Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

January 2023

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 JANUARY 2023

- Adalimumab (Amgevita) inj 20 mg per 0.4 ml prefilled syringe, inj 40 mg per 0.8 ml prefilled pen and prefilled pen – amended restriction criteria
- Adalimumab (humira - alternative brand) (Humira) inj 40 mg per 0.4 ml prefilled syringe – new listing
- Ambrisentan (Ambrisentan Viatris) tab 10 mg – new listing
- Chloramphenicol (Chlorafast) eye drops 0.5 %, 10 ml – price increase
- Cilazapril (Zapril) tab 0.5 mg, 2.5 mg and 5 mg – price increase
- Domperidone (Domperidone Viatris) tab 10 mg – new listing and addition of PSS
- Domperidone (Pharmacy Health) tab 10 mg – to be delisted 1 June 2023
- Fluconazole (Fluconazole-Claris) inj 2 mg per ml, 50 ml vial – to be delisted 1 June 2023
- Fluoxetine hydrochloride (Arrow – Fluoxetine) cap 20 mg – new listing and addition of PSS
- Fluoxetine hydrochloride (Fluox) cap 20 mg – to be delisted 1 June 2023
- Hyoscine hydrobromide (Scopoderm TTS) patch 1.5 mg – price increase
- Levonorgestrel (Levonorgestrel BNM) tab 1.5 mg – new listing and addition of PSS
- Levonorgestrel (Postinor-1) tab 1.5 mg – to be delisted 1 June 2023
- Lidocaine [lignocaine] hydrochloride (Lidocaine-Claris) inj 1%, 20 ml vial – to be delisted from 1 June 2023
- Montelukast (Montelukast Viatris) tab 5 mg and 10 mg – new listing
- Multiple Sclerosis Treatments – amended restriction criteria
- Nadolol (Nadolol BNM) tab 40 mg and tab 80 mg – new listing
- Nevirapine (Nevirapine Viatris) tab 200 mg – new listing
- Nicotine (Habitrol (Fruit)) gum 4 mg, 204 pack – new listing
- Nusinersen (Spinraza) inj 12 mg per 5 ml vial – new listing
- Oxytocin (Oxytocin BNM) inj 5 iu and 10 iu per ml, 1 ml ampoule – price increase and addition of PSS
- Paracetamol (Paracetamol (Ethics)) oral liq 120 mg per 5 ml, 200 ml – new listing and addition of PSS
- Paracetamol oral liq 120 mg per 5 ml, 1,000 ml (Paracare), oral liq 120 mg per 5 ml – 100 ml, 200 ml and 500 ml bottle – to be delisted from 1 June 2023
- Paracetamol oral liq 240 mg per 5 ml (Avallon) – delisted 1 January 2023

Summary of decisions – effective 1 January 2023 (continued)

- Pegfilgrastim (Ziextenzo) inj 6 mg per 0.6 ml syringe – new listing and addition of PSS
- Pegfilgrastim (Neulastim) inj 6 mg per 0.6 ml syringe – to be delisted 1 June 2023
- Polyethylene glycol 400 and propylene glycol (Systane Unit Dose) eye drops 0.4% and propylene glycol 0.3% preservative free, single dose – amended chemical name
- Sodium citrate with sodium lauryl sulphoacetate (Micolette) enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml – price increase and addition of PSS
- Risedronate sodium (Risedronate Sandoz) tab 35 mg – price decrease and addition of PSS
- Tranexamic acid (Mercury Pharma) tab 500 mg – price increase and addition of PSS
- Zoledronic acid (Zoledronic Acid Viatris) inj 0.05 mg per ml, 100 ml, bag, 100 ml – new listing and addition of PSS
- Zoledronic acid (Aclasta) inj 0.05 mg per ml, 100 ml, vial, 100 ml – to be delisted 1 June 2023

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

Section H changes to Part II

Effective 1 January 2023

ALIMENTARY TRACT AND METABOLISM

15 SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE (↑ price and addition of PSS)
Enema 90 mg with sodium lauryl sulphoacetate
9 mg per ml, 5 ml – **5% DV Jun-23 to 2025** ..... 35.89 50 **Micolette**

BLOOD AND BLOOD FORMING ORGANS

32 TRANEXAMIC ACID (↑ price and addition of PSS)
Tab 500 mg – **5% DV Jun-23 to 2025** ..... 10.45 60 **Mercury Pharma**

38 PEGFILGRASTIM (new listing and addition of PSS)
➔ Inj 6 mg per 0.6 ml syringe – **5% DV Jun-23 to 2025** ..... 65.00 1 **Ziextenzo**
Note – Neulastim inj 6 mg per 0.6 ml syringe to be delisted from 1 June 2023.

