Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

July 2022

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 JULY 2022

- Acetylcysteine (Martindale Pharma) inj 200 mg per ml, 10 ml ampoule – new listing and addition of PSS
- Acetylcysteine (DBL Acetylcysteine) inj 200 mg per ml, 10 ml ampoule – to be delisted 1 December 2022
- 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) inj 20 mg per 0.2 ml prefilled syringe – new listing
- Adalimumab (Humira) inj 20 mg per 0.4 ml syringe – to be delisted 1 December 2022
- Amiodarone hydrochloride tab 100 mg and 200 mg (Aratac) and inj 50 mg per ml, 3 ml ampoule (Max Health) – price decrease and addition of PSS
- Antiretrovirals – Non-Nucleoside Reverse Transcriptase Inhibitors, Nucleoside Reverse Transcriptase Inhibitors, Protease Inhibitors and Strand Transfer Inhibitors – amended restriction criteria
- Azacitidine (Azacitidine Dr Reddy's) inj 100 mg vial – amended restriction criteria
- Buprenorphine with naloxone (Buprenorphine Naloxone BNM) tab 2 mg with naloxone 0.5 mg and 8 mg with naloxone 2 mg – price decrease and addition of PSS
- Calcitriol (Calcitriol-AFT) cap 0.25 mcg and 0.5 mcg – price decrease and addition of PSS
- Cefalexin (Cephalexin ABM) cap 500 mg – price increase
- Chloramphenicol (Devatis) eye oint 1%, 5 g – price decrease and addition of PSS
- Compound electrolytes (Electral) powder for oral soln – price decrease and addition of HSS
- Cyclizine lactate (Hameln) inj 50 mg per ml, 1 ml ampoule – price decrease and addition of HSS
- Dihydrocodeine tartrate (DHC Continus) tab long-acting 60 mg – addition of PSS
- Dimethicone lotn 4%, 200 ml (healthE Dimethicone 4% Lotion) and crm 5% tube, 100 g and crm 5% pump bottle, 500 ml (healthE Dimethicone 5%) – price decrease and addition of PSS
- Emtricitabine with tenofovir disoproxil (Tenofovir Disoproxil Emtricitabine Mylan) tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a maleate) – new listing and addition of PSS

Summary of decisions – effective 1 July 2022 (continued)

- Emtricitabine with tenofovir disoproxil (Teva) tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) – to be delisted 1 December 2022
- Emtricitabine with tenofovir disoproxil tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a maleate) (Tenofovir Disoproxil Emtricitabine Mylan) and tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) (Teva) – amended restriction criteria
- Eptifibatide (Mylan) inj 2 mg per ml, 10 ml vial – new listing
- Erythromycin (as lactobionate) (Erythrocin IV) inj 1 g vial – addition of PSS
- Fludrocortisone acetate (Florinef) tab 100 mcg – price decrease and addition of PSS
- Gemtuzumab ozogamicin (Mylotarg) inj 5 mg vial – new listing
- Gentamicin sulphate (Genoptic) eye drops 0.3%, 5 ml – to be delisted 1 August 2023
- Mercaptopurine (Puri-nethol) tab 50 mg – price decrease and addition of PSS
- Metoclopramide hydrochloride (Baxter) inj 5 mg per ml, 2 ml ampoule – new listing and addition of PSS
- Metoclopramide hydrochloride (Pfizer) inj 5 mg per ml, 2 ml ampoule – to be delisted 1 December 2022
- Montelukast (Montelukast Mylan) tab 4 mg, 5 mg and 10 mg – price decrease and addition of PSS
- Morphine hydrochloride (RA-Morph) oral liq 1 mg per ml, 200 ml – price increase
- Multiple Sclerosis Treatments – amended restriction criteria
- Nimodipine (Nimotop) tab 30 mg – addition of PSS
- Nitrofurantoin (Nifuran) tab 50 mg and 100 mg – addition of PSS
- Olopatadine (Olopatadine Teva) eye drops 0.1%, 5 ml – price decrease and addition of PSS
- Oxytocin with ergometrine maleate (Syntometrine) inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule – price increase and addition of PSS
- Palivizumab (Synagis) inj 100 mg per ml, 1 ml vial – amended restriction criteria
- Pramipexole hydrochloride (Ramipex) tab 0.25 mg and 1 mg – price decrease and addition of PSS
- Sodium hyaluronate [hyaluronic acid] inj 18 mg per ml, 0.85 ml syringe (Healon GV Pro), inj 23 mg per ml, 0.6 ml syringe (Healon 5) and inj 10 mg per ml, 0.85 ml syringe (Healon) – addition of PSS

