Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

February 2023

PHARMAC
TE PĀTAKA WHAIORANGA

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Summary of decisions
EFFECTIVE 1 FEBRUARY 2023

- Abacavir sulphate with lamivudine (Kivexa) tab 600 mg with lamivudine 300 mg – price increase
- Adalimumab (Amgevita) inj 20 mg per 0.4 ml prefilled syringe and inj 40 mg per 0.8 ml prefilled pen and syringe – amended restriction criteria
- Adrenaline inj 0.15 mg per 0.3 ml auto-injector (Epipen Jr) and inj 0.3 mg per 0.3 ml auto-injector (Epipen) – new listing
- Adrenaline (DBL Adrenaline) inj 1 in 1,000, 1 ml ampoule – price increase
- Amoxicillin (Alphamox) cap 250 mg and 500 mg – price increase
- Bisoprolol fumarate (Bisoprolol Viatris) tab 2.5 mg, 5 mg and 10 mg – new listing
- Cabergoline (Dostinex) tab 0.5 mg, 2 and 8 tab pack – price increase
- Calcium folinate (DBL Leucovorin Calcium) tab 15 mg – price increase
- Ceftaroline fosamil (Zinforo) inj 600 mg vial – price increase
- Cetomacrogol with glycerol (Evara) crm 90% with glycerol 10%, 500 ml – price decrease and addition of PSS
- Cetomacrogol with glycerol (Evara) crm 90% with glycerol 10%, 1,000 ml – price increase and addition of PSS
- Clindamycin (Dalacin C) cap 150 mg – price increase
- Cytarabine (Pfizer) inj 20 mg per ml, 5 ml vial and inj 100 mg per ml, 20 ml vial – price increase
- Dacarbazine (DBL Dacarbazine) inj 200 mg vial – price increase
- Dantrolene cap 25 mg (Dantrium) and inj 20 mg vial (Dantrium IV) – price increase
- Daunorubicin (Pfizer) inj 2 mg per ml, 10 ml – price increase
- Diazepam (Hospira) inj 5 mg per ml, 2 ml ampoule – price increase
- Dinoprostone (Prostin E2) vaginal gel 1 mg and 2 mg in 3 g – price increase
- Dosulepin [dothiepin] hydrochloride (Dosulepin Viatris) cap 25 mg – new listing
- Efavirenz with emtricitabine and tenofovir disoproxil (Viatris) tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil 245 mg (300 mg as a maleate) – new listing
- Emtricitabine with tenofovir disoproxil (Tenofovir Disoproxil Emtricitabine Viatris) tab 200 mg with tenofovir disoproxil 245 mg (300 mg as a maleate) – new listing

Summary of decisions – effective 1 February 2023 (continued)

