Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

October 2022

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 OCTOBER 2022

- Aciclovir (Lovir) tab dispersible 200 mg – price increase and addition of PSS
- Adalimumab (Humira – alternative brand) inj 20 mg per 0.2 ml prefilled syringe and 0.4 ml syringe and inj 40 mg per 0.8 ml syringe (Humira) and inj 40 mg per 0.8 ml pen (HumiraPen) – amended chemical name and restriction criteria
- Azathioprine (Azamun) tab 50 mg – price increase and addition of PSS
- Bupivacaine hydrochloride with fentanyl (Bupafen) inj 1.25 mg with fentanyl 2 mcg per ml, 100 ml and 200 ml bag, 10 inj pack – delisted 1 October 2022
- Bupivacaine hydrochloride with fentanyl (Bupafen) inj 1.25 mg with fentanyl 2 mcg per ml, 100 ml and 200 ml bag, 5 inj pack – price increase and delisting revoked
- Cefuroxime (Zinnat) tab 250 mg – to be delisted 1 March 2024
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.015% with cetrimide 0.15%, 100 ml bottle – new listing
- Compound electrolytes (Plasma-Lyte 148) inj sodium 140 mmol/l, potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l, gluconate 23 mmol/l, 500 ml and 1,000 ml bag – price increase
- Compound electrolytes with glucose [dextrose] (Plasma-Lyte 148 & 5% Glucose) inj sodium 140 mmol/l, 5 mmol/l potassium, 1.5 mmol/l magnesium, 98 mmol/l chloride, 27 mmol/l acetate and 23 mmol/l gluconate, glucose 23 mmol/l (5%), 1,000 ml bag – price increase
- Compound sodium lactate [hartmann's solution] (Baxter) inj sodium 131 mmol/l with potassium 5 mmol/l, calcium 2 mmol/l, bicarbonate 29 mmol/l, chloride 111 mmol/l, 500 ml bag and 1,000 ml bag – price increase
- Darunavir (Darunavir Mylan) tab 400 mg – new listing
- Droperidol (Droperidol Panpharma) inj 2.5 mg per ml, 1 ml ampoule – new listing and addition of PSS
- Droperidol (Droleptan) inj 2.5 mg per ml, 1 ml ampoule – to be delisted 1 March 2023
- Dosulepin [dothiepin] hydrochloride (Dosulepin Viatris) tab 75 mg – new listing
- Gemtuzumab ozogamicin (Mylotarg) inj 5 mg vial – amended restriction criteria
- Glucose [dextrose] inj 5%, 50 ml bag (Baxter Glucose 5%), inj 10%, 1,000 ml bag (Baxter Glucose 10%), inj 10%, 500 ml bag (Baxter Glucose 10%) and inj 50%, 500 ml bag (Baxter Glucose 50%) – price increase

Summary of decisions – effective 1 October 2022 (continued)