Summary of decisions – effective 1 July 2022 (continued)

- Taliglucerase alfa (Elelyso) inj 200 unit vial – amended restriction criteria
- Tenofovir disoproxil (Tenofovir Disoproxil Mylan) tab 245 mg (300.6 mg as a maleate) – new listing and addition of PSS
- Tenofovir disoproxil (Tenofovir Disoproxil Teva) tab 245 mg (300.6 mg as a succinate) – to be delisted 1 December 2022
- Trastuzumab emtansine (Kadcyla) inj 100 mg vial and 160 mg vial – amended restriction criteria

Changes to General Rules

We have amended some references within restrictions and notes in Section H to reflect the health system reforms that come into effect from 1 July 2022. There are corresponding amendments to the General Rules of the Pharmaceutical Schedule.

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

Restriction for oseltamivir

2 For prophylaxis of influenza in hospitalised patients as part of a ~~DHB hospital~~ **Health NZ Hospital** approved infections control plan.

Restriction for zanamivir

2 For prophylaxis of influenza in hospitalised patients as part of a ~~DHB hospital~~ **Health NZ Hospital** approved infections control plan.

Restriction for etanercept

Initiation – adult-onset Still's disease

1.1.2 The patient has been started on tocilizumab for AOSD in a ~~DHB hospital~~ **Health NZ Hospital** ~~in accordance with the Section H rules~~; and

Restriction for secukinumab

Initiation – severe chronic plaque psoriasis, second-line biologic

1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a ~~DHB hospital~~ **Health NZ Hospital** ~~in accordance with the General Rules of the Pharmaceutical Schedule~~, for severe chronic plaque psoriasis; and

Restriction for tocilizumab

Initiation – Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)

3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a ~~DHB hospital~~ **Health NZ Hospital** ~~in accordance with the Section H rules~~; and

Initiation – adult-onset Still's disease

1.1.2 The patient has been started on tocilizumab for AOSD in a ~~DHB hospital~~ **Health NZ Hospital** ~~in accordance with the General Rules of the Pharmaceutical Schedule~~; and

Restriction for upadacitinib

Initiation – Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)

3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a ~~DHB hospital~~ **Health NZ Hospital** ~~in accordance with the Section H rules~~; and

Note for Food/Fluid Thickeners

While pre-thickened drinks and supplements have not been included in Section H, ~~Public DHB~~ **Health NZ** hospitals may continue to use such products for patients with dysphagia, provided that:

- use was established prior to 1 July 2013; and
- the product has not been specifically considered and excluded by Pharmac; and
- use of the product conforms to any applicable indication restrictions for similar products that are listed in Section H (for example, use of thickened high protein products should be in line with the restriction for high protein oral feed in Section H).

Pharmac intends to make a further decision in relation to pre-thickened drinks and supplements in the future, and will notify of any change to this situation.

Restriction for influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)

2 Patients in a long-stay inpatient mental health care unit or who are compulsorily detained long-term in a forensic unit within a ~~DHB~~ **Health NZ Hospital**.

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

Section H changes to Part II

Effective 1 July 2022

ALIMENTARY TRACT AND METABOLISM

20 TALIGLUCERASE ALFA (amended restriction criteria)

➔Inj 200 unit vial	1,072.00	1	Elelyso

Restricted

Initiation

~~Only for use in patients with approval by the Gaucher Treatment Panel.~~

Metabolic physician

Re-assessment required after 12 months

All of the following:

1 The patient has a diagnosis of symptomatic type 1 or type 3* Gaucher disease confirmed by the demonstration of specific deficiency of glucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis; and

2 Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by enzyme replacement therapy (ERT) or the disease might be reasonably expected to compromise a response to ERT; and

3 Any of the following:

3.1 Patient has haematological complications of Gaucher disease; or

3.2 Patient has skeletal complications of Gaucher disease; or

3.3 Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or

3.4 Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease; or

3.5 Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period; and

4 Taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

Note: Indication marked with * is an unapproved indication.