- Enteral feed 1kcal/ml (Fresubin Original) liquid 3.8 g protein, 13.8 g carbohydrate and 3.4 g fat per 100 ml, bag, 1,000 ml – new listing
- Enteral feed 1.5kcal/ml (Fresubin HP Energy) liquid 7.5 g protein, 17 g carbohydrate and 5.8 g fat per 100 ml, bag, 1,000 ml – new listing
- Enteral feed 2 kcal/ml (Fresubin 2kcal HP) liquid 10 g protein, 17.5 g carbohydrate and 10 g fat per 100 ml, bag, 500 ml – new listing
- Enteral feed with fibre 1kcal/ml (Fresubin Original Fibre) liquid 3.8 g protein, 13.0 g carbohydrate, 3.4 g fat and 1.5 g fibre per 100 ml, bag, 1,000 ml – new listing
- Enteral feed with fibre 1.5kcal/ml (Fresubin HP Energy Fibre) liquid 7.5 g protein, 16.2 g carbohydrate, 5.8 g fat and 1.5 g fibre per 100 ml, bag, 1,000 ml – new listing
- Eptifibatide (Eptifibatide Viatris) inj 2 mg per ml, 10 ml vial and inj 750 mcg per ml, 100 ml vial – new listing
- Ethinyloestradiol with norethisterone (Brevinor 1/28) tab 35 mcg with norethisterone 1 mg and 7 inert tab – price increase
- Fluconazole oral liquid 50 mg per 5 ml, 35 ml (Diflucan) and inj 2 mg per ml, 50 ml and 100 ml vial (Fluconazole-Baxter) – price increase
- Fluticasone (Flixotide Accuhaler) powder for inhalation, 50 mcg, 100 mcg and 250 mcg per dose, 60 dose – price decrease
- Gentamicin sulphate (Pfizer) inj 40 mg per ml, 2 ml ampoule – price increase
- Heparin sodium (Heparin Sodium Panpharma) inj 5,000 iu per ml, 5 ml vial – new listing and addition of PSS
- Heparin sodium (Pfizer) inj 5,000 iu per ml, 5 ml vial – to be delisted 1 July 2023
- Heparin sodium (Pfizer) inj 1,000 iu per ml, 5 ml ampoule – price increase
- High protein enteral feed 1.2 kcal/ml (Fresubin Intensive) liquid 10 g protein, 12.9 g carbohydrate and 3.2 g fat and 0.64 g fibre per 100 ml, bag, 500 ml – new listing
- Infliximab (Remicade) inj 100 mg – price decrease, amended HSS and restriction criteria
- Lamivudine (Lamivudine Viatris) tab 150 mg – new listing
- Lidocaine [lignocaine] hydrochloride (Lidocaine-Baxter) inj 1%, 20 ml vial, inj 2%, 5 ml ampoule and inj 2%, 20 ml vial – price increase
- Medroxyprogesterone acetate (Depo-Provera) inj 150 mg per ml, 1 ml syringe – price increase
- Minoxidil (Loniten) tab 10 mg – price increase

Summary of decisions – effective 1 February 2023 (continued)

- Misoprostol (Cytotec) tab 200 mcg – price increase
- Nicotine (Habitrol (Mint)) gum 2 mg, 204 pack – new listing
- Nicotine (Habitrol) patch 7 mg, 14 mg and 21 mg per 24 hours and lozenge 1 mg and 2 mg – price increase
- Paediatric enteral feed 1 kcal/ml (Frebini Original) liquid 2.5 g protein, 12.5 g carbohydrate and 4.4 g fat per 100 ml, 500 ml – new listing
- Paediatric enteral feed 1.5 kcal/ml (Frebini Energy) liquid 3.8 g protein, 18.7 g carbohydrate and 6.7 g fat per 100 ml, 500 ml – new listing
- Paediatric enteral feed with fibre 1kcal/ml (Frebini Original Fibre) liquid 2.5 g protein, 12.1 g carbohydrate, 4.5g fat and 0.8 g fibre per 100 ml, 500 ml – new listing
- Paediatric enteral feed with fibre 1.5kcal/ml (Frebini Energy Fibre) liquid 3.8 g protein, 18.1 g carbohydrate, 6.7 g fat and 1.1 g fibre per 100 ml, 500 ml – new listing
- Pamidronate disodium (Pamisol) inj 3 mg, 6 mg and 9 mg per ml, 10 ml vial – price increase
- Pantoprazole (Panzop Relief) tab EC 20 mg and 40 mg – new pack size listing and addition of PSS
- Pantoprazole (Panzop Relief) tab EC 20 mg and 40 mg, 100 tab – to be delisted 1 July 2023
- Peptide-based enteral feed 1kcal/ml (Survimed OPD) liquid 4.5 g protein, 14.3 g carbohydrate and 2.8 g fat per 100 ml, bag, 500 ml – new listing
- Phenylephrine hydrochloride (Neosynephrine HCL) inj 10 mg per ml, 1 ml ampoule – price increase
- Promethazine hydrochloride (Hospira) inj 25 mg per ml, 2 ml ampoule – price increase
- Rifabutin (Mycobutin) cap 150 mg – price increase
- Sulfasalazine tab 500 mg (Salazopyrin) and tab EC 500 mg (Salazopyrin EN) – price increase
- Solifenacin succinate (Solifenacin Viatris) tab 5 mg and 10 mg – new listing
- Teriparatide (Forteo) inj 250 mcg per ml, 2.4 ml cartridge – new Pharmacode listing
- Ustekinumab (Stelara) inj 130 mg vial and inj 90 mg per ml, 1 ml prefilled syringe – new listing
- Vedolizumab (Entyvio) inj 300 mg vial – new listing

