Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

November 2024



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Summary of decisions EFFECTIVE 1 NOVEMBER 2024

- Acetylcysteine (DBL Acetylcysteine) inj 200 mg per ml, 10 ml ampoule new listing and addition of PSS
- Acetylcysteine (Martindale Pharma) inj 200 mg per ml, 10 ml ampoule to be delisted
 1 April 2025
- Adalimumab (Amgevita) inj 20 mg per 0.4 ml prefilled syringe, inj 40 mg per 0.8 ml prefilled pen and inj 40 mg per 0.8 ml prefilled syringe amended restriction criteria
- Adalimumab (Humira alternative brand) (HumiraPen) inj 40 mg per 0.8 ml prefilled syringe – Pharmacode 2635003 to be delisted 1 May 2025
- Amoxicillin with clavulanic acid (Amoxiclav Devatis Forte) grans for oral liq 50 mg with clavulanic acid 12.5 mg per ml, 100 ml – new listing and addition of PSS
- Amoxicillin with clavulanic acid (Curam) grans for oral liq 50 mg with clavulanic acid 12.5 mg per ml, 100 ml – to be delisted 1 June 2025
- Aripiprazole (Abilify Maintena) inj 300 mg and 400 mg vial amended restriction criteria
- Barium sulphate with sodium bicarbonate (E-Z-Gas II) grans eff 382.2 mg per g with sodium bicarbonate 551.3 mg per g, 4 g sachet delisted 1 November 2024
- Bendamustine hydrochloride (Bendamustine Sandoz) inj 25 mg and 100 mg vial
 new listing and addition of PSS
- Bendamustine hydrochloride (Ribomustin) inj 25 mg and 100 mg vial to be delisted
 1 April 2025
- Bendamustine hydrochloride (Bendamustine Sandoz and Ribomustin) inj 25 mg and 100 mg vial – amended restriction criteria
- Calamine (healthE Calamine Aqueous) crm, aqueous, BP, 100 g addition of PSS
- Cetuximab (Erbitux) inj 5 mg per ml, 20 ml and 100 ml vial amended restriction criteria
- Citric acid with sodium bicarbonate (E-Z-Gas II) powder 382.2 mg per g with sodium bicarbonate 551.3 mg per g, 4 g sachet new listing
- Etanercept (Enbrel) inj 25 mg and 50 mg autoinjector, inj 25 mg vial and inj 50 mg syringe amended restriction criteria
- Fosfomycin (UroFos) powder for oral solution, 3 g sachet new listing and addition of PSS
- Gelatine, succinylated (Gelofusine) inj 4%, 500 ml bag price increase
- Glycine (B Braun) irrigation soln 1.5%, 3,000 ml bag price increase
- Hyoscine butylbromide (Hyoscine Butylbromide (Adiramedica)) tab 10 mg
 new listing and addition of PSS
- Hyoscine butylbromide (Buscopan) tab 10 mg to be delisted 1 April 2025

Summary of decisions – effective 1 November 2024 (continued)