CARDIOVASCULAR SYSTEM

43 CILAZAPRIL (↑ price)
➔ Tab 0.5 mg ..... 2.69 90 Zapril
➔ Tab 2.5 mg ..... 5.79 90 Zapril
➔ Tab 5 mg ..... 10.05 90 Zapril

47 NADOLOL (new Pharmacode listing)
Tab 40 mg – **1% DV Mar-22 to 2024** ..... 19.19 100 **Nadolol BNM**
Tab 80 mg – **1% DV Mar-22 to 2024** ..... 30.39 100 **Nadolol BNM**
Note – these are new Pharmacode listings, 2647540 and 2647559.

54 AMBRISENTAN (new listing)
➔ Tab 10 mg ..... 1,550.00 30 Ambrisentan Viatris

GENITO-URINARY SYSTEM

66 LEVONORGESTREL (new listing and addition of PSS)
Tab 1.5 mg – **5% DV Jun-23 to 2025** ..... 1.75 1 **Levonorgestrel BNM**
Note – Postinor-1 tab 1.5 mg to be delisted from 1 June 2023.

66 OXYTOCIN (↑ price and addition of PSS)
Inj 5 iu per ml, 1 ml ampoule – **5% DV Jun-23 to 2025** ..... 4.98 5 **Oxytocin BNM**
Inj 10 iu per ml, 1 ml ampoule – **5% DV Jun-23 to 2025** ..... 5.98 5 **Oxytocin BNM**

INFECTIONS

87 FLUCONAZOLE (delisting)
Inj 2 mg per ml, 50 ml vial ..... 2.80 1 Fluconazole-Claris
Note – Fluconazole-Claris inj 2 mg per ml, 50 ml vial to be delisted from 1 June 2023.

93 NEVIRAPINE (new Pharmacode listing)
➔ Tab 200 mg ..... 84.00 60 Nevirapine Viatris

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

Changes to Section H Part II – effective 1 January 2023 (continued)

MUSCULOSKELETAL SYSTEM

103 RISEDRONATE SODIUM (↓ price and addition of PSS)
Tab 35 mg – **5% DV Jun-23 to 2025** ..... 2.50 4 **Risedronate Sandoz**

104 ZOLEDRONIC ACID (new listing and addition of PSS)
➔ Inj 5 mg per 100 ml, bag – **5% DV Jun-23 to 2025** ..... 22.53 100 ml **Zoledronic Acid Viatris**
Note – Aclasta inj 5 mg per 100 ml, vial to be delisted from 1 June 2023.

NERVOUS SYSTEM

115 LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (delisting)
Inj 1%, 20 ml vial ..... 6.20 5 Lidocaine-Claris
Note – Lidocaine-Claris inj 1%, 20 ml vial to be delisted from 1 June 2023.

117 PARACETAMOL (new listing and addition of PSS)
Oral liq 120 mg per 5 ml – **20% DV Jun-23 to 2025** ..... 3.98 200 ml **Paracetamol (Ethics)**

117 PARACETAMOL (delisting)
Oral liq 120 mg per 5 ml ..... 5.45 1,000 ml Paracare
Oral liq 120 mg per 5 ml - 100 ml bottle
Oral liq 120 mg per 5 ml - 200 ml bottle
Oral liq 120 mg per 5 ml - 500 ml bottle
Note – oral liq 120 mg per 5 ml, 1,000 ml (Paracare), oral liq 120 mg per 5 ml – 100 ml, 200 ml and 500 ml bottle to be delisted from 1 June 2023.

117 PARACETAMOL (delisted)
Oral liq 240 mg per 5 ml ..... 11.92 200 ml Avallon
Note – Avallon oral liq 240 mg per 5 ml, 200 ml delisted from 1 January 2023.