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

Section H changes to Part II

Effective 1 February 2023

ALIMENTARY TRACT AND METABOLISM

7	SULFASALAZINE (↑ price)			
	Tab 500 mg	16.52	100	Salazopyrin
	Tab EC 500 mg	17.86	100	Salazopyrin EN
7	MISOPROSTOL (↑ price)			
	Tab 200 mcg	47.73	120	Cytotec
8	PANTOPRAZOLE (new pack size listing and addition of PSS)			
	Tab EC 20 mg – **5% DV Jul-23 to 2025**	1.99	90	**Panzop Relief**
	Tab EC 40 mg – **5% DV Jul-23 to 2025**	2.74	90	**Panzop Relief**
	Note – Panzop Relief tab EC 20 mg and 40 mg, 100 tab to be delisted from 1 July 2023.			

BLOOD AND BLOOD FORMING ORGANS

35	HEPARIN SODIUM (new listing and addition of PSS)			
	Inj 5,000 iu per ml, 5 ml vial – **5% DV Jul-23 to 2025**	83.00	10	**Heparin Sodium Panpharm**
	Note – Pfizer inj 5,000 iu per ml, 5 ml ampoule to be delisted from 1 July 2023.			
35	HEPARIN SODIUM (↑ price)			
	Inj 1,000 iu per ml, 5 ml ampoule	86.11	50	Pfizer
36	EPTIFIBATIDE (new listing)			
	➔ Inj 2 mg per ml, 10 ml vial	180.38	1	Eptifibatide Viatris
	➔ Inj 750 mcg per ml, 100 ml vial	526.50	1	Eptifibatide Viatris

CARDIOVASCULAR SYSTEM

46	BISOPROLOL FUMARATE (new listing)			
	Tab 2.5 mg	1.84	90	Bisoprolol Viatris
	Tab 5 mg	2.55	90	Bisoprolol Viatris
	Tab 10 mg	3.62	90	Bisoprolol Viatris
53	ADRENALINE (↑ price)			
	Inj 1 in 1,000, 1 ml ampoule	12.65	5	DBL Adrenaline
53	PHENYLEPHRINE HYDROCHLORIDE (↑ price)			
	Inj 10 mg per ml, 1 ml ampoule	163.38	25	Neosynephrine HCL
54	MINOXIDIL (↑ price)			
	Tab 10 mg	78.40	100	Loniten

DERMATOLOGICALS

60	CETOMACROGOL WITH GLYCEROL (↓ price and addition of PSS)			
	Crm 90% with glycerol 10% – **5% DV Jul-23 to 2025**	2.13	500 ml	**Evara**
	Note: DV limit applies to the pack sizes of greater than 100 g.			

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

60 CETOMACROGOL WITH GLYCEROL (↑ price and addition of PSS)
Crm 90% with glycerol 10% – **5% DV Jul-23 to 2025** ..... 3.50 | 1,000 ml | **Evara**
Note: DV limit applies to the pack sizes of greater than 100 g.

GENITO-URINARY SYSTEM

65 ETHINYLOESTRADIOL WITH NORETHISTERONE (↑ price)
Tab 35 mcg with norethisterone 1 mg and 7 inert tab ..... 12.25 | 84 | Brevinor 1/28

66 MEDROXYPROGESTERONE ACETATE (↑ price)
Inj 150 mg per ml, 1 ml syringe ..... 9.18 | 1 | Depo-Provera

66 DINOPROSTONE (↑ price)
Vaginal gel 1 mg in 3 g ..... 65.39 | 1 | Prostin E2
Vaginal gel 2 mg in 3 g ..... 82.33 | 1 | Prostin E2