- Ibuprofen (Ethics) oral liq 20 mg per ml, 200 ml price increase and addition of PSS
- Ibuprofen (Ibuprofen SR BNM) tab long-acting 800 mg new listing and addition of PSS
- Ibuprofen (Brufen SR) tab long-acting 800 mg to be delisted 1 April 2025
- Infliximab (Remicade) inj 100 mg amended restriction criteria
- Intra-uterine device (Choice 380 7med Nsha Silver/copper Short) IUD 29.1 mm length × 23.2 mm width – new listing and addition of PSS
- Intra-uterine device IUD 33.6 mm length × 29.9 mm width (TCu 380 Plus Normal) and IUD 35.5 mm length × 19.6 mm width (Cu 375 Standard) – addition of PSS
- Intra-uterine device IUD 29.1 mm length \times 23.2 mm width (Choice TT380 Short), IUD 33.6 mm length \times 29.9 mm width (Choice TT380 Standard) and IUD 35.5 mm length \times 19.6 mm width (Choice Load 375) delisted 1 November 2024
- lodixanol (Visipaque) inj 270 mg per ml (iodine equivalent), 50 ml and 100 ml bottle and inj 320 mg per ml (iodine equivalent), 50 ml, 100 ml and 200 ml bottle price increase
- Iohexol (Omnipaque) inj 240 mg per ml (iodine equivalent), 50 ml bottle, inj 300 mg per ml (iodine equivalent), 20 ml, 50 ml and 100 ml bottle, inj 350 mg per ml (iodine equivalent), 50 ml, 75 ml, 100 ml and 200 ml bottle and inj 350 mg per ml, 500 ml bottle – price increase
- Methylnaltrexone bromide (Relistor) inj 12 mg per 0.6 ml vial amended restriction criteria
- Midazolam (Midazolam-Baxter) inj 1 mg per ml, 5 ml ampoule and inj 5 mg per ml, 3 ml ampoule – PSS start date delayed
- Midazolam (Midazolam Viatris and Mylan Midazolam) inj 1 mg per ml, 5 ml ampoule and inj 5 mg per ml, 3 ml ampoule – price increase and delisting delayed
- Naloxone hydrochloride (DBL Naloxone Hydrochloride) inj 400 mcg per ml, 1 ml ampoule – new listing and addition of PSS
- Naloxone hydrochloride (Hameln) inj 400 mcg per ml, 1 ml ampoule to be delisted
 1 April 2025
- Niraparib (Zejula) tab 100 mg new listing
- Nivolumab (Opdivo) inj 10 mg per ml, 4 ml and 10 ml vial amended restriction criteria
- Nonacog gamma, [recombinant factor IX] (Rixubis) inj 500 iu vial to be delisted
 1 February 2025
- Octocog alfa [recombinant factor VIII] (Advate) inj 250 iu and 1,500 iu vial

 to be delisted 1 February 2025
- Oestradiol (Estrogel) gel (transdermal) 0.06% (750 mcg/ actuation), 80 g
 new listing and addition of PSS

Summary of decisions - effective 1 November 2024 (continued)

- Oil in water emulsion (Fatty Emulsion Cream (Evara)) crm, 500 g and 100 g
 new listing and addition of PSS
- Oil in water emulsion crm, 500 g (Fatty Cream AFT) and crm, 100 g (healthE Fatty Cream) – to be delisted 1 April 2025
- Paliperidone (Invega Sustenna) inj 25 mg, 50 mg, 75 mg, 100 mg and 150 mg syringe – amended restriction criteria
- Pemetrexed (Pemetrexed-AFT) inj 100 mg and 500 mg vial new listing and addition of PSS
- Pemetrexed (Juno Pemetrexed) inj 100 mg and 500 mg vial to be delisted 1 April 2025
- Pemetrexed (Pemetrexed-AFT and Juno Pemetrexed) inj 100 mg and 500 mg vial

 restrictions removed
- Risperidone (Risperidone Sandoz) tab 0.5 mg, 1 mg, 2 mg and 3 mg new listing
- Risperidone (Risperdal Consta) inj 25 mg, 37.5 mg and 50 mg vial
 amended restriction criteria
- Rurioctocog alfa pegol [recombinant factor VIII] (Adynovate) inj 250 iu and 500 iu vial – to be delisted 1 February 2025
- Secukinumab (Cosentyx) inj 150 mg per ml, 1 ml prefilled syringe
 amended restriction criteria
- Teicoplanin (Teicoplanin Medsurge) inj 400 mg vial new listing and addition of PSS
- Teicoplanin (Targocid) inj 400 mg vial –to be delisted 1 April 2025
- Teriflunomide (Teriflunomide Sandoz) tab 14 mg new listing and addition of PSS
- Teriflunomide (Aubagio) tab 14 mg to be delisted 1 April 2025
- Tocilizumab (Actemra) inj 20 mg per ml, 4 ml, 10 ml and 20 ml vial

 amended restriction criteria

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

Brand or Generic Manufacturer

Section H changes to Part II

Effective 1 November 2024

ALIMENTARY TRACT AND METABOLISM

Note - Buscopan tab 10 mg to be delisted from 1 April 2025.