121 FLUOXETINE HYDROCHLORIDE (new listing and addition of PSS)
Cap 20 mg – **5% DV Jun-23 to 2025** ..... 3.13 90 **Arrow - Fluoxetine**
Note – Fluox cap 20 mg to be delisted from 1 June 2023.

125 DOMPERIDONE (new listing and addition of PSS)
Tab 10 mg – **5% DV Jun-23 to 2025** ..... 4.00 100 **Domperidone Viatris**
Note – Pharmacy Health tab 10 mg to be delisted from 1 June 2023.

126 HYOSCINE HYDROBROMIDE (↑ price)
➔ Patch 1.5 mg ..... 17.70 2 Scopoderm TTS

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

Changes to Section H Part II – effective 1 January 2023 (continued)

130 Multiple Sclerosis Treatments (amended restriction criteria)

Restricted
Initiation – 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 confirmed by a neurologist; and
2 Patients has an EDSS score between 0 – 6.0; and
3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months; and
4 All of the following:
  4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
  4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
  4.3 Each significant attack 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 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 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 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 MRI 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 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 MRI 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).
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.

Changes to Section H Part II – effective 1 January 2023 (continued)

133 NUSINERSEN (new listing)
➔Inj 12 mg per 5 ml vial ..... 120,000.00 1 Spinraza

Restricted
Initiation
Re-assessment required after 12 months
All of the following:
1 Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and
2 Patient is 18 years of age or under; and
3 Either:
  3.1 Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age; or
  3.2 Both:
    3.2.1 Patient is pre-symptomatic; and
    3.2.2 Patient has three or less copies of SMN2

Continuation
Re-assessment required after 12 months
All of the following:
1 There has been demonstrated maintenance of motor milestone function since treatment initiation; and
2 Patient does not require invasive permanent ventilation (at least 16 hours per day), in the absence of a potentially reversible cause while being treated with nusinersen; and
3 Nusinersen not to be administered in combination other SMA disease modifying treatments or gene therapy.

136 NICOTINE (new listing)
Gum 4 mg ..... 24.17 204 Habitrol (Fruit)

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

167 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.

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Changes to Section H Part II – effective 1 January 2023 (continued)

continued...

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
- ~~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.

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

Changes to Section H Part II – effective 1 January 2023 (continued)

continued...

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 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 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
- ~~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 Patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or

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Changes to Section H Part II – effective 1 January 2023 (continued)

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~~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.

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 following average normal values corrected for age and gender; and

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Changes to Section H Part II – effective 1 January 2023 (continued)

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~~2.~~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).

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.

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

Changes to Section H Part II – effective 1 January 2023 (continued)

continued...

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
~~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 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

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Changes to Section H Part II – effective 1 January 2023 (continued)

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~~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

~~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
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 spondyloarthritis
Rheumatologist
Re-assessment required after 6 months
~~Either:~~
~~1 The patient has previously had an approval for Humira; or~~
~~2~~ All of the following:

continued...

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

Changes to Section H Part II – effective 1 January 2023 (continued)

continued...

~~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, sulfasalazine 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.

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 sulfasalazine 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 measured no more than one month prior to the date of this application; 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.

177	ADALIMUMAB (HUMIRA - ALTERNATIVE BRAND) (new listing)			
	➔ Inj 40 mg per 0.4 ml prefilled syringe	1,599.96	2	Humira

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

Changes to Section H Part II – effective 1 January 2023 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

234	MONTELUKAST (new listing)			
	Tab 5 mg	3.10	28	Montelukast Viatris
	Tab 10 mg	2.90	28	Montelukast Viatris

SENSORY ORGANS

237	CHLORAMPHENICOL (↑ price)			
	Eye drops 0.5 %	7.50	10 ml	Chlorafast
242	**POLYETHYLENE GLYCOL** ~~MACROGOL~~ 400 AND PROPYLENE GLYCOL (amended chemical name)			
	Eye drops 0.4% with propylene glycol 0.3% preservative free, single dose	10.78	30	Systane Unit Dose

Effective 1 December 2022

VACCINES

273	MENINGOCOCCAL (A, C, Y AND W-135) CONJUGATE VACCINE (new listing)			
	➔ Inj 4 mcg of each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial	0.00	5	Menactra

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

Index
Pharmaceuticals and brands

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