Continuation

Metabolic physician or any relevant practitioner on the recommendation of a metabolic physician

Re-assessment required after 3 years

All of the following:

1 Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started; and

2 Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and

3 Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and five yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose; and

4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and

5 Patient is adherent with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

25 CALCITRIOL (↓ price and addition of PSS)

Cap 0.25 mcg – **5% DV Dec-22 to 2025**	7.89	100	**Calcitriol-AFT**
Cap 0.5 mcg – **5% DV Dec-22 to 2025**	13.68	100	**Calcitriol-AFT**

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer
Changes to Section H Part II – effective 1 July 2022 (continued)				
BLOOD AND BLOOD FORMING ORGANS				
35	EPTIFIBATIDE (new listing)			
	➔Inj 2 mg per ml, 10 ml vial	180.38	1	Mylan
40	COMPOUND ELECTROLYTES (↓ price and addition of PSS)			
	Powder for oral soln – **5% DV Dec-22 to 2025**	9.53	50	**Electral**
CARDIOVASCULAR SYSTEM				
43	AMIODARONE HYDROCHLORIDE (↓ price and addition of PSS)			
	Tab 100 mg – **5% DV Dec-22 to 2025**	3.49	30	**Aratac**
	Tab 200 mg – **5% DV Dec-22 to 2025**	4.49	30	**Aratac**
	Inj 50 mg per ml, 3 ml ampoule – **5% DV Dec-22 to 2025**	15.22	10	**Max Health**
46	NIMODIPINE (addition of PSS)			
	Tab 30 mg – **5% DV Dec-22 to 2025**	350.00	100	**Nimotop**
DERMATOLOGICALS				
55	DIMETHICONE (↓ price and addition of PSS)			
	Lotn 4% – **5% DV Dec-22 to 2025**	4.25	200 ml	**healthE Dimethicone 4% Lotion**
56	DIMETHICONE (↓ price and addition of PSS)			
	Crm 5% tube – **5% DV Dec-22 to 2025**	1.47	100 g	**healthE Dimethicone 5%**
	Crm 5% pump bottle – **5% DV Dec-22 to 2025**	4.30	500 ml	**healthE Dimethicone 5%**
GENITO-URINARY SYSTEM				
62	OXYTOCIN WITH ERGOMETRINE MALEATE (↑ price and addition of PSS)			
	Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule – **5% DV Dec-22 to 2025**	32.40	5	**Syntometrine**
HORMONE PREPARATIONS				
67	FLUDROCORTISONE ACETATE (↓ price and addition of PSS)			
	Tab 100 mcg – **5% DV Dec-22 to 2025**	11.46	100	**Florinef**
INFECTIONS				
77	CEFALEXIN (↑ price)			
	Cap 500 mg	5.95	20	Cephalexin ABM
79	ERYTHROMYCIN (AS LACTOBIONATE) (addition of PSS)			
	Inj 1 g vial – **5% DV Dec-22 to 2025**	10.00	1	**Erythrocin IV**

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

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

83 NITROFURANTOIN (addition of PSS)

Tab 50 mg – **5% DV Dec-22 to 2024**	22.20	100	**Nifuran**
Tab 100 mg – **5% DV Dec-22 to 2024**	37.50	100	**Nifuran**

89 Antiretrovirals (amended restriction criteria – affected criteria shown only)
Non-Nucleoside Reverse Transcriptase Inhibitors

Initiation – Post-exposure prophylaxis following ~~non-occupational~~ exposure to HIV
Both:

1 Treatment course to be initiated within 72 hours post exposure; and
2 Any of the following:
   - 2.1 Patient has had **condomless** ~~unprotected receptive~~ anal intercourse **or receptive vaginal intercourse** with a known HIV positive person **with an unknown or detectable viral load greater than 200 copies per ml;** or
   - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
   - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required**; or**
   - **2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.**

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm.org.au/hiv/hiv-management/pep/).

89 Antiretrovirals (amended restriction criteria – affected criteria shown only)
Nucleoside Reverse Transcriptase Inhibitors

Initiation – Post-exposure prophylaxis following ~~non-occupational~~ exposure to HIV
Both:

1 Treatment course to be initiated within 72 hours post exposure; and
2 Any of the following:
   - 2.1 Patient has had **condomless** ~~unprotected receptive~~ anal intercourse **or receptive vaginal intercourse** with a known HIV positive person **with an unknown or detectable viral load greater than 200 copies per ml;** or
   - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
   - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required**; or**
   - **2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.**

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm.org.au/hiv/hiv-management/pep/).