14 METHYLNALTREXONE BROMIDE (amended restriction criteria – new criteria shown only)

→ Inj 12 mg per 0.6 ml vial	36.00	1	Relistor
	246.00	7	Relistor

Restricted

Initiation - Opioid induced constipation outside of palliative care

Limited to 14 days treatment

All of the following:

- 1 Individual has opioid induced constipation; and
- 2 Oral and rectal treatments for opioid induced constipation, including bowel-cleansing preparations, are ineffective or inappropriate; and
- 3 Mechanical bowel obstruction has been excluded.

BLOOD AND BLOOD FORMING ORGANS

34	NONACOG GAMMA, [RECOMBINANT FACTOR IX] (delisting) → Inj 500 iu vial	1	RIXUBIS
34	OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) (delisting) → Inj 250 iu vial	1 1 5.	Advate Advate
34	RURIOCTOCOG ALFA PEGOL [RECOMBINANT FACTOR VIII] (delisting) → Inj 250 iu vial	1 1 25.	Adynovate Adynovate
42	GELATINE, SUCCINYLATED († price) Inj 4%, 500 ml bag139.10	10	Gelofusine

DERMATOLOGICALS

67	CALAMINE (addition of PSS) Crm, aqueous, BP – 5% DV Apr-25 to 2027	100 g	healthE Calamine Aqueous
68	OIL IN WATER EMULSION (new listing and addition of PSS) Crm, 500 g – 5% DV Apr-25 to 2027	500 g	Fatty Emulsion Cream (Evara)
	Crm, 100 g – 5% DV Apr-25 to 2027 1.43 Note: DV limit applies to the pack sizes of 100 g or less. Note – Fatty Cream AFT crm, 500 g and healthE Fatty Cream crm, 100 g to	100 g be delisted	Fatty Emulsion Cream (Evara) d from 1 April 2025.

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

Changes to Section H Part II – effective 1 November 2024 (continued)

GENITO-URINARY SYSTEI	URINARY SYSTEM	VI
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74	INTRA-UTERINE DEVICE (new listing and addition of PSS) IUD 29.1 mm length × 23.2 mm width – 5% DV Nov-24 to 2025	29.80	1	Choice 380 7med Nsha Silver/ copper Short
74	INTRA-UTERINE DEVICE (addition of PSS) IUD 33.6 mm length × 29.9 mm width	00.00		TOU 200 Plus Newsel
	 5% DV Nov-24 to 2025 IUD 35.5 mm length × 19.6 mm width 	26.80	ı	TCu 380 Plus Normal
	– 5% DV Nov-24 to 2025	33.00	1	Cu 375 Standard
74	INTRA-UTERINE DEVICE (delisted)			
	IUD 29.1 mm length \times 23.2 mm width			
	IUD 33.6 mm length \times 29.9 mm width	29.80	1	Choice TT380 Standard
	IUD 35.5 mm length × 19.6 mm width			
	Note – Choice TT380 Short IUD 29.1 mm length \times 23.2 mm v width and Choice Load 375 IUD 35.5 mm length \times 19.6 mm v			

HORMONE PREPARATIONS

79	OESTRADIOL (new listing and addition of PSS)		
	Gel (transdermal) 0.06% (750 mcg/ actuation)		
	- 5% DV Nov-24 to 31-Oct-202714.25	80 g	Estrogel

INFECTIONS

91	AMOXICILLIN WITH CLAVULANIC ACID (new listing and addition of PSS) Grans for oral liq 50 mg with clavulanic acid 12.5 mg per ml – 5% DV Jun-25 to 2027		
94	FOSFOMYCIN (new listing and addition of PSS) → Powder for oral solution, 3 g sachet - 5% DV Apr-25 to 202718.70	1	UroFos
94	TEICOPLANIN (new listing and addition of PSS) → Inj 400 mg vial – 5% DV Apr-25 to 2027	1	Teicoplanin Medsurge