- Glucose with potassium chloride and sodium chloride (Baxter) inj 4% glucose with potassium chloride 20 mmol/l and sodium chloride 0.18%, 1,000 ml bag, inj 5% glucose with potassium chloride 20 mmol/l and sodium chloride 0.45%, 1,000 ml bag and inj 5% glucose with potassium chloride 20 mmol/l and sodium chloride 0.9%, 1,000 ml bag – price increase
- Glucose with sodium chloride (Baxter) inj 4% glucose and sodium chloride 0.18%, 1,000 ml bag, inj 5% glucose and sodium chloride 0.45%, 1,000 ml bag and inj 5% glucose and sodium chloride 0.9%, 1,000 ml bag – price increase
- Iloprost (Vebulis) nebuliser soln 10 mcg per ml, 2 ml – new listing and addition of PSS
- Iloprost (Ventavis) nebuliser soln 10 mcg per ml, 2 ml – to be delisted 1 March 2023
- Iloprost (Ilomedin) inj 50 mcg in 0.5 ml ampoule – new listing
- Iloprost (Clinect) inj 50 mcg in 0.5 ml ampoule – to be delisted 1 December 2022
- Lidocaine [lignocaine] hydrochloride (Lidocaine-Baxter) inj 1%, 5 ml ampoule – price increase
- Lisinopril (Teva Lisinopril) tab 5 mg, 10 mg and 20 mg – new listing
- Macrogol 400 and propylene glycol (Systane Unit Dose) eye drops 0.4% and propylene glycol 0.3%, preservative free, single dose – new pack size listing
- Macrogol 400 and propylene glycol (Systane Unit Dose) eye drops 0.4% and propylene glycol 0.3%, preservative free, single dose, 24 pack – to be delisted 1 June 2023
- Mannitol (Baxter) inj 10%, 1,000 ml bag and inj 20%, 500 ml bag – price increase
- Metformin hydrochloride (Metformin Viatris) tab immediate-release 500 mg – new listing
- Methadone hydrochloride (AFT) inj 10 mg per ml, 1 ml – price increase
- Mitomycin C (Teva) inj 20 mg vial – price decrease
- Morphine sulphate (Medsurge) inj 5 mg per ml, 10 mg per ml, 15 mg per ml and 30 mg per ml, 1 ml ampoule – new listing and addition of PSS
- Morphine sulphate (DBL Morphine Sulphate) inj 5 mg per ml, 10 mg per ml, 15 mg per ml and 30 mg per ml, 1 ml ampoule – to be delisted from 1 March 2023
- Naphazoline hydrochloride (Naphcon Forte) eye drops 0.1%, 15 ml – to be delisted 1 September 2023

Summary of decisions – effective 1 October 2022 (continued)

- Ondansetron (Ondansetron-AFT) inj 2 mg per ml, 2 ml and 4 ml ampoule – new listing and addition of PSS
- Ondansetron (Ondansetron Kabi) inj 2 mg per ml, 4 ml ampoule – to be delisted 1 March 2023
- Ondansetron (Ondansetron-Baxter) inj 2 mg per ml, 2 ml ampoule – price decrease and to be delisted 1 March 2023
- Orphenadrine citrate (Norflex) tab 100 mg – new Pharmacode listing
- Paroxetine (Loxamine) tab 20 mg – price increase
- Paroxetine (Loxamine) tab 20 mg – Pharmacode 2443015 to be delisted 1 January 2023
- Perindopril (Coversyl) tab 8 mg – new listing
- Potassium chloride with sodium chloride (Baxter) inj 10 mmol potassium chloride with 0.29% sodium chloride, 100 ml bag, inj 20 mmol potassium chloride with 0.9% sodium chloride, 1,000 ml bag, inj 40 mmol potassium chloride with 0.9% sodium chloride, 1,000 ml bag and inj 40 mmol potassium chloride with 0.9% sodium chloride, 100 ml bag – price increase
- Sodium chloride inj 0.45%, 500 ml bag, inj 3%, 1,000 ml and inj 0.9%, 50 ml, 100 ml, 250 ml, 500 ml and 1,000 ml bag (Baxter) and inj 0.9%, 50 ml and 100 ml bag (Baxter-Viaflo) – price increase
- Sodium chloride irrigation soln 0.9%, 30 ml ampoule (Interpharma) and irrigation soln 0.9%, 1,000 ml bottle (Baxter Sodium Chloride 0.9%) – price increase
- Sodium cromoglicate (Allerfix) eye drops 2%, 10 ml – new listing and addition of PSS
- Sodium cromoglicate (Rexacrom) eye drops 2%, 10 ml – to be delisted 1 March 2023
- Ticagrelor (Ticagrelor Sandoz) tab 90 mg – new listing and addition of PSS
- Ticagrelor (Brilinta) tab 90 mg – to be delisted 1 March 2023
- Tocilizumab (Actrema) inj 20 mg per ml, 4 ml vial, 10 ml vial, and 20 ml vial – amended restriction criteria
- Water (Baxter) inj, 1,000 ml bag – price increase
- Water (Baxter Water for Irrigation) irrigation soln, 1,000 ml bottle – price increase

We have amended or removed some explanatory notes in Hospital medicines (Section H). These notes are standalone pieces of clinical information, and this information is better accessed in the New Zealand Formulary monographs.

A summary of the changes to Section H is provided below (only the relevant parts are shown).