HORMONE PREPARATIONS

67 SOLIFENACIN SUCCINATE (new listing)
Tab 5 mg ..... 2.05 | 30 | Solifenacin Viatris
Tab 10 mg ..... 3.72 | 30 | Solifenacin Viatris

72 CABERGOLINE (↑ price)
➔ Tab 0.5 mg ..... 4.43 | 2 | Dostinex
17.94 | 8 | Dostinex

INFECTIONS

79 GENTAMICIN SULPHATE (↑ price)
Inj 40 mg per ml, 2 ml ampoule ..... 18.38 | 10 | Pfizer

81 CEFTAROLINE FOSAMIL (↑ price)
➔ Inj 600 mg vial ..... 1,834.25 | 10 | Zinforo

83 AMOXICILLIN (↑ price)
Cap 250 mg ..... 43.45 | 500 | Alphamox
Cap 500 mg ..... 66.44 | 500 | Alphamox

85 CLINDAMYCIN (↑ price)
➔ Cap 150 mg ..... 5.30 | 24 | Dalacin C

87 FLUCONAZOLE (↑ price)
➔ Oral liquid 50 mg per 5 ml ..... 129.02 | 35 ml | Diflucan
➔ Inj 2 mg per ml, 50 ml vial ..... 3.11 | 1 | Fluconazole-Baxter
➔ Inj 2 mg per ml, 100 ml vial ..... 3.83 | 1 | Fluconazole-Baxter

90 RIFABUTIN (↑ price)
➔ Cap 150 mg ..... 353.71 | 30 | Mycobutin

94 ABACAVIR SULPHATE WITH LAMIVUDINE (↑ price)
➔ Tab 600 mg with lamivudine 300 mg ..... 75.00 | 30 | Kivexa

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

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

94 EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPROXIL (new listing)
➔Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil 245 mg (300 mg as a maleate) ..... 106.88 30 Viatris

94 LAMIVUDINE (new listing)
➔Tab 150 mg..... 84.50 60 Lamivudine Viatris

98 EMTRICITABINE WITH TENOFOVIR DISOPROXIL (new listing)
➔Tab 200 mg with tenofovir disoproxil 245 mg (300 mg as a maleate) ..... 15.45 30 Tenofovir Disoproxil Emtricitabine Viatris

MUSCULOSKELETAL SYSTEM

104 PAMIDRONATE DISODIUM (↑ price)
Inj 3 mg per ml, 10 ml vial ..... 32.49 1 Pamisol
Inj 6 mg per ml, 10 ml vial ..... 88.11 1 Pamisol
Inj 9 mg per ml, 10 ml vial ..... 94.34 1 Pamisol

110 TERIPARATIDE (new Pharmacode listing)
➔Inj 250 mcg per ml, 2.4 ml cartridge ..... 490.00 1 Forteo
Note – this is a new Pharmacode listing, 2650908.

112 DANTROLENE (↑ price)
Cap 25 mg ..... 112.13 100 Dantrium
Inj 20 mg vial..... 994.56 6 Dantrium IV

NERVOUS SYSTEM

118 LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (↑ price)
Inj 1%, 20 ml vial..... 6.85 5 Lidocaine-Baxter
Inj 2%, 5 ml ampoule..... 9.00 25 Lidocaine-Baxter
Inj 2%, 20 ml vial..... 7.15 5 Lidocaine-Baxter

123 DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE (new listing)
➔Cap 25 mg ..... 7.83 50 Dosulepin Viatris

125 DIAZEPAM (↑ price)
Inj 5 mg per ml, 2 ml ampoule ..... 27.92 5 Hospira

140 NICOTINE (new listing)
Gum 2 mg..... 21.42 204 Habitrol (Mint)

140 NICOTINE (↑ price)
Patch 7 mg per 24 hours ..... 19.14 28 Habitrol
Patch 14 mg per 24 hours ..... 21.05 28 Habitrol
Patch 21 mg per 24 hours ..... 24.12 28 Habitrol
Lozenge 1 mg..... 19.76 216 Habitrol
Lozenge 2 mg..... 21.65 216 Habitrol