MUSCULOSKELETAL SYSTEM

116	IBUPROFEN († price and addition of PSS) Oral liq 20 mg per ml – 5% DV Apr-25 to 2027	200 ml	Ethics
116	IBUPROFEN (new listing and addition of PSS) Tab long-acting 800 mg – 5% DV Apr-25 to 2027	30	Ibuprofen SR BNM

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

Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 November 2024 (continued)

NERVOUS SYSTEM

133	RISPERIDONE	(new	listing)	
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THOI ETHOOTE (HOW HOUNG)			
Tab 0.5 mg	4.01	60	Risperidone Sandoz
Tab 1 mg	3.68	60	Risperidone Sandoz
Tab 2 mg	5.38	60	Risperidone Sandoz
Tab 3 mg		60	Risperidone Sandoz
ARIPIPRAZOLE (amended restriction criteria)			
→ Inj 300 mg vial	273.56	1	Abilify Maintena
→ Inj 400 mg vial	341.96	1	Abilify Maintena

Restricted

Initiation

134

Re-assessment required after 12 months

Either:

1 Either:

- 1.1 The patient has had an initial Special Authority approval for risperidone depot injection or paliperidone depot injection or olanzapine depot injection; or
- 1.2 All of the following:
 - 1.2.1 The patient has schizophrenia or other psychotic disorder; and
 - 1.2.2 The patient has received treatment with oral atypical antipsychotic agents but has been unable to adhere; and
 - 1.2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months; or

1 Both:

- 1.1 Patient has a current Special Authority approval for olanzapine depot injection, risperidone depot injection or paliperidone depot injection; and
- 1.2 Patient has tried but has experienced an inadequate response to, or intolerable side effects from, prior therapy with olanzapine depot injection, risperidone depot injection or paliperidone depot injection; or
- 2 Patient has been unable to access olanzapine depot injection due to supply issues with olanzapine depot injection, or otherwise would have been initiated on olanzapine depot injection but has been unable to due to supply issues with olanzapine depot injection (see note below for the olanzapine Special Authority criteria for new olanzapine depot injection patients prior to 1 April 2024).

Notes: The Olanzapine depot injection Special Authority criteria that apply to criterion 2 in this Aripiprazole Special Authority application are as follows:

- The patient has had an initial Special Authority approval for paliperidone depot injection or risperidone depot injection; or
- All of the following:
 - . The patient has schizophrenia; and
 - The patient has tried but has not been able to adhere failed to comply with treatment using oral atypical
 antipsychotic agents; and
 - The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Continuation

Re-assessment required after 12 months

The initiation of aripiprazole depot injection has been associated with fewer days of intensive intervention than prior to the initiation of an atypical antipsychotic depot injection.

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

Changes to Section H Part II - effective 1 November 2024 (continued)

135 PALIPERIDONE (amended restriction criteria)

→ Inj 25 mg syringe	194.25	1	Invega Sustenna
→ Inj 50 mg syringe	271.95	1	Invega Sustenna
→ Inj 75 mg syringe		1	Invega Sustenna
→ Inj 100 mg syringe	435.12	1	Invega Sustenna
→Inj 150 mg syringe		1	Invega Sustenna

Restricted

Initiation

Re-assessment required after 12 months

Fither

- 1 The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection or aripiprazole depot injection; or
- 2 All of the following:
 - 2.1 The patient has schizophrenia or other psychotic disorder; and
 - 2.2 The patient been unable to adhere to treatment has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
 - 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Continuation

Re-assessment required after 12 months

The initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

135 RISPERIDONE (amended restriction criteria)

→ Inj 25 mg vial	135.98	1	Risperdal Consta
→ Inj 37.5 mg vial	178.71	1	Risperdal Consta
→ Ini 50 mg vial	217.56	1	Risperdal Consta

Restricted

Initiation

Re-assessment required after 12 months

Either

- 1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection or aripiprazole depot injection; or
- 2 All of the following:
 - 2.1 The patient has schizophrenia or other psychotic disorder; and
 - 2.2 The patient has not been able to adhere to tried but failed to comply with treatment using oral atypical antipsychotic agents; and
 - 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Continuation

