.07	28	Escitalopram (Ethics)
Tab 20 mg - 1% DV Oct-21 to 2023	1.92	28	Escitalopram (Ethics)

Note – Escitalopram-Apotex tab 10 mg and tab 20 mg to be delisted from 1 October 2021.

114 CLONAZEPAM (delisting)

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130 BENDAMUSTINE HYDROCHLORIDE (amended restriction criteria – new criteria shown only)

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

Restricted

Initiation - Hodakin's lymphoma*

Limited to 6 months treatment

Relevant specialist or medical practitioner on the recommendation of a relevant specialist All of the following:

- 1. Patient has Hodgkin's lymphoma requiring treatment; and
- 2. Patient has a ECOG performance status of 0-2; and
- 3. Patient has received one prior line of chemotherapy; and
- 4. Patient's disease relapsed or was refractory following prior chemotherapy; and
- 5. Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m² twice per cycle, for a maximum of four cycles.
 Notes: Indications marked with * are unapproved indications.

135 LENALIDOMIDE (amended restriction criteria – affected criteria shown only)

LEW LIDOWIDE (amondod rostriotion ontona	andotoa ontona onown only		
→ Cap 5 mg	5,122.76	28	Revlimid
→ Cap 10 mg	4,655.25	21	Revlimid
	6,207.00	28	Revlimid
→ Cap 15 mg	5,429.39	21	Revlimid
	7,239.18	28	Revlimid
→ Can 25 mg	7 627 00	21	Revlimid

Restricted

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
- **54**. Lenalidomide to be administered at a maximum dose of 15 mg/day.

Continuation - Maintenance following first line autologous SCT

Haematologist

Reassessment required after 6 months

Both:

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

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

Changes to Section H Part II - effective 1 May 2021 (continued)

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

→ Inj 25 mg autoinjector – 5% DV Feb-21 to 2024	690.00	4	Enbrel
→ Inj 25 mg vial – 5% DV Sep-19 to 2024	690.00	4	Enbrel
→ Inj 50 mg autoinjector – 5% DV Sep-19 to 2024	1,050.00	4	Enbrel
→ Inj 50 mg syringe – 5% DV Sep-19 to 2024	1,050.00	4	Enbrel

Restricted

Initiation — psoriatic arthritis

Rheumatologist

Reassessment required after 6 months

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab or secukinumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
 - 2.2 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
 - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
 - 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
 - 2.4.2 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
 - 2.5 Any of the following:
 - 2.5.1 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
 - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
 - 2.5.3 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.

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

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

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

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

Restricted

Initiation — psoriatic arthritis

Rheumatologist

Reassessment required after 6 months

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis: and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept or secukinumab; or
 - 1.2.2 The patient has received insufficient benefit from etanercept or secukinumab to meet the renewal criteria for etanercept or secukinumab for psoriatic arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
 - 2.2 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
 - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
 - 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
 - 2.4.2 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
 - 2.5 Any of the following:
 - 2.5.1 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
 - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
 - 2.5.3 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.

168 INFLIXIMAB (amended restriction criteria – affected criteria shown only)

Restricted

Initiation – psoriatic arthritis

Rheumatologist

Reassessment required after 4 months

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept and/or secukinumab; or
 - 2.2 Following 3 to 4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

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

Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 May 2021 (continued)

193 SECUKINUMAB (new pack size listing and amended restriction criteria – new criteria shown only)

→ Inj 150 mg per ml, 1 ml prefilled syringe	799.50	1	Cosentyx
→ Inj 150 mg per ml, 1 ml prefilled syringe	1,599.00	2	Cosentyx

Restricted

Initiation — ankylosing spondylitis, second-line biologic

Rheumatologist

Re-assessment required after 3 months

Roth:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either
 - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
 - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Continuation - ankylosing spondylitis, second-line biologic

Rheumatologist

Re-assessment required after 6 months

All of the following:

- 1 Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate; and
- 3 Secukinumab to be administered at doses no greater than 150 mg monthly.

Initiation — psoriatic arthritis

Rheumatologist

Re-assessment required after 6 months

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab or etanercept for psoriatic arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab or etanercept; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept for psoriatic arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
 - 2.2 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
 - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
 - 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
 - 2.4.2 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
 - 2.5 Any of the following:
 - 2.5.1 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
 - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or

continued...