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

143 DAUNORUBICIN (↑ price)
Inj 2 mg per ml, 10 ml vial ..... 171.93 | 1 | Pfizer

144 CYTARABINE (↑ price)
Inj 20 mg per ml, 5 ml vial ..... 472.00 | 5 | Pfizer
Inj 100 mg per ml, 20 ml vial ..... 48.80 | 1 | Pfizer

146 DACARBAZINE (↑ price)
Inj 200 mg vial..... 72.11 | 1 | DBL Dacarbazine

158 CALCIUM FOLINATE (↑ price)
Tab 15 mg..... 135.33 | 10 | DBL Leucovorin Calcium

170 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 – Crohn's disease - adults
~~Gastroenterologist~~ **Any relevant practitioner**
*Re-assessment required after **6** 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 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 experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

continued...

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

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

continued...

Initiation – Crohn's disease - children
~~Gastroenterologist~~ **Any relevant practitioner**
*Re-assessment required after **6** ~~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 experienced an adequate response to treatment but PCDAI score cannot be assessed.

Initiation – Crohn's disease - fistulising
~~Gastroenterologist~~ **Any relevant practitioner**
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); 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.

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 – ulcerative colitis
~~Gastroenterologist~~ **Any relevant practitioner**
*Re-assessment required after **6** ~~3~~ months*
All of the following:
1 Patient has ~~histologically confirmed~~ **active** ulcerative colitis; and
2 Either:
  2.1 Patients SCCAI score is greater than or equal to 4; or
  2.2 Patients PUCAI score is greater than or equal to **20** ~~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.

continued...

Changes to Section H Part II – effective 1 February 2023 (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 when the patient was initiated on ~~adalimumab~~ **biologic therapy**; or
2 The PUCAI score has reduced by **10** ~~30~~ points or more from the PUCAI score when the patient was initiated on ~~adalimumab~~ **biologic therapy**

Initiation – Inflammatory bowel arthritis – axial
Rheumatologist
Reassessment 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 had axial inflammatory pain for six months or more; and
3 Patient is unable to take NSAIDs; and
4 Patient has **unequivocal** ~~bilateral~~ sacroiliitis demonstrated by radiological imaging **or MRI**; 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 Patient has 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
Reassessment required after 2 years
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 – Inflammatory bowel arthritis - peripheral
Rheumatologist
Reassessment 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~~ **experienced a response** to at least three months of methotrexate or azathioprine at a maximum tolerated dose **(unless contraindicated)**; and
4 Patient has tried and not ~~responded to~~ **experienced a response** to at least three months of sulfasalazine at a maximum tolerated dose **(unless contraindicated)**; 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 measured no more than one month prior to the date of this application; 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
Reassessment required after 2 years
Either:
1 Following initial treatment, patient has experienced 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 continues to experience at least a 30% improvement in active joint count from baseline in the opinion of the treating physician.

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

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

190 INFLIXIMAB (↓ price, amended HSS and amended restriction criteria – new and affected criteria shown only)
➔ Inj 100 mg – **5% DV Sep-20 to** ~~2024~~ **2025** ..... 428.00 1 **Remicade**

Restricted
Initiation – Crohn's disease (adults)
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **6** ~~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 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 ~~systemic~~ therapy with immunomodulators ~~at maximum tolerated doses (unless contraindicated)~~ and corticosteroids; ~~and~~
~~4 Surgery (or further surgery) is considered to be clinically inappropriate; and~~
~~5 Patient must be reassessed for continuation after 3 months of therapy~~

Continuation – Crohn's disease (adults)
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **2 years** ~~6 months~~*
Both:
1 Any of the following:
1.1 CDAI score has reduced by 100 points from the CDAI score, **or HBI score has reduced by 3 points, from** when the patient was initiated on infliximab; or
1.2 CDAI score is 150 or less, **or HBI is 4 or less**; or
1.3 The patient has experienced an adequate response to treatment but CDAI score **and/or HBI score** cannot be assessed; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

Initiation – Crohn's disease (children)
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **6** ~~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 experienced an inadequate response to, or 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; and~~
~~5 Patient must be reassessed for continuation after3 months of therapy.~~

continued...