Re-assessment required after 12 months

The initiation of risperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

Price	
(ex man. Excl. GST)	
\$	Р

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 November 2024 (continued)

138	TERIFLUNOMIDE (new listing and addition of PSS) Note: Treatment on two or more funded multiple sclerosis treatments si → Tab 14 mg – 5% DV Apr-25 to 2026	multaneous 28	ely is not permitted. Teriflunomide Sandoz
140	MIDAZOLAM (PSS start date delayed) Inj 1 mg per ml, 5 ml ampoule – 5% DV Jan May -25 to 2027 7.80 Inj 5 mg per ml, 3 ml ampoule – 5% DV Jan May -25 to 2027 4.75	10 5	Midazolam-Baxter Midazolam-Baxter
140	MIDAZOLAM († price and delisting delayed) Inj 1 mg per ml, 5 ml ampoule	10	Midazolam Viatris Mylan Midazolam
	Inj 5 mg per ml, 3 ml ampoule	5	Midazolam Viatris Mylan Midazolam

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

Note - delisting delayed until 1 May 2025.

146	BENDAMUSTINE HYDROCHLORIDE (new listing and addition of PSS) → Inj 25 mg vial – 5% DV Apr-25 to 2027	1	Bendamustine Sandoz Bendamustine Sandoz
	Note – Ribomustin inj 25 mg and 100 mg vial to be delisted from 1 April	2025.	
146	BENDAMUSTINE HYDROCHLORIDE (amended restriction criteria – affecti	ed criteria sh	nown only)
	→ Inj 25 mg vial – 5% DV Apr-25 to 2027	1	Ribomustin
	50.05		Bendamustine Sandoz
	→ Inj 100 mg vial – 5% DV Apr-25 to 2027	1	Ribomustin
	200.20		Rendamustine Sandoz

Restricted

Initiation - treatment naive CLL*

All of the following:

- 1 The patient has Binet stage B or C, or progressive stage A chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is chemotherapy treatment naive: and
- 3 The patient is unable to tolerate toxicity of full-dose FCR; and
- 2 4 Patient has ECOG performance status 0-2; and
- 5 Patient has a Cumulative Illness Rating Scale (CIRS) score of < 6; and
- 3 6 Bendamustine is to be administered at a maximum dose of 100 mg/m² on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

Notes: Indication marked with a * includes indications that are unapproved. 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL). Chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

Initiation - Indolent, Low-grade lymphomas

Re-assessment required after 9 months

All of the following:

- 1 The patient has Indolent low grade NHL requiring treatment; and
- 2 The patient has ECOG a WHO performance status of 0-2; and

continued...

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

Changes to Section H Part II – effective 1 November 2024 (continued) continued...

- 3 Any of the following:
 - 3.1 Both
 - 3.1.1 Patient is treatment naïve; and
 - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
 - 3.2 Both:
 - 3.2.1 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemoimmunotherapy regimen; and
 - 3.2.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
 - 3.3 All of the following:
 - 3.3.1 The patient has not received prior bendamustine therapy; and
 - 3.3.2 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 3.3.3 Patient has had a rituximab treatment-free interval of 12 months or more; or
 - 3.4 Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Continuation - Indolent, Low-grade lymphomas

Re-assessment required after 9 months

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
 - 1.1.1.2 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

Note: 'Indolent, low-grade lymphomas' include follicular, mantle cell, marginal zone and lymphoplasmacytic/Waldenstroms macroglobulinaemia.

150 PEMETREXED (new listing and addition of PSS)

Inj 100 mg vial – 5% DV Apr-25 to 2027	8.99	1	Pemetrexed-AFT
Inj 500 mg vial – 5% DV Apr-25 to 2027	29.99	1	Pemetrexed-AFT
N			

Note – Juno Pemetrexed inj 100 mg and 500 mg vial to be delisted from 1 April 2025.

