Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

March 2022

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 MARCH 2022

- Adalimumab (Amgevita) inj 20 mg per 0.4 ml prefilled syringe, inj 40 mg per 0.8 ml prefilled pen and syringe – new listing
- Adalimumab (Humira) inj 20 mg per 0.4 ml syringe, inj 40 mg per 0.8 ml pen and syringe – amended chemical name and restriction criteria - initiation criteria removed
- Alprostadil hydrochloride (Prostin VR) inj 500 mcg per ml, 1 ml ampoule – price increase
- Antithymocyte globulin (equine) (ATGAM) inj 50 mg per ml, 5 ml ampoule – price increase
- Atenolol (Atenolol-AFT) oral liq 5 mg per ml, 300 ml – price increase
- Azithromycin (Zithromax) grans for oral liq 200 mg per 5 ml (40 mg per ml), 15 ml – price increase
- Benzathine benzylpenicillin (Bicillin LA) inj 900 mg (1.2 million units) in 2.3 ml syringe – price increase
- Bleomycin sulphate (DBL Bleomycin Sulfate) inj 15,000 iu vial – price increase
- Desferrioxamine mesilate (DBL Desferrioxamine Mesylate for Inj BP) inj 500 mg vial – price increase
- Erythromycin (as ethylsuccinate) (E-Mycin) grans for oral liq 200 mg per 5 ml (Pharmacode 2618877), 400 mg per 5 ml, 100 ml (Pharmacode 2618869) – new Pharmacode listing
- Etanercept (Enbrel) inj 25 mg autoinjector, vial and inj 50 mg autoinjector, syringe – amended restriction criteria
- Ethinyloestradiol (NZ Medical and Scientific) tab 10 mcg – addition of restriction and delisting
- Ferrous fumarate with folic acid (Ferro-F-Tab) tab 310 mg (100 mg elemental) with folic acid 350 mcg, 100 tab pack – new listing and addition of PSS
- Ferrous fumarate with folic acid (Ferro-F-Tab) tab 310 mg (100 mg elemental) with folic acid 350 mcg, 60 tab pack – to be delisted 1 August 2022
- Flucortolone caproate with flucortolone pivalate and cinchocaine (Ultraproct) oint 950 mcg with flucortolone pivalate 920 mcg and cinchocaine hydrochloride 5 mg per g, 30 g and suppos 630 mcg with flucortolone pivalate 610 mcg and cinchocaine hydrochloride 1 mg – price increase
- Glyceryl trinitrate (Hospira) inj 5 mg per ml, 10 ml ampoule – price increase
- Heparin sodium (Pfizer) in 1,000 iu per ml and 5,000 iu per ml, 5 ml ampoule – price increase

Summary of decisions – effective 1 March 2022 (continued)

- High protein oral feed 2.4 kcal/ml (e.g. Fortisip Compact Protein) liquid 14.6 g protein, 25.3 g carbohydrate and 9.6 g fat per 100 ml, 125 ml bottle – new listing
- Hydroxocobalamin (Neo-B12) inj 1 mg per ml, 1 ml ampoule – price increase
- Idarubicin hydrochloride (Zavedos) inj 5 mg and 10 mg vial – price increase
- Influenza vaccine (Afluria Quad Junior (2022 Formulation)) inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) – new listing
- Influenza vaccine (Afluria Quad Junior (2021 Formulation)) inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) – delisted 1 March 2022
- Influenza vaccine (Afluria Quad (2022 Formulation)) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) – new listing and amended restriction criteria
- Influenza vaccine (Flurad Quad (2021 Formulation)) inj 60 mcg in 0.5 ml syringe (adjuvanted quadrivalent vaccine) – delisted 1 March 2022
- Influenza vaccine (Influvac Tetra (2021 Formulation)) inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) – delisted 1 March 2022
- Influenza vaccine (Afluria Quad (2021 Formulation)) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) – delisted 1 March 2022
- Iohexol (Omnipaque) inj 350 mcg per ml, 500 ml bottle – new listing
- Isoflurane (Aerrane) soln for inhalation 100%, 250 ml bottle – increase price
- Low electrolyte oral feed 2 kcal/ml (Novasource Renal (Vanilla)) liquid 9.1 g protein, 19 g carbohydrate and 10 g fat per 100 ml, 200 ml bottle – new listing
- Low electrolyte oral feed 2 kcal/ml (Novasource Renal (Vanilla)) liquid 9.1 g protein, 19 g carbohydrate and 10 g fat per 100 ml, carton, 237 ml – to be delisted 1 September 2022
- Methylprednisolone acetate (Depo-Medrol) inj 40 mg per ml, 1 ml vial – price increase
- Methylprednisolone (as sodium succinate) tab 100 mg (Medrol), inj 40 mg, 125 mg and 500 mg vial (Solu-Medrol Act-O-Vial) and inj 1 g vial (Solu-Medrol) – price increase
- Mitomycin C inj 5 mg vial – new listing
- Norfloxacin (Arrow-Norfloxacin) tab 400 mg – price increase
- Oil in water emulsion (healthE Fatty Cream) crm, 100 g – price increase, addition of PSS and addition of note
- Oral feed (Sustagen Hospital Formula (chocolate) and Sustagen Hospital Formula (vanilla)) powder 23 g protein, 65 g carbohydrate and 2.5 g fat per 100 g, can – brand name change