Note in the Restriction for sacubitril with valsartan

Continuation

~~Note: Due to the angiotensin II receptor blocking activity of sacubitril with valsartan it should not be co-administered with an ACE inhibitor or another ARB.~~

Note in the Restriction for propylthiouracil

~~Note: Propylthiouracil is not recommended for patients under the age of 18 years unless the patient is pregnant and other treatments are contraindicated.~~

Note in the Restriction for febuxostat

Initiation - Gout

~~Note: In chronic renal insufficiency, particularly when the glomerular filtration rate is 30 ml/minute or less, probenecid may not be effective. The efficacy and safety of febuxostat have not been fully evaluated in patients with severe renal impairment (creatinine clearance less than 30 ml/minute). No dosage adjustment of febuxostat is necessary in patients with mild or moderate renal impairment. Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.~~

Notes in the Restriction for lacosamide

Initiation

Note: ~~"Optimal treatment" is defined as treatment which is indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight and other features affecting the pharmacokinetics of the drug with good evidence of compliance.~~ Patients of childbearing age are not required to have a trial of sodium valproate.

Continuation

Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life compared with that prior to starting lacosamide treatment ~~(see Note).~~

~~Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective~~

Note in the Restriction for sirolimus

Initiation — refractory seizures associated with tuberous sclerosis complex*

Note: ~~"Optimal treatment" is defined as treatment, which is indicated and clinically appropriate for the patient, given in adequate doses for the patients age, weight and other features affecting the pharmacokinetics of the drug, with good evidence of adherence.~~ Patients of childbearing age are not required to have a trial of sodium valproate.

Note in the Restriction for vigabatrin

Initiation

~~Note: ``Optimal treatment with other antiepilepsy agents'' is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.~~

~~Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.~~

Continuation

~~Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.~~
~~Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.~~

Note in the Restriction for everolimus

~~Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.~~

Note in the Restriction for pegylated interferon alfa-2A

Initiation – Hepatitis B

~~Notes: Approved dose is 180 mcg once weekly.~~

~~The recommended dose of Pegylated Interferon alfa-2a is 180 mcg once weekly.~~

~~In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon alfa-2a dose should be reduced to 135 mcg once weekly.~~

~~In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.~~

~~Pegylated Interferon alfa-2a is not approved for use in children~~

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

Section H changes to Part II

Effective 1 October 2022

ALIMENTARY TRACT AND METABOLISM

11	METFORMIN HYDROCHLORIDE (new listing)			
	Tab immediate-release 500 mg	14.74	1,000	Metformin Viatris

BLOOD AND BLOOD FORMING ORGANS

36	TICAGRELOR (new listing and addition of PSS)			
	➔ Tab 90 mg – **5% DV Mar-23 to 2024**	23.85	56	**Ticagrelor Sandoz**
	Note – Brilinta tab 90 mg to be delisted from 1 March 2023.			
39	COMPOUND ELECTROLYTES (↑ price)			
	Inj sodium 140 mmol/l, potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l, gluconate 23 mmol/l, 500 ml bag	57.06	18	Plasma-Lyte 148
	Inj sodium 140 mmol/l, potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l, gluconate 23 mmol/l, 1,000 ml bag	29.28	12	Plasma-Lyte 148
39	COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE] (↑ price)			
	Inj sodium 140 mmol/l, 5 mmol/l potassium, 1.5 mmol/l magnesium, 98 mmol/l chloride, 27 mmol/l acetate and 23 mmol/l gluconate, glucose 23 mmol/l (5%), 1,000 ml bag	227.64	12	Plasma-Lyte 148 & 5% Glucose
39	COMPOUND SODIUM LACTATE [HARTMANN'S SOLUTION] (↑ price)			
	Inj sodium 131 mmol/l with potassium 5 mmol/l, calcium 2 mmol/l, bicarbonate 29 mmol/l, chloride 111 mmol/l, 500 ml bag	25.20	18	Baxter
	Inj sodium 131 mmol/l with potassium 5 mmol/l, calcium 2 mmol/l, bicarbonate 29 mmol/l, chloride 111 mmol/l, 1,000 ml bag	16.92	12	Baxter
39	GLUCOSE [DEXTROSE] (↑ price)			
	Inj 5%, 50 ml bag	154.20	60	Baxter Glucose 5%
	Inj 10%, 1,000 ml bag	120.36	12	Baxter Glucose 10%
	Inj 10%, 500 ml bag	118.26	18	Baxter Glucose 10%
	Inj 50%, 500 ml bag	362.34	18	Baxter Glucose 50%
39	GLUCOSE WITH POTASSIUM CHLORIDE AND SODIUM CHLORIDE (↑ price)			
	Inj 4% glucose with potassium chloride 20 mmol/l and sodium chloride 0.18%, 1,000 ml bag	218.52	12	Baxter
	Inj 5% glucose with potassium chloride 20 mmol/l and sodium chloride 0.45%, 1,000 ml bag	171.84	12	Baxter
	Inj 5% glucose with potassium chloride 20 mmol/l and sodium chloride 0.9%, 1,000 ml bag	303.72	12	Baxter