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

90 Antiretrovirals (amended restriction criteria – affected criteria shown only)
Protease Inhibitors

Initiation – Post-exposure prophylaxis following ~~non-occupational~~ exposure to HIV
Both:
1 Treatment course to be initiated within 72 hours post exposure; and
2 Any of the following:
- 2.1 Patient has had **condomless** ~~unprotected receptive~~ anal intercourse **or receptive vaginal intercourse** with a known HIV positive person **with an unknown or detectable viral load greater than 200 copies per ml;** or
- 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
- 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required**; or**
- **2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.**

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm.org.au/hiv/hiv-management/pep/).

91 Antiretrovirals (amended restriction criteria – affected criteria shown only)
Strand Transfer Inhibitors

Initiation – Post-exposure prophylaxis following ~~non-occupational~~ exposure to HIV
Both:
1 Treatment course to be initiated within 72 hours post exposure; and
2 Any of the following:
- 2.1 Patient has had **condomless** ~~unprotected receptive~~ anal intercourse **or receptive vaginal intercourse** with a known HIV positive person **with an unknown or detectable viral load greater than 200 copies per ml;** or
- 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
- 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required**; or**
- **2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.**

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm.org.au/hiv/hiv-management/pep/).

92 TENOFOVIR DISOPROXIL (new listing and addition of PSS)
Tab 245 mg (300.6 mg as a maleate)
– **5% DV Dec-22 to 2025** ..... 15.00 30 **Tenofovir Disoproxil Mylan**

Note – Tenofovir Disoproxil Teva tab 245 mg (300.6 mg as a succinate) to be delisted from 1 December 2022.

93 EMTRICITABINE WITH TENOFOVIR DISOPROXIL (new listing and addition of PSS)
➔ Tab 200 mg with tenofovir disoproxil 245 mg
(300.6 mg as a maleate) – **5% DV Dec-22 to 2025** ..... 15.45 30 **Tenofovir Disoproxil Emtricitabine Mylan**

Note – Teva tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) to be delisted from 1 December 2022.

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

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

93 EMTRICITABINE WITH TENOFOVIR DISOPROXIL (amended restriction criteria – affected criteria shown only)

➔ Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a maleate) – **5% DV Dec-22 to 2025**	15.45	30	**Tenofovir Disoproxil Emtricitabine Mylan**
➔ Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate)	61.15		Teva

Restricted

Initiation – Pre-exposure prophylaxis

Re-assessment required after 3 ***24*** *months*

~~All of the following~~ **Both**:

~~1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and~~

~~2 Patient has undergone testing for HIV, syphilis and Hep B if not immune and a full STI screen in the previous two weeks; and~~

~~3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 3 months and is not contraindicated for treatment; and~~

~~4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and~~

5~~1~~ Patient has tested HIV negative ~~and is not at risk of HIV seroconversion~~**, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion**; and

~~6 Either:~~

~~6.1 All of the following:~~

~~6.1.1 Patient is male or transgender; and~~

~~6.1.2 Patient has sex with men; and~~

~~6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and~~

~~6.1.4 Any of the following:~~

~~6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or~~

~~6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or~~

~~6.1.4.3 Patient has used methamphetamine in the last three months; or~~

~~6.2 All of the following:~~

~~6.2.1 Patient has a regular partner who has HIV infection; and~~

~~6.2.2 Partner is either not on treatment or has a detectable viral load; and~~

~~6.2.3 Condoms have not been consistently used.~~

2 The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate.

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines (https://ashm.org.au/HIV/PrEP/)

Continuation – Pre-exposure prophylaxis

Re-assessment required after 3 ***24*** *months*

~~All of the following~~ **Both**:

~~1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and~~

~~2 Patient has undergone testing for HIV, syphilis and Hep B if not immune and a full STI screen in the previous two weeks; and~~

~~3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months and is not contraindicated for treatment; and~~

continued...

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

continued...