Summary of decisions – effective 1 March 2022 (continued)

- Papaverine hydrochloride (Hospira) inj 12 mg per ml, 10 ml ampoule – price increase
- Paracetamol (Gacet) suppos 125 mg and 250 mg – price increase
- Paroxetine (Loxamine) tab 20 mg (Pharmacode 2626799) – new Pharmacode listing
- Phenytoin sodium (Hospira) inj 50 mg per ml, 2 ml ampoule and 5 ml ampoule – price increase
- Potassium dihydrogen phosphate (Hospira) inj 1 mmol per ml, 10 ml ampoule – price increase
- Propamidine isethionate eye drops 0.1% – to be delisted 1 April 2022
- Promethazine hydrochloride (Allersoothe) tab 10 mg, 25 mg and oral liq 1 mg per ml – price increase
- Sevoflurane (Baxter) soln for inhalation 100%, 250 ml bottle – increase price
- Sodium alginate with sodium bicarbonate and calcium carbonate (Acidex) oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml – price increase
- Sugammadex (Sugammadex BNM) inj 100 mg per ml, 2 ml vial and 5 ml vial – new listing and addition of PSS
- Sugammadex (Bridion) inj 100 mg per ml, 2 ml vial and 5 ml vial – to be delisted 1 August 2022
- Varicella zoster vaccine [shingles vaccine] (Zostavax) varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine] – amended restriction criteria
- Voriconazole (Vfend) powder for oral suspension 40 mg per ml – price increase

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

Section H changes to Part II

Effective 1 March 2022

ALIMENTARY TRACT AND METABOLISM

5	SODIUM ALGINATE WITH SODIUM BICARBONATE AND CALCIUM CARBONATE (↑ price)			
	Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml	5.50	500 ml	Acidex
7	FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE (↑ price)			
	Oint 950 mcg with fluocortolone pivalate 920 mcg and cinchocaine hydrochloride 5 mg per g	11.06	30 g	Ultraproct
	Suppos 630 mcg with fluocortolone pivalate 610 mcg and cinchocaine hydrochloride 1 mg	7.30	12	Ultraproct
21	FERROUS FUMARATE WITH FOLIC ACID (pack size change and addition of PSS)			
	Tab 310 mg (100 mg elemental) with folic acid 350 mcg			
	– **5% DV Aug-22 to 2024**	5.98	100	**Ferro-F-Tabs**
	Note – Ferro-F-Tabs 60 tab pack (Pharmacode 2219476) to be delisted 1 August 2022.			
24	HYDROXOCOBALAMIN (↑ price)			
	Inj 1 mg per ml, 1 ml ampoule	2.84	3	Neo-B12

BLOOD AND BLOOD FORMING ORGANS

34	HEPARIN SODIUM (↑ price)			
	Inj 1,000 iu per ml, 5 ml ampoule	72.84	50	Pfizer
	Inj 5,000 iu per ml, 5 ml ampoule	289.05	50	Pfizer
39	POTASSIUM DIHYDROGEN PHOSPHATE (↑ price)			
	Inj 1 mmol per ml, 10 ml ampoule	174.57	10	Hospira

CARDIOVASCULAR SYSTEM

44	ATENOLOL (↑ price)			
	Oral liq 5 mg per ml	49.85	300 ml	Atenolol-AFT
50	GLYCERYL TRINITRATE (↑ price)			
	Inj 5 mg per ml, 10 ml ampoule	118.00	5	Hospira
51	ALPROSTADIL HYDROCHLORIDE (↑ price)			
	Inj 500 mcg per ml, 1 ml ampoule	2,030.33	5	Prostin VR
52	PAPAVERINE HYDROCHLORIDE (↑ price)			
	Inj 12 mg per ml, 10 ml ampoule	257.12	5	Hospira

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

DERMATOLOGICALS

58 OIL IN WATER EMULSION (↑ price, addition of PSS and addition of note)

Crm, 100 g – **5% DV Aug-22 to 2024**	1.59	1	**healthE Fatty Cream**

Note: DV limit applies to the pack sizes of 100 g or less.