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

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

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer
40	GLUCOSE WITH SODIUM CHLORIDE (↑ price)			
	Inj 4% glucose and sodium chloride 0.18%, 1,000 ml bag	175.44	12	Baxter
	Inj 5% glucose and sodium chloride 0.45%, 1,000 ml bag	175.32	12	Baxter
	Inj 5% glucose and sodium chloride 0.9%, 1,000 ml bag	186.24	12	Baxter
40	POTASSIUM CHLORIDE WITH SODIUM CHLORIDE (↑ price)			
	Inj 10 mmol potassium chloride with 0.29% sodium chloride, 100 ml bag	512.16	48	Baxter
	Inj 20 mmol potassium chloride with 0.9% sodium chloride, 1,000 ml bag	175.20	12	Baxter
	Inj 40 mmol potassium chloride with 0.9% sodium chloride, 1,000 ml bag	272.16	12	Baxter
	Inj 40 mmol potassium chloride with 0.9% sodium chloride, 100 ml bag	829.92	48	Baxter
40	SODIUM CHLORIDE (↑ price)			
	Inj 0.45%, 500 ml bag	76.68	18	Baxter
	Inj 3%, 1,000 ml bag	150.72	12	Baxter
	Inj 0.9%, 50 ml bag	118.20	60	Baxter
		147.75	75	Baxter-Viaflo
	Inj 0.9%, 100 ml bag	84.48	48	Baxter
		105.60	60	Baxter-Viaflo
	Inj 0.9%, 250 ml bag	48.00	24	Baxter
	Inj 0.9%, 500 ml bag	23.94	18	Baxter
	Inj 0.9%, 1,000 ml bag	16.32	12	Baxter
41	WATER (↑ price)			
	Inj, 1,000 ml bag	20.52	12	Baxter
47	MANNITOL (↑ price)			
	Inj 10%, 1,000 ml bag	802.56	12	Baxter
	Inj 20%, 500 ml bag	1,178.10	18	Baxter

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

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

CARDIOVASCULAR SYSTEM

41 PERINDOPRIL (new listing)
Tab 8 mg ..... 5.02 30 Coversyl

42 LISINOPRIL (new listing)
Tab 5 mg – **5% DV Oct-22 to 2025** ..... 11.07 90 **Teva Lisinopril**
Tab 10 mg – **5% DV Oct-22 to 2025** ..... 11.67 90 **Teva Lisinopril**
Tab 20 mg – **5% DV Oct-22 to 2025** ..... 14.69 90 **Teva Lisinopril**

55 ILOPROST (new listing and addition of PSS)
➔ Nebuliser soln 10 mcg per ml, 2 ml
– **5% DV Mar-23 to 2025** ..... 185.03 30 **Vebulis**
Note – Ventavis nebuliser soln 10 mcg per ml, 2 ml to be delisted from 1 March 2023

55 ILOPROST (new listing)
Inj 50 mcg in 0.5 ml ampoule ..... 380.00 5 Ilomedin
Note – Clinect inj 50 mcg in 0.5 ml ampoule to be delisted from 1 December 2022.

INFECTIONS

79 CEFUROXIME (delisting)
Tab 250 mg ..... 45.93 50 Zinnat
Note – Zinnat tab 250 mg brand only to be delisted from 1 March 2024.