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

continued...

Continuation – Crohn's disease (children)
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **2 years** ~~6 months~~*
Both:
1 Any of the following:
  1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
  1.2 PCDAI score is 15 or less; or
  1.3 The patient has experienced an adequate response to treatment but PCDAI score cannot be assessed; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

Initiation – fistulising Crohn's disease
Gastroenterologist
*Reassessment required after **6** ~~4~~ months*
Both:
1 Patient has confirmed Crohn's disease; and
2 ~~Either~~ **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); **or**
  2.3 Patient has complete peri-anal fistula.

Continuation – fistulising Crohn's disease
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **2 years** ~~6 months~~*
Both:
1 Either:
  1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  1.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

Initiation – acute ~~severe~~ fulminant ulcerative colitis
Gastroenterologist
Limited to 6 weeks treatment
Both:
1 Patient has acute, ~~severe~~ fulminant ulcerative colitis; and
2 Treatment with intravenous or high dose oral corticosteroids has not been successful.

Continuation – ~~severe~~ fulminant ulcerative colitis
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **2 years** ~~6 months~~*
Both:
1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

continued...

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

continued...

Initiation – ulcerative colitis
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **6** ~~3 months~~*
All of the following:
1 Patient has ~~histologically confirmed~~ **active** ulcerative colitis; and
2 Either:
2.1 ~~Patient is 18 years or older and the Simple Clinical Colitis Activity Index (~~**Patients** SCCAI~~)~~ is greater than or equal to 4; or
2.2 ~~Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (~~**Patients** PUCAI~~)~~ score is greater than or equal to **20** ~~65~~; and
3 Patient has experienced an inadequate response to, or intolerable side effects from, prior ~~systemic~~ therapy with immunomodulators ~~at maximum tolerated doses for an adequate duration (unless contraindicated)~~ and **systemic** corticosteroids; ~~and~~
~~4 Surgery (or further surgery) is considered to be clinically inappropriate.~~

Continuation – ulcerative colitis
~~Gastroenterologist~~ **Any relevant practitioner**
*Reassessment required after **2 years** ~~6 months~~*
~~All of the following~~ **Both**:
~~1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and~~
1 ~~2~~ Either:
1.1 ~~2.1 Patient is 18 years or older and~~ the SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or
1.2 ~~2.2 Patient is under 18 years and~~ the PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab; and
2 ~~3~~ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

Initiation – Inflammatory bowel arthritis (axial)
Reassessment 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 had axial inflammatory pain for six months or more; and
3 Patient is unable to take NSAIDs; and
4 Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI; and
5 Patient has not experienced an adequate response to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
6 Patient has 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)
Reassessment required after 2 years
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 – Inflammatory bowel arthritis (peripheral)
Reassessment 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 experienced an adequate response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated); and

continued...

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

continued...

4 Patient has tried and not experienced an adequate response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated); 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 measured no more than one month prior to the date of this application; 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)
Reassessment required after 2 years
Either:

1 Following initial treatment, patient has experienced 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 continues to experience at least a 30% improvement in active joint count from baseline in the opinion of the treating physician.

226 USTEKINUMAB (new listing)

➔ Inj 130 mg vial	4,162.00	1	Stelara
➔ Inj 90 mg per ml, 1 ml prefilled syringe	4,162.00	1	Stelara

Restriction
Initiation – Crohn's disease – adults
Reassessment required after 6 months
Either:

1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or

2 Both:

2.1 Patient has active Crohn's disease; and

2.2 Either;

2.2.1 Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or

2.2.2 Both;

2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and

2.2.2.2 Other biologics for Crohn's disease are contraindicated

Continuation – Crohn's disease - adults
Reassessment required after 12 months
Both:

1 Any of the following:

1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or

1.2 CDAI score is 150 or less, or HBI is 4 or less; or

1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and

2 Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks.

continued...

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

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

continued...