HORMONE PREPARATIONS

69 METHYLPREDNISOLONE (AS SODIUM SUCCINATE) (↑ price)

Tab 100 mg	223.10	20	Medrol
Inj 40 mg vial	22.30	1	Solu-Medrol Act-O-Vial
Inj 125 mg vial	34.10	1	Solu-Medrol Act-O-Vial
Inj 500 mg vial	26.88	1	Solu-Medrol Act-O-Vial
Inj 1 g vial	32.84	1	Solu-Medrol

69 METHYLPREDNISOLONE ACETATE (↑ price)

Inj 40 mg per ml, 1 ml vial	47.06	5	Depo-Medrol

70 ETHINYLOESTRADIOL – **Restricted: For continuation only** (addition of restriction and delisting)

➔ Tab 10 mcg	17.60	100	NZ Medical and Scientific

Note – NZ Medical and Scientific tab 10 mcg to be delisted 1 February 2023.

INFECTIONS

79 AZITHROMYCIN (↑ price)

➔ Grans for oral liq 200 mg per 5 ml (40 mg per ml)	16.97	15 ml	Zithromax

80 ERYTHROMYCIN (AS ETHYLSUCCINATE) (new Pharmacode listing)

Grans for oral liq 200 mg per 5 ml	5.00	100 ml	E-Mycin
Grans for oral liq 400 mg per 5 ml	6.77	100 ml	E-Mycin

Note – E-Mycin grans for oral liq 200 mg per 5 ml new listing for Pharmacode 2618877. E-Mycin grans for oral liq 400 mg per 5 ml new listing for Pharmacode 2618869.

81 BENZATHINE BENZYLPENICILLIN (↑ price)

Inj 900 mg (1.2 million units) in 2.3 ml syringe	375.97	10	Bicillin LA

82 NORFLOXACIN (↑ price)

Tab 400 mg	245.00	100	Arrow-Norfloxacin

86 VORICONAZOLE (↑ price)

➔ Powder for oral suspension 40 mg per ml	1,523.22	70 ml	Vfend

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

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

MUSCULOSKELETAL SYSTEM

106 SUGAMMADEX (brand change and addition of PSS)

➔Inj 100 mg per ml, 2 ml vial – **5% DV Aug-22 to 2024**	384.00	10	**Sugammadex BNM**
➔Inj 100 mg per ml, 5 ml vial – **5% DV Aug-22 to 2024**	960.00	10	**Sugammadex BNM**

Note – Bridion inj 100 mg per ml, 2 ml vial and 5 ml vial to be delisted 1 August 2022.

NERVOUS SYSTEM

110 ISOFLURANE (↑ price)

Soln for inhalation 100%, 250 ml bottle	2,730.00	6	Aerrane

111 SEVOFLURANE (↑ price)

Soln for inhalation 100%, 250 ml bottle	930.00	6	Baxter

114 PARACETAMOL (↑ price)

Suppos 125 mg	3.59	10	Gacet
Suppos 250 mg	4.18	10	Gacet

117 PAROXETINE (new Pharmacode listing)

Tab 20 mg – **1% DV Mar-20 to 2022**	3.61	90	**Loxamine**

Note – this listing is for Pharmacode 2626799.

118 PHENYTOIN SODIUM (↑ price)

Inj 50 mg per ml, 2 ml ampoule	104.58	5	Hospira
Inj 50 mg per ml, 5 ml ampoule	154.01	5	Hospira