93 DARUNAVIR (new listing)
➔ Tab 400 mg – **1% DV Oct-22 to 2023** ..... 132.00 60 **Darunavir Mylan**
Note – this is a new Pharmacode listing, 2595486.

95 ACICLOVIR (↑ price and addition of PSS)
Tab dispersible 200 mg – **5% DV Mar-23 to 2025** ..... 1.78 25 **Lovir**

MUSCULOSKELETAL SYSTEM

107 ORPHENADRINE CITRATE (new Pharmacode listing)
Tab 100 mg – **5% DV Jan-22 to 2024** ..... 20.76 100 **Norflex**
Note – this is a new Pharmacode listing, 2645564. Pharmacode 255009 to be delisted from 1 July 2023.

NERVOUS SYSTEM

112 BUPIVACAINE HYDROCHLORIDE WITH FENTANYL (delisted)
Inj 1.25 mg with fentanyl 2 mcg per ml,
100 ml bag ..... 245.00 10 Bupafen
Inj 1.25 mg with fentanyl 2 mcg per ml,
200 ml bag ..... 255.00 10 Bupafen
Note – Bupafen inj 1.25 mg with fentanyl 2 mcg per ml, 100 ml and 200 ml bag, 10 inj pack delisted from 1 October 2022.

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

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

112	BUPIVACAINE HYDROCHLORIDE WITH FENTANYL (↑ price and delisting revoked)			
	Inj 1.25 mg with fentanyl 2 mcg per ml, 100 ml bag – **5% DV Jan-23 to 2025**	122.50	5	**Bupafen**
	Inj 1.25 mg with fentanyl 2 mcg per ml, 200 ml bag – **5% DV Jan-23 to 2025**	127.50	5	**Bupafen**
113	LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (↑ price)			
	Inj 1%, 5 ml ampoule	9.50	25	Lidocaine-Baxter
116	METHADONE HYDROCHLORIDE (↑ price)			
	Inj 10 mg per ml, 1 ml vial	68.90	10	AFT
116	MORPHINE SULPHATE (new listing and addition of PSS)			
	Inj 5 mg per ml, 1 ml ampoule – **5% DV Mar-23 to 2025**	5.38	5	**Medsurge**
	Inj 10 mg per ml, 1 ml ampoule – **5% DV Mar-23 to 2025**	4.68	5	**Medsurge**
	Inj 15 mg per ml, 1 ml ampoule – **5% DV Mar-23 to 2025**	5.53	5	**Medsurge**
	Inj 30 mg per ml, 1 ml ampoule – **5% DV Mar-23 to 2025**	6.28	5	**Medsurge**
	Note – DBL Morphine Sulphate inj 5 mg per ml, 10 mg per ml, 15 mg per ml and 30 mg per ml, 1 ml ampoule to be delisted from 1 March 2023.			
118	DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE (new listing)			
	➔ Tab 75 mg	3.85	30	Dosulepin Viatris
119	PAROXETINE (↑ price)			
	Tab 20 mg – **5% DV Jan-23 to 2025**	4.11	90	**Loxamine**
	Note – this price increase applies to Pharmacode 2626799.			
119	PAROXETINE (delisting)			
	Tab 20 mg	4.11	90	Loxamine
	Note – this delist applies to Pharmacode 2443015 from 1 January 2023. Pharmacode 2626799 delisting revoked.			
123	DROPERIDOL (new listing and addition of PSS)			
	Inj 2.5 mg per ml, 1 ml ampoule – **5% DV Mar-23 to 2025**	43.85	10	**Droperidol Panpharma**
	Note – Droleptan inj 2.5 mg per ml, 1 ml ampoule to be delisted from 1 March 2023.			
123	ONDANSETRON (new listing and addition of PSS)			
	Inj 2 mg per ml, 2 ml ampoule – **5% DV Mar-23 to 2025**	1.42	5	**Ondansetron-AFT**
	Inj 2 mg per ml, 4 ml ampoule – **5% DV Mar-23 to 2025**	1.89	5	**Ondansetron-AFT**
	Note – Ondansetron Kabi inj 2 mg per ml, 4 ml ampoule to be delisted from 1 March 2023.			
123	ONDANSETRON (↓ price and delisting)			
	Inj 2 mg per ml, 2 ml ampoule	1.40	5	Ondansetron-Baxter
	Note – Ondansetron-Baxter inj 2 mg per ml, 2 ml ampoule to be delisted from 1 March 2023.			