~~4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and~~

~~5~~**1** Patient has tested HIV negative ~~and is not at risk of HIV seroconversion~~**, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion**; and

~~6 Either:~~

~~6.1 All of the following:~~

~~6.1.1 Patient is male or transgender; and~~

~~6.1.2 Patient has sex with men; and~~

~~6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and~~

~~6.1.4 Any of the following:~~

~~6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or~~

~~6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or~~

~~6.1.4.3 Patient has used methamphetamine in the last three months; or~~

~~6.2 All of the following:~~

~~6.2.1 Patient has a regular partner who has HIV infection; and~~

~~6.2.2 Partner is either not on treatment or has a detectable viral load; and~~

~~6.2.3 Condoms have not been consistently used.~~

2 The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate.

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for (https://ashm.org.au/HIV/PrEP/)

NERVOUS SYSTEM

109	PRAMIPEXOLE HYDROCHLORIDE (↓ price and addition of PSS)			
	Tab 0.25 mg – **5% DV Dec-22 to 2025**	5.51	100	**Ramipex**
	Tab 1 mg – **5% DV Dec-22 to 2025**	18.66	100	**Ramipex**
114	DIHYDROCODEINE TARTRATE (addition of PSS)			
	Tab long-acting 60 mg – **5% DV Dec-22 to 2025**	8.60	60	**DHC Continus**
114	MORPHINE HYDROCHLORIDE (↑ price)			
	Oral liq 1 mg per ml	11.98	200 ml	RA-Morph
121	CYCLIZINE LACTATE (↓ price and addition of PSS)			
	Inj 50 mg per ml, 1 ml ampoule – **5% DV Dec-22 to 2025**	16.36	10	**Hameln**
122	METOCLOPRAMIDE HYDROCHLORIDE (new listing and addition of PSS)			
	Inj 5 mg per ml, 2 ml ampoule – **5% DV Dec-22 to 2025**	7.00	10	**Baxter**
	Note – Pfizer inj 5 mg per ml, 2 ml ampoule to be delisted from 1 December 2022.			

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

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

126 Multiple Sclerosis Treatments (amended restriction criteria)

Initial application – (Multiple sclerosis)
Neurologist or general physician
Re-assessment required after 12 months
All of the following:

1 Diagnosis of multiple sclerosis (MS) **meets the McDonald 2017 diagnostic criteria for MS and has been** ~~be~~ confirmed by a neurologist~~. Diagnosis must include MRI confirmation~~; and
~~2 Patients must have Clinically Definite Relapsing multiple sclerosis with or without underlying progression; and~~
2 Patient ~~must have~~ **has** an EDSS score 0 - 6.0; and
3 Patient has had at least one significant **attack** ~~relapse~~ of MS in the previous 12 months or two significant **attacks** ~~relapses~~ in the past 24 months; and
4 All of the following:
  4.1 Each significant **attack** ~~relapse~~ must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the **attack** ~~relapse~~, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
  4.2 Each significant **attack** ~~relapse~~ is associated with characteristic symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
  4.3 Each significant **attack** ~~relapse~~ has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
  4.4 Each significant **attack** ~~relapse~~ can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and
  4.5 Either:
    4.5.1 Each significant **attack** ~~relapse~~ is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
    4.5.2 Each significant **attack** ~~relapse~~ is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
5 Evidence of new inflammatory activity on an MR**I** scan within the past 24 months; and
6 Any of the following:
  6.1 A sign of that new inflammatory activity **on MRI scanning (in criterion 5 immediately above)** is a gadolinium enhancing lesion; or
  6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
  6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
  6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent **attack** ~~relapse~~ that occurred within the last 2 years; or
  6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MR**I** scan.

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

Continuation – Multiple sclerosis
Neurologist or general physician
Patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use unilateral or bilateral aids at any time in the last six months (i.e. the patient has walked 100 metres or more with or without aids in the last six months).

131 BUPRENORPHINE WITH NALOXONE (↓ price and addition of PSS)

➔ Tab 2 mg with naloxone 0.5 mg – **5% DV Dec-22 to 2025**	11.76	28	**Buprenorphine Naloxone BNM**
➔ Tab 8 mg with naloxone 2 mg – **5% DV Dec-22 to 2025**	34.00	28	**Buprenorphine Naloxone BNM**

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

135 AZACITIDINE (amended restriction criteria)

➔Inj 100 mg vial – **5% DV Dec-21 to 2024** ..... 75.06 1 **Azacitidine Dr Reddy's**

Restricted
Initiation
Haematologist
Re-assessment required after 12 months
All of the following:
1 Any of the following:
  1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
  1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
  1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
2 The patient has performance status (WHO/ECOG) grade 0-2; and
~~3 The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and~~
3 The patient has an estimated life expectancy of at least 3 months

Continuation
Haematologist or medical practitioner on the recommendation of a haematologist
Re-assessment required after 12 months
Both:
1 No evidence of disease progression; and
2 The treatment remains appropriate and patient is benefitting from treatment.