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

135 BLEOMYCIN SULPHATE (↑ price)

Inj 15,000 iu vial	185.16	1	DBL Bleomycin Sulfate

136 IDARUBICIN HYDROCHLORIDE (↑ price)

Inj 5 mg vial	109.74	1	Zavedos
Inj 10 mg vial	233.64	1	Zavedos

137 MITOMYCIN C (new listing)

Inj 5 mg vial

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

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

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

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

Restricted
Initiation — ~~rheumatoid a~~**Arthritis - rheumatoid**
Rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
  1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
  1.2 Either:
    1.2.1 The patient has experienced intolerable side effects ~~from adalimumab~~; or
    1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for ~~adalimumab for~~ rheumatoid arthritis; or
2 All of the following:
  2.1 Patient has had ~~severe and active erosive~~ 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 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  2.3 Patient has tried and not responded to at least three months of ~~oral or parenteral~~ methotrexate at ~~a dose of at least 20 mg weekly or~~ a maximum tolerated dose **(unless contraindicated)**; and
  2.4 Patient has tried and not responded to at least three months of ~~oral or parenteral~~ methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses **(unless contraindicated)**; and
  2.5 ~~Any of the following~~ **Either**:
    2.5.1 Patient has tried and not responded to at least three months of ~~oral or parenteral~~ methotrexate in combination with the maximum tolerated dose of ciclosporin; or
    ~~2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or~~
    2.5.2~~2.5.3~~ 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 ~~oral or parenteral~~ methotrexate; and
  2.6 Either:
    2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least ~~20~~ **15** swollen~~, tender~~ joints; or
    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. ~~; and~~
  ~~2.7 Either:~~
    ~~2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or~~
    ~~2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.~~

Continuation — ~~rheumatoid a~~**Arthritis - rheumatoid**
Any relevant practitioner ~~Rheumatologist~~
*Re-assessment required after **2 years** ~~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

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

continued...

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 Etanercept to be administered at doses no greater than 50 mg every 7 days.

163 ADALIMUMAB (AMGEVITA) (new listing)

➔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
Both:
1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
2 Either:
  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 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
All of the following:
1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
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
3 Patient has 3 or more active lesions; and
4 The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

Continuation — Hidradenitis suppurativa
Any relevant practitioner
Re-assessment required after 2 years
Both:
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 DLQI improvement of 4 or more from baseline.

Initiation — Plaque psoriasis - severe chronic
Dermatologist
Re-assessment required after 4 months
Either:
1 Both:
  1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and

continued...

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

continued...

1.2 Either:
1.2.1 Patient has experienced intolerable side effects; or
1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or

2 All of the following:
2.1 Either:
2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
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
2.3 A PASI assessment or (DLQI) assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

Continuation — Plaque psoriasis - severe chronic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Both:
1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
1.2 Either:
1.2.1 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
1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or

2 Both:
2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
2.2 Either:
2.2.1 The patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
2.2.2 The patient has 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.

Initiation — pyoderma gangrenosum
Dermatologist
Both:
1 Patient has pyoderma gangrenosum*; and
2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response.
Note: Indications marked with * are unapproved indications.

Initiation — Crohn's disease - adults
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1 Patient has active Crohn's disease; and

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

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2 Any of the following:
  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 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
  2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation — Crohn's disease – adults
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced 3 points, from when the patient was initiated on adalimumab; or
2 CDAI score is 150 or less, or HBI is 4 or less; or
3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

Initiation — Crohn's disease - children
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1 Paediatric patient has active Crohn's disease; and
2 Either:
  2.1 Patient has a (PCDAI) score of greater than or equal to 30; or
  2.2 Patient has extensive small intestine disease; and
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation — Crohn's disease - children
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
2 PCDAI score is 15 or less; or
3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

Initiation — Crohn's disease - fistulising
Gastroenterologist
Re-assessment required after 6 months
All of the following:
1 Patient has confirmed Crohn's disease; and
2 Any of the following:
  2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
  2.2 Patient has one or more rectovaginal fistula(e); and or
  2.3 Patient has complex peri-anal fistula; and
3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

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

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Continuation — Crohn's disease - fistulising
Any relevant practitioner
Re-assessment required after 2 years
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.

Initiation — Ocular inflammation - chronic
Any relevant practitioner
Re-assessment required after 4 months
Either:
1 Patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
2 Both:
  2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
  2.2 Any of the following:
    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 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
    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.

Continuation — Ocular inflammation - chronic
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1 The patient has had a good clinical response following 12 weeks' initial treatment; or
2 Following each 2 year 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
3 Following each 2 year 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.

Initiation — Ocular inflammation - severe
Any relevant practitioner
Re-assessment required after 4 months
Either:
1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
2 Both:
  2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
  2.2 Any of the following:
    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 Patient developed new inflammatory symptoms while receiving high dose steroids; or
    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.

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

continued...

Continuation — Ocular inflammation - severe
Any relevant practitioner
Re-assessment required after 2 years
Any of the following:
1 The patient has had a good clinical response following 3 initial doses; or
2 Following each 2 year 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
3 Following each 2 year 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.

Initiation — ankylosing spondylitis
Rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
  1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
  1.2 Either:
    1.2.1 The patient has experienced intolerable side effects; or
    1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
2 All of the following:
  2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
  2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
  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
  2.5 Either:
    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
    2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender; 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 and is no more than 1 month old at the time of application.