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

137 MITOMYCIN C (↓ price)

Inj 20 mg vial	1,250.00	1	Teva

174 ADALIMUMAB (HUMIRA – **ALTERNATIVE BRAND**) (amended chemical name and restriction criteria)

➔ Inj 20 mg per 0.2 ml prefilled syringe	1,599.96	2	Humira
➔ 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

~~Continuation – polyarticular course juvenile idiopathic arthritis~~
~~Rheumatologist or named specialist~~
~~*Re-assessment required after 6 months*~~
~~Both:~~
~~1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~
~~2 Either:~~
~~2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or~~
~~2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.~~

~~Continuation – oligoarticular course juvenile idiopathic arthritis~~
~~Rheumatologist or named specialist~~
~~*Re-assessment required after 6 months*~~
~~Both:~~
~~1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~
~~2 Either:~~
~~2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or~~
~~2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.~~

~~Continuation – fistulising Crohn's disease~~
~~Gastroenterologist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1 The number of open draining fistulae have decreased from baseline by at least 50%; or~~
~~2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.~~

~~Continuation – Crohn's disease - adults~~
~~Gastroenterologist~~
~~*Re-assessment required after 3 months*~~
~~Both:~~
~~1 Either:~~
~~1.1 Either:~~
~~1.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or~~
~~1.1.2 CDAI score is 150 or less; or~~
~~1.2 Both:~~

continued...

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

continued...

~~1.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and~~

~~1.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and~~

~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Continuation – Crohn's disease - children~~

~~Gastroenterologist~~

~~*Re-assessment required after 3 months*~~

~~Both:~~

~~1 Any of the following:~~

~~1.1 PCDAI score has reduced by 100 points from the PCDAI score when the patient was initiated on adalimumab; or~~

~~1.2 PCDAI score is 150 or less; or~~

~~1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and~~

~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Continuation – rheumatoid arthritis~~

~~Rheumatologist~~

~~*Re-assessment required after 6 months*~~

~~All of the following:~~

~~1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~

~~2 Either:~~

~~2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or~~

~~2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and~~

~~3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Continuation – ankylosing spondylitis~~

~~Rheumatologist~~

~~*Re-assessment required after 6 months*~~

~~All of the following:~~

~~1 Following 12 weeks' initial treatment and subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and~~

~~2 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and~~

~~3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Continuation – psoriatic arthritis~~

~~Rheumatologist~~

~~*Re-assessment required after 6 months*~~

~~Both:~~

~~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 adalimumab treatment in the opinion of the treating physician; and~~

~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

continued...

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

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

continued...

~~Continuation – plaque psoriasis~~
~~Dermatologist~~
~~*Re-assessment required after 6 months*~~
~~Both:~~
~~1 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 adalimumab 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-adalimumab treatment baseline value; or~~
~~1.1.2.2 Following each prior adalimumab 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~~
~~1.2.2 Either:~~
~~1.2.2.1 Following each prior adalimumab 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 adalimumab 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~~
~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Continuation – pyoderma gangrenosum~~
~~Dermatologist~~
~~All of the following:~~
~~1 Patient has shown clinical improvement; and~~
~~2 Patient continues to require treatment; and~~
~~3 A maximum of 8 doses.~~

~~Continuation – adult-onset Still's disease~~
~~Rheumatologist~~
~~*Re-assessment required after 6 months*~~
~~The patient has a sustained improvement in inflammatory markers and functional status.~~

~~Continuation – severe Behcet's disease~~
~~Any relevant practitioner~~
~~*Re-assessment required after 6 months*~~
~~Both:~~
~~1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and~~
~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Continuation – severe ocular inflammation~~
~~*Re-assessment required after 12 months*~~
~~Both:~~
~~1 Any of the following:~~
~~1.1 The patient has had a good clinical response following 3 initial doses; or~~
~~1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½ + anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or~~

continued...