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

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

2.5.3 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.

Continuation — psoriatic arthritis

Rheumatologist

Re-assessment required after 6 months Roth:

DUIII.

- 1 Either:
 - 1.1 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
 - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and
- 2 Secukinumab to be administered at doses no greater than 300 mg monthly.

RESPIRATORY SYSTEM AND ALLERGIES

212 SODIUM CROMOGLICATE (delisting delayed)

Aerosol inhaler 5 mg per dose

Note – delisting delayed until 1 November 2021.

SENSORY ORGANS

218 MIXED SALT SOLUTION FOR EYE IRRIGATION (new listing)
Eye irrigation solution calcium chloride 0.048% with
magnesium chloride 0.03%, potassium chloride 0.075%,
sodium acetate 0.39%, sodium chloride 0.64% and
sodium citrate 0.17%, 500 ml bag

e.g. Balanced Salt Solution

220 HYPROMELLOSE († price)

Changes to Section H Part II - effective 9 April 2021

VACCINES

255 INFLUENZA VACCINE (new listing and amended restriction criteria)

Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) ... 9.00

1 Influvac Tetra (2021 Formulation)

Restricted

Initiation – cardiovascular disease for patients 3 and 4 years of age (inclusive)

Any of the following:

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

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

Initiation - chronic respiratory disease for patients 3 and 4 years of age (inclusive)

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 3 and 4 years of age (inclusive) Either:

- 1 Any of the following:
 - 1.1 Diabetes; or
 - 1.2 Chronic renal disease; or
 - 1.3 Any cancer, excluding basal and squamous skin cancers if not invasive; or
 - 1.4 Autoimmune disease: or
 - 1.5 Immune suppression or immune deficiency; or
 - 1.6 HIV: or
 - 1.7 Transplant recipient; or
 - 1.8 Neuromuscular and CNS diseases/ disorders; or
 - 1.9 Haemoglobinopathies; or
 - 1.10 Is a child on long term aspirin; or
 - 1.11 Has a cochlear implant; or
 - 1.12 Errors of metabolism at risk of major metabolic decompensation; or
 - 1.13 Pre and post splenectomy; or
 - 1.14 Down syndrome; or
 - 1.15 Has been hospitalised for respiratory illness or has a history of significant respiratory illness; or
- 2 Patients in a long-stay inpatient mental health care unit or who are compulsorily detained long-term in a forensic unit within a DHB hospital.

continued...

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

Changes to Section H Part II – effective 9 April 2021 (continued) continued...

Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)90.00 10 Afluria Quad (2021 Formulation)

Restricted

Initiation - People over 65

The patient is 65 years of age or over.

Initiation – cardiovascular disease for patients 3 5 years and over

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 3 5 years and over

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 ${\bf 3}\ {\bf 5}$ years and over Either:

- 1 Any of the following:
 - 1.1 Diabetes; or
 - 1.2 Chronic renal disease: or
 - 1.3 Any cancer, excluding basal and squamous skin cancers if not invasive; or
 - 1.4 Autoimmune disease; or
 - 1.5 Immune suppression or immune deficiency; or
 - 1.6 HIV; or
 - 1.7 Transplant recipient; or
 - 1.8 Neuromuscular and CNS diseases/ disorders; or
 - 1.9 Haemoglobinopathies; or
 - 1.10 Is a child on long term aspirin; or
 - 1.11 Has a cochlear implant; or
 - 1.12 Errors of metabolism at risk of major metabolic decompensation; or
 - 1.13 Pre and post splenectomy; or
 - 1.14 Down syndrome; or
 - 1.15 Is pregnant; or
 - 1.16 Is a child aged four or less (but over three years) who has been hospitalised for respiratory illness or has a history of significant respiratory illness; or
- 2 Patients in a long-stay inpatient mental health care unit or who are compulsorily detained long-term in a forensic unit within a DHB hospital.

Note - this listing is from 9 April 2021

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Revlimid	
Riboflavin 5	
Ribomustin	
Rivotril	Ī
Secukinumab10	
Sodium cromoglicate 1	1
aurine	

New Zealand Permit No. 478



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

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