136 MERCAPTOPURINE (↓ price and addition of PSS)

Tab 50 mg – **5% DV Dec-22 to 2025** ..... 25.90 25 **Puri-nethol**

161 GEMTUZUMAB OZOGAMICIN (new listing)

➔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 and cytarabine (AraC); and
8 Gemtuzumab ozogamicin to be funded for one course only; and
9 Either:
  9.1 Gemtuzumab ozogamicin to be administered as one dose at 3 mg per m^2 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).

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

161 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 – Behcet's disease - severe
Any relevant practitioner
Either:
1 The patient has previously had an approval for Humira; or
2 Both:
2.1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
2.2 Either:
2.2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
2.2.2 The patient has severe gastrointestinal, rheumatological and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).
Note: Indications marked with * are unapproved indications.

Initiation – Hidradenitis suppurativa
Dermatologist
Re-assessment required after 4 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
2.2 Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or patient has demonstrated intolerance to or has contraindications for systemic antibiotics; and
2.3 Patient has 3 or more active lesions; and
2.4 The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

Initiation – Plaque psoriasis - severe chronic
Dermatologist
Re-assessment required after 4 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
2.1 Both:
2.1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
2.1.2 Either:
2.1.2.1 Patient has experienced intolerable side effects; or
2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or

continued...

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

continued...

2.2 All of the following:
2.2.1 Either:
2.2.1.1 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
2.2.1.2 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
2.2.2 Patient has tried, but had an inadequate response 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
2.2.3 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.

Initiation – pyoderma gangrenosum
Dermatologist
Either:
1 The patient has previously had an approval for Humira; or
2 Both:
2.1 Patient has pyoderma gangrenosum*; and
2.2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response.
Note: Indications marked with * are unapproved indications.

Initiation – Crohn's disease - adults
Gastroenterologist
Re-assessment required after 3 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has severe active Crohn's disease; and
2.2 Any of the following:
2.2.1 Patient has a CDAI score of greater than or equal to 300 or HBI score of greater than or equal to 10; or
2.2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
2.2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
2.2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initiation – Crohn's disease - children
Gastroenterologist
Re-assessment required after 3 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Paediatric patient has severe active Crohn's disease; and
2.2 Either:
2.2.1 Patient has a PCDAI score of greater than or equal to 30; or
2.2.2 Patient has extensive small intestine disease; and

continued...

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

continued...

2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initiation – Crohn's disease - fistulising
Gastroenterologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has confirmed Crohn's disease; and
2.2 Any of the following:
2.2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
2.2.2 Patient has one or more rectovaginal fistula(e); or
2.2.3 Patient has complex peri-anal fistula; and
2.3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

Initiation – Ocular inflammation - chronic
Any relevant practitioner
Re-assessment required after 4 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
2.1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
2.2 Both:
2.2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
2.2.2 Any of the following:
2.2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
2.2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
2.2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

Initiation – Ocular inflammation - severe
Any relevant practitioner
Re-assessment required after 4 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
2.1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
2.2 Both:
2.2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
2.2.2 Any of the following:
2.2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
2.2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
2.2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

continued...

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

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

continued...

Initiation – ankylosing spondylitis
Rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
- 2.1 Both:
  - 2.1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
  - 2.1.2 Either:
    - 2.1.2.1 The patient has experienced intolerable side effects; or
    - 2.1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
- 2.2 All of the following:
  - 2.2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
  - 2.2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
  - 2.2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.2.5 Either:
    - 2.2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
    - 2.2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender; and
  - 2.2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

Initiation – Arthritis - oligoarticular course juvenile idiopathic
Named specialist or rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
- 2.1 Both:
  - 2.1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
  - 2.1.2 Either:
    - 2.1.2.1 Patient has experienced intolerable side effects; or
    - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or
- 2.2 All of the following:
  - 2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
  - 2.2.3 Either:
    - 2.2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose).

continued...