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

continued...

~~1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and~~

~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if adalimumab is withdrawn.~~

~~Continuation – chronic ocular inflammation~~

~~*Re-assessment required after 12 months*~~

~~Both:~~

~~1 Any of the following:~~

~~1.1 The patient has had a good clinical response following 12 weeks' initial treatment; or~~

~~1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or~~

~~1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and~~

~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if adalimumab is withdrawn.~~

~~Continuation – hidradenitis suppurativa~~

~~Dermatologist~~

~~*Re-assessment required after 6 months*~~

~~All of the following:~~

~~1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and~~

~~2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and~~

~~3 Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.~~

Initiation – Behcet's disease – severe
Any relevant Practitioner
Re-assessment required after 6 months
All of the following:

1 Either:
- **1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or**
- **1.1 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and**

2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation - Behcet's disease - severe
Any relevant practitioner
Re-assessment required after 6 months
Both:

1 The patient has had a good clinical response to treatment with measurably improved quality of life; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

continued...

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

continued...

Initiation - Hidradenitis suppurativa
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
All of the following:
1 Either:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

Continuation - Hidradenitis suppurativa
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
All of the following:
1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and
3 Adalimumab is to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

Initiation - Psoriasis - severe chronic plaque
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
All of the following:
1 Either:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation - Psoriasis - severe chronic plaque
Dermatologist or Practitioner on the recommendation of a dermatologist
Re-assessment required after 6 months
Both:
1 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 adalimumab 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-adalimumab treatment baseline value; or

continued...

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

continued...

1.1.2.2 Following each prior adalimumab 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

1.2.2 Either:

1.2.2.1 Following each prior adalimumab 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 adalimumab 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-adalimumab treatment baseline value; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initiation - Pyoderma gangrenosum
Dermatologist
Re-assessment required after 6 months
All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 A maximum of 8 doses.

Continuation - Pyoderma gangrenosum
Dermatologist
Re-assessment required after 6 months
Both:

1 The patient has demonstrated clinical improvement and continues to require treatment; and

2 A maximum of 8 doses

Initiation - Crohn's disease - adult
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
All of the following:

1 Any of the following:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or

1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

continued...

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

continued...

Continuation - Crohn's disease - adult
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
Both:
1 Any of the following:
1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
1.2 CDAI score is 150 or less; or
1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initiation – Crohn's disease - children
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
All of the following
1 Any of the following:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation – Crohn's disease - children
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
Both:
1 Any of the following:
1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
1.2 PCDAI score is 15 or less; or
1.3 The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initiation - Crohn's disease - fistulising
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
All of the following
1 Any of the following:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and

continued...

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

continued...

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation – Crohn's disease - fistulising
Gastroenterologist or Practitioner on the recommendation of a gastroenterologist
Re-assessment required after 6 months
Both:

1 Either:

1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or

1.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and

2 Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Initiation - Ocular inflammation – chronic
Any relevant practitioner
Re-assessment required after 12 months
All of the following:

1 Any of the following:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or

1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation - Ocular inflammation – chronic
Any relevant practitioner
Re-assessment required after 12 months
Both

1 Any of the following

1.1 The patient has had a good clinical response following 12 weeks initial treatment; or

1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or

1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and

2 Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Initiation - Ocular inflammation – severe
Any relevant practitioner
Re-assessment required after 12 months
All of the following:

1 Any of the following:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

continued...

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

continued...

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or

1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation – Ocular inflammation – severe
Any relevant practitioner
Re-assessment required after 12 months
Both:

1 Any of the following:

1.1 The patient has had a good clinical response following 3 initial doses; or

1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or

1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and

2 Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Initiation - Ankylosing spondylitis
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation - Ankylosing spondylitis
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
Both:

1 Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and

2 Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Initiation - Arthritis – oligoarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

continued...

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

continued...