Initiation – Crohn's disease – children*
Reassessment required after 6 months
Either:
1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
2 Both:
  2.1 Patient has active Crohn's disease; and
  2.2 Either;
    2.2.1 Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    2.2.2 Both;
      2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      2.2.2.2 Other biologics for Crohn's disease are contraindicated

Note: Indication marked with * is an unapproved indication

Continuation – Crohn's disease – children*
Reassessment required after 12 months
Both:
1 Any of the following:
  1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
  1.2 PCDAI score is 15 or less; or
  1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
2 Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks.

Note: Indication marked with * is an unapproved indication

Initiation – ulcerative colitis
Reassessment required after 6 months
Either:
1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
2 Both:
  2.1 Patient has active ulcerative colitis; and
  2.2 Either;
    2.2.1 Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    2.2.2 Both;
      2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis; and
      2.2.2.2 Other biologics for ulcerative colitis are contraindicated

Continuation – ulcerative colitis
Reassessment required after 12 months
Both:
1 Either
  1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or
  1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy*; and
2 Ustekinumab to be used at a dose no greater than 90 mg every 8 weeks.

Note: Criterion marked with * is for an unapproved indication

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

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

227 VEDOLIZUMAB (new listing)

➔ Inj 300 mg vial ..... 3,313.00 1 Entyvio

Restricted

Initiation – Crohn's disease – Adults

Reassessment required after 6 months

All of the following:

1 Patient has active Crohn's disease; and

2 Any of the following:

- 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
- 2.2 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
- 2.3 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
- 2.4 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
- 2.5 Patient has an ileostomy or colostomy, and has intestinal inflammation; and

3 Any of the following:

- 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
- 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
- 3.3 Immunomodulators and corticosteroids are contraindicated.

Continuation – Crohn's disease - adults

Reassessment required after 2 years

Both:

1 Any of the following:

- 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
- 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
- 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and

2 Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Initiation – Crohn's disease – children*

Reassessment required after 6 months

All of the following:

1 Paediatric patient has active Crohn's disease; and

2 Any of the following:

- 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
- 2.2 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
- 2.3 Patient has extensive small intestine disease; and

3 Any of the following:

- 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
- 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
- 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with * is an unapproved indication

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

Continuation – Crohn's disease – children*
Reassessment required after 2 years
Both:
1 Any of the following:
  1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
  1.2 PCDAI score is 15 or less; or
  1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
2 Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.
Note: Indication marked with * is an unapproved indication

Initiation – ulcerative colitis
Reassessment required after 6 months
All of the following:
1 Patient has active ulcerative colitis; and
2 Any of the following:
  2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
  2.2 Patient has a SCCAI score is greater than or equal to 4; or
  2.3 Patient's PUCAI score is greater than or equal to 20*; and
3 Any of the following:
  3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  3.3 Immunomodulators and corticosteroids are contraindicated..
Note: Indication marked with * is an unapproved indication

Continuation – ulcerative colitis
Reassessment required after 2 years
Both:
1 Either
  1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or
  1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy *; and
2 Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks.
Note: Indication marked with * is an unapproved indication

RESPIRATORY SYSTEM AND ALLERGIES

231 ADRENALINE (new listing)

➔ Inj 0.15 mg per 0.3 ml auto-injector			
– **5% DV Jul-23 to 2025**	90.00	1	**Epipen Jr**
➔ Inj 0.3 mg per 0.3 ml auto-injector			
– **5% DV Jul-23 to 2025**	90.00	1	**Epipen**

Restricted
Initial – anaphylaxis
Either:
1 Patient has experienced a previous anaphylactic reaction which has resulted in presentation to a hospital or emergency department; or
2 Patient has been assessed to be at significant risk of anaphylaxis by a relevant practitioner.