Continuation — ankylosing spondylitis
Any relevant practitioner
Re-assessment required after 2 years
For applications where 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.

Initiation — Arthritis - oligoarticular course juvenile idiopathic
Named specialist or rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
  1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
  1.2 Either:
    1.2.1 Patient has experienced intolerable side effects; or

continued...

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

continued...

1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or

2 All of the following:
- 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 Patient has had oligoarticular course JIA for 6 months duration or longer; and
- 2.3 Either:
  - 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
  - 2.3.2 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).

Continuation — Arthritis - oligoarticular course juvenile idiopathic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Following 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 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.

Initiation — Arthritis - polyarticular course juvenile idiopathic
Named specialist or rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
- 1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
  - 1.2.1 Patient has experienced intolerable side effects; or
  - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or

2 All of the following:
- 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 Patient has had polyarticular course JIA for 6 months duration or longer; and
- 2.3 Any of the following:
  - 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
  - 2.3.2 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
  - 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Continuation — Arthritis - polyarticular course juvenile idiopathic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Following 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 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.

continued...

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

continued...

Initiation — Arthritis - psoriatic
Rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
  1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
  1.2 Either:
    1.2.1 Patient has experienced intolerable side effects; or
    1.2.2 Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis; or
2 All of the following:
  2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
  2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
  2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
  2.4 Either:
    2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  2.5 Any of the following:
    2.5.1 Patient has 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 elevated 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.

Continuation — Arthritis - psoriatic
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician; or
2 Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician.

Initiation — Arthritis - rheumatoid
Rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
  1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
  1.2 Either:
    1.2.1 The patient has experienced intolerable side effects; or
    1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or
2 All of the following:
  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 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

continued...

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

continued...

2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
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
2.5 Either:
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
2.5.2 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
2.6 Either:
2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
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.

Continuation — Arthritis - rheumatoid
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Following 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 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.

Initiation — Still's disease - adult-onset (AOSD)
Rheumatologist
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for (AOSD); and
1.2 Either:
1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
2 All of the following:
2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
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
2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initiation — ulcerative colitis
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1 Patient has histologically confirmed active ulcerative colitis; and
2 Either:
2.1 Patient's SCCAI score is greater than or equal to 4; or
2.2 Patient's PUCAI score is greater than or equal to 65; and
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
4 Surgery (or further surgery) is considered to be clinically inappropriate.

continued...

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

continued...

Continuation – ulcerative colitis
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on adalimumab; or
2 The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on adalimumab.

Initiation — undifferentiated spondyloarthritis
Rheumatologist
Re-assessment required after 6 months
All of the following:
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 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
3 Any of the following:
  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
  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
  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

Continuation — undifferentiated spondyloarthritis
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Following 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 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

Initiation — inflammatory bowel arthritis – axial
Rheumatologist
Re-assessment required after 6 months
All of the following:
1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2 Patient has axial inflammatory pain for six months or more; and
3 Patient is unable to take NSAIDs; and
4 Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
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.

Continuation — inflammatory bowel arthritis – axial
Any relevant practitioner
Re-assessment required after 2 years
For applications where 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.

continued...

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

continued...

Initiation — inflammatory bowel arthritis – peripheral
Rheumatologist
Re-assessment required after 6 months
All of the following:
1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
3 Patient has tried and not responded to at least three months of methotrexate or azathioprine at a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of sulphasalazine at a maximum tolerated dose; and
5 Any of the following:
  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
  5.2 Patient has an ESR greater than 25 mm per hour; or
  5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Continuation — inflammatory bowel arthritis – peripheral
Any relevant practitioner
Re-assessment required after 2 years
Either:
1 Following initial treatment, 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 Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

173 ADALIMUMAB **(HUMIRA)** (amended chemical name and restriction criteria – initiation criteria removed)

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

Restricted
~~Initiation – polyarticular course juvenile idiopathic arthritis~~
~~Rheumatologist or named specialist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1 Both:~~
~~1.1 The patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and~~
~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from etanercept; or~~
~~1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for polyarticular course JIA; or~~
~~2 All of the following:~~
~~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 Patient has had polyarticular course JIA for 6 months duration or longer; and~~
~~2.3 Any of the following:~~
~~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~~

continued...

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

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

continued...

~~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~~

~~2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.~~

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.

~~Initiation – oligoarticular course juvenile idiopathic arthritis~~
~~Rheumatologist or named specialist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~

~~1 Both:~~
  ~~1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and~~
  ~~1.2 Either:~~
    ~~1.2.1 The patient has experienced intolerable side effects from etanercept; or~~
    ~~1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for oligoarticular course JIA; or~~

~~2 All of the following:~~
  ~~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 Patient has had oligoarticular course JIA for 6 months duration or longer; and~~
  ~~2.3 Any of the following:~~
    ~~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~~
    ~~2.3.2 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); or~~
    ~~2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.~~

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.

continued...