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Continuation - Arthritis – oligoarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initiation - Arthritis - polyarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Continuation - Arthritis - polyarticular course juvenile idiopathic
Rheumatologist or named specialist
Re-assessment required after 6 months
For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initiation – Arthritis – psoriatic
Rheumatologist or named specialist
Re-assessment required after 6 months
All of the following:

1 Either

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Continuation - Arthritis - psoriatic
Rheumatologist or named specialist
Re-assessment required after 6 months
Both:

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

continued...

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

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

continued...

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initiation – Arthritis – rheumatoid
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:
1 Either:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Either:
4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Continuation – Arthritis – rheumatoid
Rheumatologist, or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
Both:
1 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2 Either:
2.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
2.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Initiation - Still's disease – adult-onset (AOSD)
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
All of the following:
1 Either:
1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Continuation - Still's disease – adult-onset (AOSD)
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 6 months
The patient has demonstrated a sustained improvement in inflammatory markers and functional status.

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

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

180 GEMTUZUMAB OZOGAMICIN (amended restriction criteria)

➔ Inj 5 mg vial	12,973.00	1	Mylotarg

Restricted
Initiation
All of the following:
1 Patient has not received prior chemotherapy for this condition; and
2 Patient has de novo CD33-positive acute myeloid leukaemia; and
3 Patient does not have acute promyelocytic leukaemia; and
4 Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC); and
5 Patient is being treated with curative intent; and
6 Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate; and
7 Patient must be considered eligible for standard intensive remission induction chemotherapy with ~~daunorubicin~~ **standard anthracycline** and cytarabine (AraC); and
8 Gemtuzumab ozogamicin to be funded for one course only **(one dose at 3 mg per m² body surface area or up to 2 vials of 5 mg as separate doses)**~~; and~~
~~9 Either:~~
~~9.1 Gemtuzumab ozogamicin to be administered at one dose at 3 mg per m² body surface area; or~~
~~9.2 Up to 10 mg of gemtuzumab ozogamicin to be administered~~

Notes: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

209 TOCILIZUMAB (amended restriction – 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	1,100.00	1	Actemra

Restricted
Initiation – moderate to severe COVID-19~~*~~
Therapy limited to 1 dose
All of the following:
1 Patient has confirmed (or probable) COVID-19; and
2 Oxygen saturation of <92% on room air, or requiring supplemental oxygen; and
3 Patient has significantly increased laboratory markers of systemic inflammation (eg CRP, PCT or ferritin); and
4 Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated; and
5 Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose.
~~Note: indications marked with * are unapproved indications.~~

218 AZATHIOPRINE (↑ price and addition of PSS)

Tab 50 mg – **5% DV Mar-23 to 2025**	8.10	100	**Azamun**

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

SENSORY ORGANS

232 SODIUM CROMOGLICATE (new listing and addition of PSS)
Eye drops 2% – **5% DV Mar-23 to 2025** ..... 2.62 10 ml **Allerfix**
Note – Rexacrom eye drops 2% to be delisted from 1 March 2023.

232 NAPHAZOLINE HYDROCHLORIDE (delisting)
Eye drops 0.1% ..... 4.15 15 ml Naphcon Forte
Note – Naphcon Forte eye drops 0.1% brand only to be delisted from 1 September 2023.

235 MACROGOL 400 AND PROPYLENE GLYCOL (new pack size listing)
Eye drops 0.4% with propylene glycol 0.3% preservative free, single dose ..... 10.78 30 Systane Unit Dose
Note – Systane Unit Dose eye drops 0.4% with propylene glycol 0.3% preservative free, single dose, 24 pack to be delisted from 1 June 2023.

VARIOUS

243 CHLORHEXIDINE WITH CETRIMIDE (new listing)
Irrigation soln 0.015% with cetrimide 0.15%, 100 ml bottle.... 155.76 24 Baxter

243 SODIUM CHLORIDE (↑ price)
Irrigation soln 0.9%, 30 ml ampoule ..... 10.00 20 Interpharma
Irrigation soln 0.9%, 1,000 ml bottle ..... 16.10 10 Baxter Sodium Chloride 0.9%

243 WATER (↑ price)
Irrigation soln, 1,000 ml bottle ..... 18.60 10 Baxter Water for Irrigation

Index
Pharmaceuticals and brands

New Zealand
Permit No. 478

Permit

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