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

Changes to Section H Part II - effective 1 November 2024 (continued)

150 PEMETREXED (restrictions removed)

Inj 100 mg vial – 5% DV Apr-25 to 2027	60.89	1	Juno Pemetrexed
	8.99		Pemetrexed-AFT
Inj 500 mg vial – 5% DV Apr-25 to 2027	217.77	1	Juno Pemetrexed
	29.99		Pemetrexed-AFT

Restricted

Initiation - Mesothelioma

Re-assessment required after 8 months

Roth

- 1 Patient has been diagnosed with mesothelioma: and
- 2 Pemetrexed to be administered at a dose of 500 mg/m² every 21 days in combination with cisplatin or carboplatin for a maximum of 6 eveles.

Continuation - Mesothelioma

Re-assessment required after 8 months

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed to be administered at a dose of 500mg/m² every 21 days for a maximum of 6 cycles.

Initiation - Non small cell lung cancer

Re-assessment required after 8 months

Both:

- 1 Patient has locally advanced or metastatic non-squamous non-small cell lung carcinoma; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has chemotherapy-naïve disease; and
 - 2.1.2 Pemetrexed is to be administered at a dose of 500 mg/m²-every 21 days in combination with cisplatin or earboplatin for a maximum of 6 cycles; or

2.2 All of the following:

- 2.2.1 Patient has had first-line treatment with platinum based chemotherapy; and
- 2.2.2 Patient has not received prior funded treatment with pemetrexed; and
- 2.2.3 Pemetrexed is to be administered at a dose of 500 mg/m² every 21 days for a maximum of 6 cycles.

Continuation - Non small cell lung cancer

Re-assessment required after 8 months

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed is to be administered at a dose of 500mg/m² every 21 days.

153 NIRAPARIB (new listing)

→ Tab 100 mg	13 393 50	84	7eiula

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

Changes to Section H Part II – effective 1 November 2024 (continued)

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

217 111211021 1 (4111011404100110110110114	uncotou cintona cincini cinj		
→ Inj 25 mg autoinjector	690.00	4	Enbrel
→ Inj 25 mg vial	690.00	4	Enbrel
→ Inj 50 mg autoinjector	1,050.00	4	Enbrel
→ Inj 50 mg syringe	1,050.00	4	Enbrel

Restricted

Initiation – severe chronic plaque psoriasis, treatment-naive

Dermatologist

Limited to 4 months treatment

All of the following:

1 Any of the following Either:

- 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and or
- 1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin: and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, or foot, genital or flexural areas at least 2 of the 3 PASI symptom sub-scores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Continuation - severe chronic plaque psoriasis

Dermatologist

Re-assessment required after 6 months

Both:

1 Any of the following Either:

- 1.1 Both:
 - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 1.1.2 Either:
 - 1.1.2.1 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-etanercept treatment baseline value: or
 - 1.1.2.2 Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
- 1.2 Both:
 - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 122 Fither:
 - 1.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom sub-scores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or continued...

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

Changes to Section H Part II – effective 1 November 2024 (continued)

continued...

1.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-etanercept treatment baseline value; and or

- 1.3 Both:
 - 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
 - 1.3.2 Either
 - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept; and
- 2 Etanercept to be administered at doses no greater than 50 mg every 7 days.
- 177 ADALIMUMAB (AMGEVITA) (amended restriction criteria affected criteria shown only)
 - → Inj 20 mg per 0.4 ml prefilled syringe

– 5% DV Oct-22 to 31 Jul 2026	190.00	1	Amgevita
→ Inj 40 mg per 0.8 ml prefilled pen			•
– 5% DV Oct-22 to 31 Jul 2026	375.00	2	Amgevita
→ Inj 40 mg per 0.8 ml prefilled syringe			
- 5% DV Oct-22 to 31 Jul 2026	375.00	2	Amgevita

Restricted

Initiation - Plaque psoriasis - severe chronic

Dermatologist

Re-assessment required after 4 months

Either:

- 1 Both:
 - 1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects; or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
- 2 All of the following:
 - 2.1 Any of the following Either:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and or
 - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
 - 2.2 Patient has tried, but received insufficient therapeutic effect from, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
 - 2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

Continuation - Plaque psoriasis - severe chronic

Re-assessment required after 2 years

Any of the following Either:

- 1 Both:
 - 1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 1.2 Either:

continued...