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

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

continued...

~~Initiation – fistulising Crohn's disease~~
~~Gastroenterologist~~
~~*Re-assessment required after 4 months*~~
~~All of the following:~~
~~1 Patient has confirmed Crohn's disease; and~~
~~2 Either:~~
~~2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or~~
~~2.2 Patient has one or more rectovaginal fistula(e); and~~
~~3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.~~

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.

~~Initiation – Crohn's disease - adults~~
~~Gastroenterologist~~
~~*Re-assessment required after 3 months*~~
~~All of the following:~~
~~1 Patient has severe active Crohn's disease; and~~
~~2 Any of the following:~~
~~2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or~~
~~2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or~~
~~2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or~~
~~2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and~~
~~3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and~~
~~4 Surgery (or further surgery) is considered to be clinically inappropriate.~~

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:
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.

continued...

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

continued...

~~Initiation – Crohn's disease - children~~
~~Gastroenterologist~~
~~*Re-assessment required after 3 months*~~
~~All of the following:~~
~~1 Paediatric patient has severe active Crohn's disease; and~~
~~2 Either:~~
~~2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or~~
~~2.2 Patient has extensive small intestine disease; and~~
~~3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and~~
~~4 Surgery (or further surgery) is considered to be clinically inappropriate.~~

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.

~~Initiation – rheumatoid arthritis~~
~~Rheumatologist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1 Both:~~
~~1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and~~
~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from etanercept; or~~
~~1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis; or~~
~~2 All of the following:~~
~~2.1 Patient has had severe and active erosive 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 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~
~~2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and~~
~~2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and~~
~~2.5 Any of the following:~~
~~2.5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or~~
~~2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or~~
~~2.5.3 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 oral or parenteral methotrexate; and~~

continued...

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

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

continued...

~~2.6 Either:~~
~~2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or~~
~~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; and~~
~~2.7 Either:~~
~~2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or~~
~~2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.~~

Continuation – 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.

~~Initiation – ankylosing spondylitis~~
~~Rheumatologist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1 Both:~~
~~1.1 The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and~~
~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from etanercept; or~~
~~1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis; or~~
~~2 All of the following:~~
~~2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and~~
~~2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and~~
~~2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and~~
~~2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and~~
~~2.5 Either:~~
~~2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (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~~
~~2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and~~
~~2.6 Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.~~

continued...

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

continued...

~~Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of starting treatment.~~

~~Average normal chest expansion corrected for age and gender:~~

~~Age Male Female~~
~~18-24 7.0 cm 5.5 cm~~
~~25-34 7.5 cm 5.5 cm~~
~~35-44 6.5 cm 4.5 cm~~
~~45-54 6.0 cm 5.0 cm~~
~~55-64 5.5 cm 4.0 cm~~
~~65-74 4.0 cm 4.0 cm~~
~~75+ 3.0 cm 2.5 cm~~

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.

~~Initiation – psoriatic arthritis~~
~~Rheumatologist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1 Both:~~
~~1.1 The patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and~~
~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from etanercept or secukinumab; or~~
~~1.2.2 The patient has received insufficient benefit from etanercept or secukinumab to meet the renewal criteria for etanercept or secukinumab for psoriatic arthritis; or~~
~~2 All of the following:~~
~~2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and~~
~~2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and~~
~~2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and~~
~~2.4 Either:~~
~~2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or~~
~~2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and~~
~~2.5 Any of the following:~~
~~2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or~~
~~2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or~~
~~2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.~~

continued...

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

continued...

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.

~~Initiation – plaque psoriasis, prior TNF use~~
~~Dermatologist~~
~~*Limited to 4 months treatment*~~
~~Both:~~
~~1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and~~
~~2 Either:~~
  ~~2.1 The patient has experienced intolerable side effects from etanercept; or~~
  ~~2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis.~~

~~Initiation – plaque psoriasis, treatment-naive~~
~~Dermatologist~~
~~*Limited to 4 months treatment*~~
~~All of the following:~~
~~1 Either:~~
  ~~1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or~~
  ~~1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and~~
~~2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and~~
~~3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and~~
~~4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of initiation.~~
~~Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.~~

continued...

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

Changes to Section H Part II – effective 1 March 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.