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

continued...

Initiation – Arthritis - polyarticular course juvenile idiopathic
Named specialist or rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
- 2.1 Both:
  - 2.1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
  - 2.1.2 Either:
    - 2.1.2.1 Patient has experienced intolerable side effects; or
    - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
- 2.2 All of the following:
  - 2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
  - 2.2.3 Any of the following:
    - 2.2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6- month trial of methotrexate.

Initiation – Arthritis - psoriatic
Rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
- 2.1 Both:
  - 2.1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
  - 2.1.2 Either:
    - 2.1.2.1 Patient has experienced intolerable side effects; or
    - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis; or
- 2.2 All of the following:
  - 2.2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
  - 2.2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
  - 2.2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
  - 2.2.4 Either:
    - 2.2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    - 2.2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

continued...

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

continued...

2.2.5 Any of the following:
2.2.5.1 Patient has CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
2.2.5.2 Patient has an elevated ESR greater than 25 mm per hour; or
2.2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initiation – Arthritis - rheumatoid
Rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
2.1 Both:
2.1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
2.1.2 Either:
2.1.2.1 The patient has experienced intolerable side effects; or
2.1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or
2.2 All of the following:
2.2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
2.2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
2.2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated); and
2.2.5 Either:
2.2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
2.2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
2.2.6 Either:
2.2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
2.2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

Initiation – Still's disease - adult-onset (AOSD)
Rheumatologist
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
2.1 Both:
2.1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for (AOSD); and
2.1.2 Either:
2.1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
2.1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or

continued...

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

continued...

2.2 All of the following:
2.2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
2.2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and
2.2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initiation – ulcerative colitis
~~Rheumatologist~~ **Gastroenterologist**
Re-assessment required after 3 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has histologically confirmed active ulcerative colitis; and
2.2 Either:
2.2.1 Patient's SCCAI score is greater than or equal to 4; or
2.2.2 Patient's PUCAI score is greater than or equal to 65; and
2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids; and
2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initiation – undifferentiated spondyloarthiritis
Rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
2.2 Patient has tried and not responded to at least three months of each of methotrexate, sulphasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
2.3 Any of the following:
2.3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
2.3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
2.3.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.
Note: Indications marked with * are unapproved indications.

Initiation – inflammatory bowel arthritis – axial
Rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2.2 Patient has axial inflammatory pain for six months or more; and
2.3 Patient is unable to take NSAIDs; and
2.4 Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
2.5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

continued...

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

continued...

Initiation – inflammatory bowel arthritis – peripheral
Rheumatologist
Re-assessment required after 6 months
Either:
1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2.2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
2.3 Patient has tried and not responded to at least three months of methotrexate, or azathioprine at a maximum tolerated dose; and
2.4 Patient has tried and not responded to at least three months of sulphasalazine at a maximum tolerated dose; and
2.5 Any of the following:
2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
2.5.2 Patient has an ESR greater than 25 mm per hour; or
2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

171	ADALIMUMAB (HUMIRA) (new listing)			
	➔ Inj 20 mg per 0.2 ml prefilled syringe	1,599.96	2	Humira

171	ADALIMUMAB (HUMIRA) (delisting)			
	➔ Inj 20 mg per 0.4 ml syringe	1,599.96	2	Humira

Note – Humira inj 20 mg per 0.4 ml syringe to be delisted from 1 December 2022.

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

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

199 PALIVIZUMAB (amended restriction criteria – affected criteria shown only)

➔ Inj 100 mg per ml, 1 ml vial	1,700.00	1	Synagis

Initiation – RSV prophylaxis for the 2022/2023 RSV seasons, in the context of COVID-19
Paediatrician
Re-assessment required after 6 months
Either:

1 Infant was born in the last 2 years and has severe lung, airway, neurological or neuromuscular disease that requires **ongoing, life-sustaining** community ventilation; or
2 Both:
  2.1 Infant was born in the last 12 months; and
  2.2 Any of the following:
    2.2.1 Patient was born at less than 28 weeks gestation; or
    2.2.2 Both:
      2.2.2.1 Patient was born at less than 32 weeks gestation; and
      2.2.2.2 Either:
        2.2.2.2.1 Patient has chronic lung disease; or
        2.2.2.2.2 Patient is Māori or any Pacific ethnicity; or
    2.2.3 Both:
      2.2.3.1 Patient has haemodynamically significant heart disease; and
      2.2.3.2 Any of the following:
        2.2.3.2.1 Patient has unoperated simple congenital heart disease with significant left to right shunt (see note a); or
        2.2.3.2.2 Patient has unoperated or surgically palliated complex congenital heart disease; or
        2.2.3.2.3 Patient has severe pulmonary hypertension (see note b); or
        2.2.3.2.4 Patient has moderate or severe LV failure (see note c).