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

Changes to Section H Part II - effective 1 November 2024 (continued)

continued...

- 1.2.1 The patient has experienced a 75% or more reduction in PASI score, or is sustained at this level, when compared with the pre-treatment baseline value; or
- 1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
- 2 Both:
 - 2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2 Either
 - 2.2.1 The patient has experienced a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values: or
 - 2.2.2 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value: or
- 3 Both:
 - 3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
 - 3.2 Either
 - 3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing adalimumab.
- 187 ADALIMUMAB (HUMIRA ALTERNATIVE BRAND) (delisting)

198 CETUXIMAB (amended restriction criteria)

 → Inj 5 mg per ml, 20 ml vial
 364.00
 1
 Erbitux

 → Inj 5 mg per ml, 100 ml vial
 1,820.00
 1
 Erbitux

Restricted

Initiation - head and neck cancer, locally advanced

Medical oncologist

All of the following:

- 1 Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck; and
- 2 Patient is contraindicated to, or is intolerant of, cisplatin Cisplatin is contraindicated or has resulted in intolerable side effects; and
- 3 Patient has good performance status an ECOG performance score of 0-2; and
- 4 To be administered in combination with radiation therapy.

Initiation - colorectal cancer, metastatic

Reassessment required after 6 months

All of the following:

- 1 Patient has metastatic colorectal cancer located on the left side of the colon (see Note); and
- 2 There is documentation confirming disease is RAS and BRAF wild-type; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 Patient has not received prior funded treatment with cetuximab; and
- 5 Either:
 - 5.1 Cetuximab is to be used in combination with chemotherapy, or
 - 5.2 Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment

Continuation - colorectal cancer, metastatic

Reassessment required after 6 months

No evidence of disease progression

Note: Left-sided colorectal cancer comprises of the distal one-third of the transverse colon, the splenic flexure, the descending colon, the sigmoid colon, or the rectum.

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

Changes to Section H Part II – effective 1 November 2024 (continued)

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

1 Remicade

Restricted

Initiation – plaque psoriasis

Dermatologist

Re-assessment required after 3 doses

Fither:

- 1 Both:
 - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab; or
 - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; or
- 2 All of the following:

2.1 Any of the following Either:

- 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and or
- 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, cyclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, or foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Continuation - plaque psoriasis

Dermatologist

Re-assessment required after 3 doses

Both:

1 Any of the following Either:

- 1.1 Both:
 - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 1.1.2 Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value; or
- 1.2 Both:
 - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and

continued...

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

Changes to Section H Part II – effective 1 November 2024 (continued) continued...

1.2.2 Either:

- 1.2.2.1 Following each prior infliximab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values: or
- 1.2.2.2 Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value; and or
- 1.3 Both:
 - 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
 - 1.3.2 Either:
 - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.
- 224 SECUKINUMAB (amended restriction criteria affected criteria shown only)

Restricted

Initiation – severe chronic plaque psoriasis, first-line biologic

Dermatologist

Re-assessment required after 4 months

All of the following:

- 1 Any of the following Either:
 - 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and or
 - 1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin: and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, or foot, genital or flexural areas, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Continuation - severe chronic plaque psoriasis, first-line biologic

Dermatologist

Re-assessment required after 6 months

Both:

1 Either:

continued...

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

Changes to Section H Part II – effective 1 November 2024 (continued) continued...

1.1 Either:

- 1.1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
- 1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and or
- 1.2 Both:
 - 1.2.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
 - 1.2.2 Either:
 - 1.2.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 1.2.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

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

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

Restricted

Initiation - cytokine release syndrome

Therapy limited to 3 doses

Either:

1 Both All of the following:

- 1.1 The patient is enrolled in the Children's Oncology Group AALL1731 trial; and
- 1.1 1.2 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and
- 1.2 1.3 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg,maximum of 12 mg/kg); or
- 2 All of the following:
 - 2.1 The patient is enrolled in the Malaghan Institute of Medical Research ENABLE trial programme; and
 - 2.2 The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CAR T-Cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma; and
 - 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