~~Initiation – pyoderma gangrenosum~~
~~Dermatologist~~
~~All of the following:~~
~~1 Patient has pyoderma gangrenosum*; and~~
~~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; and~~
~~3 A maximum of 8 doses.~~
~~Note: Indications marked with * are unapproved indications.~~

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.

~~Initiation – adult-onset Still's disease~~
~~Rheumatologist~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1 Both:~~
  ~~1.1 Either:~~
    ~~1.1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD); or~~
    ~~1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the Section H rules; and~~

continued...

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

continued...

~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or~~
~~1.2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or~~
~~2 All of the following:~~
~~2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and~~
~~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, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and~~
~~2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.~~

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.

~~Initiation – severe Behcet's disease~~
~~Any relevant practitioner~~
~~*Re-assessment required after 3 months*~~
~~All of the following:~~
~~1 The patient has severe Behcet's disease that is significantly impacting the patient's quality of life (see Notes); and~~
~~2 Either:~~
~~2.1 The patient has severe ocular, neurological, gastrointestinal, rheumatological, mucocutaneous and/or vasculitic symptoms and has not responded adequately to treatment with infliximab (see Notes); or~~
~~2.2 The patient has severe ocular, neurological, gastrointestinal, rheumatological, mucocutaneous and/or vasculitic symptoms and has experienced intolerable side effects from treatment with infliximab; and~~
~~3 The patient is experiencing significant loss of quality of life; and~~
~~4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~
~~Note: Behcet's disease diagnosed according to the International Study Group for Behcet's disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al, J Rheumatol. 2004;31:931-7.~~

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.

~~Initiation – severe ocular inflammation~~
~~*Re-assessment required after 4 months*~~
~~Either:~~
~~1 Both:~~
~~1.1 The patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; and~~
~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from infliximab; or~~
~~1.2.2 The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab for severe ocular inflammation; or~~
~~2 Both:~~
~~2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and~~
~~2.2 Any of the following:~~
~~2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or~~

continued...

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

continued...

~~2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or~~
~~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.~~

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
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.

~~Initiation – chronic ocular inflammation~~
~~*Re-assessment required after 4 months*~~
~~Either:~~
~~1 Both:~~
~~1.1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; and~~
~~1.2 Either:~~
~~1.2.1 The patient has experienced intolerable side effects from infliximab; or~~
~~1.2.2 The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab for chronic ocular inflammation; or~~
~~2 Both:~~
~~2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and~~
~~2.2 Any of the following:~~
~~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 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or~~
~~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.~~

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.

continued...

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

continued...

~~Initiation – hidradenitis suppurativa~~
~~Dermatologist~~
~~*Re-assessment required after 4 months*~~
~~All of the following:~~
~~1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and~~
~~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~~
~~3 The patient has 3 or more active lesions (e.g. inflammatory nodules, abscesses, draining fistulae); and~~
~~4 The patient has a Dermatology Quality of Life Index of 10 or more and the assessment is no more than 1 month old at time of application; and~~
~~5 Following the initial loading doses, adalimumab is to be administered at doses no greater than 40mg every 7 days.~~

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.

208	ANTITHYMOCYTE GLOBULIN (EQUINE) (↑ price)			
	Inj 50 mg per ml, 5 ml ampoule	2,774.48	5	ATGAM
252	LOW ELECTROLYTE ORAL FEED 2 KCAL/ML (pack size change)			
	➔ Liquid 9.1 g protein, 19 g carbohydrate and 10 g fat per 100 ml, 200 ml bottle	13.24	4	Novasource Renal (Vanilla)

Note – Novasource Renal (Vanilla), 237 ml carton to be delisted 1 September 2022.

RESPIRATORY SYSTEM AND ALLERGIES

214	PROMETHAZINE HYDROCHLORIDE (↑ price)			
	Tab 10 mg	2.02	50	Allersoothe
	Tab 25 mg	2.27	50	Allersoothe
	Oral liq 1 mg per ml	3.39	100 ml	Allersoothe

SENSORY ORGANS

220 PROPAMIDINE ISETHIONATE (delisting presentation)
Eye drops 0.1%
Note – this presentation is to be delisted 1 April 2022.