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

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

231	PROMETHAZINE HYDROCHLORIDE (↑ price)			
	Inj 25 mg per ml, 2 ml ampoule	21.09	5	Hospira
236	FLUTICASONE (↓ price)			
	Powder for inhalation 50 mcg per dose	8.61	60 dose	Flixotide Accuhaler
	Powder for inhalation 100 mcg per dose	7.81	60 dose	Flixotide Accuhaler
	Powder for inhalation 250 mcg per dose	11.93	60 dose	Flixotide Accuhaler

SPECIAL FOODS

264	ENTERAL FEED 2 KCAL/ML (new listing)			
	➔ Liquid 10 g protein, 17.5 g carbohydrate and			
	10 g fat per 100 ml, bag	6.50	500 ml	Fresubin 2kcal HP
264	HIGH PROTEIN ENTERAL FEED 1.2 KCAL/ML (new listing)			
	➔ Liquid 10 g protein, 12.9 g carbohydrate and			
	3.2 g fat and 0.64 g fibre per 100 ml, bag	9.60	500 ml	Fresubin Intensive
264	PEPTIDE-BASED ENTERAL FEED 1KCAL/ML (new listing)			
	➔ Liquid 4.5 g protein, 14.3 g carbohydrate and			
	2.8 g fat per 100 ml, bag	9.60	500 ml	Survimed OPD
269	PAEDIATRIC ENTERAL FEED 1 KCAL/ML (new listing)			
	➔ Liquid 2.5 g protein, 12.5 g carbohydrate			
	and 4.4 g fat per 100 ml	6.50	500 ml	Frebini Original
270	PAEDIATRIC ENTERAL FEED 1.5 KCAL/ML (new listing)			
	➔ Liquid 3.8 g protein, 18.7 g carbohydrate and			
	6.7 g fat per 100 ml	6.50	500 ml	Frebini Energy
270	PAEDIATRIC ENTERAL FEED WITH FIBRE 1KCAL/ML (new listing)			
	➔ Liquid 2.5 g protein, 12.1 g carbohydrate, 4.5g fat			
	and 0.8 g fibre per 100 ml	7.00	500 ml	Frebini Original Fibre
270	PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML (new listing)			
	➔ Liquid 3.8 g protein, 18.1 g carbohydrate, 6.7 g fat			
	and 1.1 g fibre per 100 ml	7.00	500 ml	Frebini Energy Fibre
272	ENTERAL FEED 1.5 KCAL/ML (new listing)			
	➔ Liquid 7.5 g protein, 17 g carbohydrate and 5.8 g			
	fat per 100 ml, bag	9.60	1,000 ml	Fresubin HP Energy
272	ENTERAL FEED 1 KCAL/ML (new listing)			
	➔ Liquid 3.8 g protein, 13.8 g carbohydrate and			
	3.4 g fat per 100 ml, bag	6.50	1,000 ml	Fresubin Original
272	ENTERAL FEED WITH FIBRE 1KCAL/ML (new listing)			
	➔ Liquid 3.8 g protein, 13.0 g carbohydrate,			
	3.4 g fat and 1.5 g fibre per 100 ml, bag	7.00	1,000 ml	Fresubin Original Fibre

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

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

272 ENTERAL FEED WITH FIBRE 1.5KCAL/ML (new listing)
➔Liquid 7.5 g protein, 16.2 g carbohydrate, 5.8 g fat and 1.5 g fibre per 100 ml, bag — 9.80 — 1,000 ml — Fresubin HP Energy Fibre

Effective 1 January 2023

CARDIOVASCULAR SYSTEM

45 FLECAINIDE ACETATE (↑ price)
Cap long-acting 100 mg — 108.65 — 90 — Flecainide Controlled Release Teva
Cap long-acting 200 mg — 167.92 — 90 — Flecainide Controlled Release Teva

INFECTIONS

82 ROXITHROMYCIN (↑ price)
Tab 150 mg — 29.50 — 50 — Arrow-Roxithromycin
Tab 300 mg — 35.50 — 50 — Arrow-Roxithromycin

RESPIRATORY SYSTEM AND ALLERGIES

232 CETIRIZINE HYDROCHLORIDE (↑ price)
Tab 10 mg — 7.50 — 100 — Zista

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

266 AZATHIOPRINE (new listing)
Inj 100 mg vial

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

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