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

Changes to Section H Part II – effective 1 November 2024 (continued)

238 NIVOLUMAB (amended restriction criteria – new criteria shown only)

→ 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 - Renal cell carcinoma

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist

Re-assessment required after 4 months

Either:

- 1 Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Patient has metastatic renal-cell carcinoma; and
 - 2.2 The disease is of predominant clear-cell histology; and
 - 2.3 Patient has an ECOG performance score of 0-2; and
 - 2.4 Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy; and
 - 2.5 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

Continuation - Renal cell carcinoma

Any relevant practitioner

Re-assessment required after 4 months

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease: and
- 2 No evidence of disease progression; and

ACETYL CYCTEINE (now listing and addition of DCC)

3 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

VARIOUS

200	ACETILG TO TEINE (HEW IISHING AND AUGINOTION OF POS)	
	Inj 200 mg per ml, 10 ml ampoule – 5% DV Apr-25 to 2027 42.99	DBL Acetylcysteine
	Note – Martindale Pharma inj 200 mg per ml, 10 ml ampoule to be delisted from 1 Ap	ril 2025.
005	NALOVONE INVENDED IN ORDER (now listing and addition of DCC)	

265 NALOXONE HYDROCHLORIDE (new listing and addition of PSS)
Inj 400 mcg per ml, 1 ml ampoule – **5% DV Apr-25 to 2027**...13.29 5
Note – Hameln inj 400 mcg per ml, 1 ml ampoule to be delisted from 1 April 2025.

268 IODIXANOL († price)

Inj 270 mg per ml (iodine equivalent), 50 ml bottle275.00	10	Visipaque
Inj 270 mg per ml (iodine equivalent), 100 ml bottle505.00	10	Visipaque
Inj 320 mg per ml (iodine equivalent), 50 ml bottle280.00	10	Visipaque
Inj 320 mg per ml (iodine equivalent), 100 ml bottle510.00	10	Visipaque
Inj 320 mg per ml (iodine equivalent), 200 ml bottle 1,020.00	10	Visipaque

		Price (ex man. Excl. G	2T\	Brand or Generic
		\$	Per	Manufacturer
Chan	ges to Section H Part II – effective 1 Novemb	er 2024 (conti	nued)	
268	IOHEXOL († price)			
	Inj 240 mg per ml (iodine equivalent), 50 ml bottle	117.00	10	Omnipaque
	Inj 300 mg per ml (iodine equivalent), 20 ml bottle	110.00	10	Omnipaque
	Inj 300 mg per ml (iodine equivalent), 50 ml bottle	121.00	10	Omnipaque
	Inj 300 mg per ml (iodine equivalent), 100 ml bottle	200.00	10	Omnipaque
	Inj 350 mg per ml (iodine equivalent), 50 ml bottle	125.00	10	Omnipaque
	Inj 350 mg per ml (iodine equivalent), 75 ml bottle	160.00	10	Omnipaque
	Inj 350 mg per ml (iodine equivalent), 100 ml bottle		10	Omnipaque
	Inj 350 mg per ml (iodine equivalent), 200 ml bottle		10	Omnipaque
	Inj 350 mg per ml, 500 ml bottle	655.00	6	Omnipaque
268	BARIUM SULPHATE WITH SODIUM BICARBONATE (deliste Grans eff 382.2 mg per g with sodium bicarbonate 551.3 mg per g, 4 g sachet	90.25	50 ng per g, 4	E-Z-Gas II ! g sachet delisted 1 November 2024.
269	CITRIC ACID WITH SODIUM BICARBONATE (new listing) Powder 382.2 mg per g with sodium bicarbonate 551.3			
	per g, 4 g sachet	90.25	50	E-Z-Gas II
270	GLYCINE († price) Irrigation soln 1.5%, 3,000 ml bag	96.28	4	B Braun
Effec	tive 1 October 2024			
NERV	OUS SYSTEM			
144	NALTREXONE HYDROCHLORIDE (new listing) → Tab 50 mg	102.60	30	Naitrexone Max Health

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