VARIOUS

228	DESFERRIOXAMINE MESILATE (↑ price)			
	Inj 500 mg vial	151.31	10	DBL Desferrioxamine Mesylate for Inj BP
231	IOHEXOL (new listing)			
	Inj 350 mg per ml, 500 ml bottle	465.00	6	Omnipaque

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

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

SPECIAL FOODS

247 HIGH PROTEIN ORAL FEED 2.4 KCAL/ML (new listing)

Only to be used for patients currently on or would be using Fortisip or Fortisip Multifibre

➔ Liquid 14.6 g protein, 25.3 g carbohydrate and 9.6 g fat per 100 ml, 125 ml bottle — *e.g. Fortisip Compact Protein*

Restricted
Initiation
Any of the following:
For patients with malnutrition, defined as any of the following:
1 Any of the following:
1.1 BMI < 18.5; or
1.2 Greater than 10% weight loss in the last 3-6 months; or
1.3 BMI < 20 with greater than 5% weight loss in the last 3-6 months; or
2 For patients who have, or are expected to, eat little or nothing for 5 days; or
3 For patients who have a poor absorptive capacity and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism; or
4 For use pre- and post-surgery; or
5 For patients being tube-fed; or
6 For tube-feeding as a transition from intravenous nutrition; or
7 For any other condition that meets the community Special Authority criteria.
Note – to be delisted 1 July 2022.

254 ORAL FEED (brand name change)

➔ Powder 23 g protein, 65 g carbohydrate and 2.5 g fat per 100 g, can	14.00	840 g	Sustagen Hospital Formula ~~Active~~ (Chocolate) Sustagen Hospital Formula ~~Active~~ (Vanilla)

VACCINES

261 INFLUENZA VACCINE

➔ Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)			
(delisted)	9.00	1	Afluria Quad Junior (2021 Formulation)
(new listing)	11.00		Afluria Quad Junior (2022 Formulation)
➔ Inj 60 mcg in 0.5 ml syringe (adjuvanted quadrivalent vaccine)			
(delisted)	90.00	10	Fluad Quad (2021 Formulation)
➔ Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine)			
(delisted)	9.00	1	Influvac Tetra (2021 Formulation)

continued...

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

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

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

continued...

➔ Inj 60 mcg in 0.5 ml syringe
(quadrivalent vaccine) (amended restriction criteria – affected criteria shown only)

(delisted)	90.00	10	Afluria Quad (2021 Formulation)
(new listing)	110.00		Afluria Quad (2022 Formulation)

Restricted
Initiation – cardiovascular disease for patients ~~5~~ **3** years and over
Any of the following:
1 Ischaemic heart disease; or
2 Congestive heart failure; or
3 Rheumatic heart disease; or
4 Congenital heart disease; or
5 Cerebro-vascular disease.
Note: hypertension and/or dyslipidaemia without evidence of end-organ disease is excluded from funding.

Initiation – chronic respiratory disease for patients ~~5~~ **3** years and over
Either:
1 Asthma, if on a regular preventative therapy; or
2 Other chronic respiratory disease with impaired lung function.
Note: asthma not requiring regular preventative therapy is excluded from funding.

Initiation – Other conditions for patients ~~5~~ **3** years and over
Either:
1 Any of the following:
- 1.1 Diabetes; or
- 1.2 chronic renal disease; or
- 1.3 Any cancer, excluding basal and squamous skin cancers if not invasive; or
- 1.4 Autoimmune disease; or
- 1.5 Immune suppression or immune deficiency; or
- 1.6 HIV; or
- 1.7 Transplant recipient; or
- 1.8 Neuromuscular and CNS diseases/ disorders; or
- 1.9 Haemoglobinopathies; or
- 1.10 Is a child on long term aspirin; or
- 1.11 Has a cochlear implant; or
- 1.12 Errors of metabolism at risk of major metabolic decompensation; or
- 1.13 Pre and post splenectomy; or
- 1.14 Down syndrome; or
- 1.15 Is pregnant; or
- **1.16 Is a child 3 to 4 years of age (inclusive) who has been hospitalised for respiratory illness or has a history of significant respiratory illness; or**

2 Patients in a long-stay inpatient mental health care unit or who are compulsorily detained long-term in a forensic unit within a DHB hospital.

Note – Afluria Quad Junior (2021 Formulation) inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine), inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine), Fluad Quad (2021 Formulation) inj 60 mcg in 0.5 ml syringe (adjuvanted quadrivalent vaccine) and Influvac Tetra (2021 Formulation) inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) to be delisted 1 March 2022.

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

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

265 VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (amended restriction criteria)

➔ Varicella zoster virus (Oka strain) live attenuated

vaccine [shingles vaccine]	0.00	1	Zostavax
		10	Zostavax

Restricted
Initiation – people aged 65 years
Therapy limited to 1 dose
One dose for all people aged 65 years.
~~Initiation – people aged between 66 and 80 years~~
~~*Therapy limited to 1 dose*~~
~~One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 December 2021.~~

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Pharmaceuticals and brands

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Pharmaceuticals and brands

New Zealand
Permit No. 478

Permit

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