Notes:

a) Patient requires/will require heart failure medication, and/or patient has significant pulmonary hypertension, and/or patient will require surgical palliation/definitive repair within the next 3 months.
b) Mean pulmonary artery pressure more than **25**~~45~~ mmHg.
c) LV Ejection Fraction less than 40%.

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

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

209 TRASTUZUMAB EMTANSINE (amended restriction criteria)

➔Inj 100 mg vial	2,320.00	1	Kadcyla
➔Inj 160 mg vial	3,712.00	1	Kadcyla

Restricted

Initiation – early breast cancer

All of the following:

1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and

2 Documentation of pathological invasive residual disease in the breast and/or auxiliary lymph nodes following completion of surgery; and

3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and

4 Disease has not progressed during neoadjuvant therapy; and

5 Patient has left ventricular ejection fraction of 45% or greater; and

6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and

7 Trastuzumab emtansine to be discontinued at disease progression; and

8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

Initiation – **metastatic breast cancer**

Re-assessment required after 6 months

All of the following:

1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and

2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and

3 Either:

3.1 The patient has received prior therapy for metastatic disease*; or

3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and

4 Patient has a good performance status (ECOG 0-1); and

5 Either:

5.1 Patient does not have symptomatic brain metastases; or

5.2 Patient has brain metastases and has received prior local CNS therapy; and

6 **Patient has not received prior funded trastuzumab emtansine treatment; and**

7 Treatment to be discontinued at disease progression.

Continuation – **metastatic breast cancer**

Re-assessment required after 6 months

Both:

1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and

2 Treatment to be discontinued at disease progression.

Note: *Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

RESPIRATORY SYSTEM AND ALLERGIES

222 MONTELUKAST (↓ price and addition of PSS)

Tab 4 mg – **5% DV Dec-22 to 2025**	3.10	28	**Montelukast Mylan**
Tab 5 mg – **5% DV Dec-22 to 2025**	3.10	28	**Montelukast Mylan**
Tab 10 mg – **5% DV Dec-22 to 2025**	2.90	28	**Montelukast Mylan**

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

SENSORY ORGANS

224 GENTAMICIN SULPHATE (delisting)
Eye drops 0.3% ..... 11.40 5 ml Genoptic
Note – Genoptic eye drops 0.3%, brand only to be delisted from 1 August 2023.

225 CHLORAMPHENICOL (↓ price and addition of PSS)
Eye oint 1% – **5% DV Dec-22 to 2025** ..... 1.09 5 g **Devatis**

227 OLOPATADINE (↓ price and addition of PSS)
Eye drops 0.1% – **5% DV Dec-22 to 2025** ..... 2.17 5 ml **Olopatadine Teva**

228 SODIUM HYALURONATE [HYALURONIC ACID] (addition of PSS)
Inj 18 mg per ml, 0.85 ml syringe
– **5% DV Dec-22 to 2025**..... 50.00 1 **Healon GV Pro**
Inj 23 mg per ml, 0.6 ml syringe
– **5% DV Dec-22 to 2025**..... 60.00 1 **Healon 5**
Inj 10 mg per ml, 0.85 ml syringe
– **5% DV Dec-22 to 2025**..... 28.50 1 **Healon**

VARIOUS

232 ACETYLCYSTEINE (new listing and addition of PSS)
Inj 200 mg per ml, 10 ml ampoule
– **5% DV Dec-22 to 2024**..... 52.88 10 **Martindale Pharma**
Note – DBL Acetylcysteine inj 200 mg per ml, 10 ml ampoule to be delisted from 1 December 2022.

New Zealand
Permit No. 478

Permit

Pharmaceutical Management Agency
Level 9, 40 Mercer Street, PO Box 10254, Wellington 6143, New Zealand
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