Pharmaceutical Management Agency

Section H Update for Hospital Pharmaceuticals

Effective 1 January 2017

Cumulative for December 2016 and January 2017

PHARMAC
Pharmaceutical Management Agency

Contents

Summary of decisions
EFFECTIVE 1 JANUARY 2017

- Allopurinol (Allopurinol-Apotex) tab 100 mg and 300 mg – HSS added
- Allopurinol (Apo-Allopurinol) tab 100 mg and 300 mg – HSS removed
- Benzbromarone (Benbromarone AL 100) tab 100 mg – website address amended
- Bupropion hydrochloride (Zyban) tab modified-release 150 mg – price increase
- Calcium carbonate (Calsource) tab eff 1.75 g (1 g elemental), 30 tab pack – to be delisted 1 July 2017
- Clopidogrel (Arrow – Clopid) tab 75 mg – price decrease and addition of HSS
- Diazepam (Stesolid) rectal tubes 5 mg and 10 mg – price increase
- Didanosine [DDI] cap 125 mg, 200 mg, 250 mg and 400 mg – to be delisted 1 July 2017
- Disulfiram (Antabuse) tab 200 mg – price increase
- Erlotinib (Tarceva) tab 100 mg and 150 mg – price decrease and HSS removed
- Etanercept (Enbrel) inj 50 mg autoinjector – new Pharmacode listing
- Fluphenazine decanoate (e.g. Modecate) inj 25 mg per ml, 2 ml ampoule – new listing
- Glyceryl trinitrate (Nitronal) inj 1 mg per ml, 50 ml vial – to be delisted 1 July 2017
- Human papillomavirus (6, 11, 16, 18, 31, 33, 45, 52 and 58) vaccine [HPV] (Gardasil 9) inj 270 mcg in 0.5 ml syringe – new listing
- Human papillomavirus (6, 11, 16, and 18) vaccine [HPV] (Gardasil) inj 120 mcg in 0.5 ml syringe – to be delisted 1 October 2017
- Iodised oil (Lipiodol Ultra Fluid) inj 38% w/w (480 mg per ml), 10 ml ampoule – price increase
- Naltrexone hydrochloride (Naltraccord) tab 50 mg – price increase
- Obinutuzumab (Gazyva) inj 25 mg per ml, 40 ml vial – new listing
- Oestradiol (Estradot) patch 75 mcg per day – new listing and addition of HSS
- Oral feed (Ensure (chocolate and vanilla) powder 15.9 g protein, 57.4 g carbohydrate and 14 g fat per 100 g, can, 850 g – price increase
- Oral feed (Ensure (chocolate and vanilla) powder 16 g protein, 59.8 g carbohydrate and 14 g fat per 100 g, can, 850 g – price increase
- Paediatric oral feed (Pediasure (Vanilla)) powder 14.9 g protein, 54.3 g carbohydrate and 24.7 g fat per 100 g, can, 850 g – price increase
- Pertuzumab (Perjeta) inj 30 mg per ml, 14 ml vial – new listing

Summary of decisions – effective 1 January 2017 (continued)

- Phenylephrine hydrochloride (Neosynephrine HCL) inj 10 mg per ml, 1 ml ampoule – new listing of ampoule presentation
- Phenylephrine hydrochloride (Neosynephrine HCL) inj 10 mg per ml, 1 ml vial – delisted 1 January 2017
- Pirfenidone (Esbriet) cap 267 mg – new listing
- Risedronate sodium (Risedronate Sandoz) tab 35 mg – price decrease and addition of HSS
- Rituximab (Mabthera) inj 10 mg per ml, 10 ml and 50 ml vial – amended restriction
- Sodium chloride (InterPharma) inj 0.9%, 5 ml and 20 ml ampoules – new listing and addition of HSS
- Sodium chloride (Pfizer) inj 0.9%, 10 ml ampoule – price decrease and addition of HSS
- Sodium chloride (Multichem), inj 0.9%, 5 ml, 10 ml and 20 ml ampoules – to be delisted 1 March 2017
- Somatropin (Omnitrope) inj 5 mg, 10 mg and 15 mg cartridge – amended restriction
- Sumatriptan (Arrow-Sumatriptan) inj 12 mg per ml, 0.5 ml cartridge – to be delisted 1 July 2017
- Tocilizumab (Actemra) inj 20 mg per, 4 ml, 10 ml and 20 ml vial – amended restriction
- Tramadol hydrochloride oral soln 10 mg per ml – new listing
- Tramadol hydrochloride oral drops 100 mg per ml – to be delisted 1 July 2017
- Trastuzumab (Herceptin) inj 150 mg and 440 mg vial – amended restriction
- Trifluoperazine hydrochloride tab 1 mg, 2 mg and 5 mg – restriction added and to be delisted 1 December 2017
- Water (InterPharma) inj 5 ml and 20 ml ampoules – new listing and addition of HSS
- Water (Pfizer) inj 10 ml ampoules – new listing and addition of HSS
- Water (Multichem) inj 5 ml, 10 ml and 20 ml ampoules – to be delisted 1 March 2017

Effective 1 December 2016

- Cetirizine hydrochloride (Zetop) tab 10 mg – price decrease and delisting delayed until 1 March 2017
- Cetirizine hydrochloride (Zista) tab 10 mg – HSS delayed until 1 March 2017

Summary of decisions – effective 22 November 2016

- Potassium chloride (Span-K) tab long-acting 600 mg (8 mmol) – HSS suspended
- Sodium bicarbonate (Sodibic) cap 840 mg – new Pharmacode listed

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

Section H changes to Part II

Effective 1 January 2017

ALIMENTARY TRACT AND METABOLISM

22 CALCIUM CARBONATE (delisting)

Tab eff 1.75 g (1 g elemental)	6.21	30	Calsource

Note – Calsource tab eff 1.75 g (1 g elemental), 30 tab pack, to be delisted from 1 July 2017. The 10 tab pack remains listed.

BLOOD AND BLOOD FORMING ORGANS

35 CLOPIDOGREL (↓ price and addition of HSS)

Tab 75 mg – **1% DV Mar-17 to 2019**	5.44	84	**Arrow - Clopid**

38 SODIUM CHLORIDE (brand change)

Inj 0.9%, 5 ml ampoule – **1% DV Mar-17 to 2019**	7.00	50	**InterPharma**
Inj 0.9%, 20 ml ampoule – **1% DV Mar-17 to 2019**	7.50	30	**InterPharma**

Note – Multichem sodium chloride inj 0.9%, 5 ml and 20 ml ampoules, and Pfizer sodium chloride inj 0.9%, 5 ml ampoule to be delisted from 1 March 2017.

38 SODIUM CHLORIDE (↓ price and addition of HSS)

Inj 0.9%, 10 ml ampoule – **1% DV Mar-17 to 2019**	6.63	50	**Pfizer**

Note – Multichem sodium chloride inj 0.9%, 10 ml ampoule to be delisted from 1 March 2017.

39 WATER (brand change)

Inj 5 ml ampoule – **1% DV Mar-17 to 2019**	7.00	50	**InterPharma**
Inj 10 ml ampoule – **1% DV Mar-17 to 2019**	6.63	50	**Pfizer**
Inj 20 ml ampoule – **1% DV Mar-17 to 2019**	7.50	30	**InterPharma**

Note – Multichem water inj 5 ml, 10 ml and 20 ml ampoules to be delisted from 1 March 2017.

CARDIOVASCULAR SYSTEM

49 GLYCERYL TRINITRATE (delisting)

Inj 1 mg per ml, 50 ml vial	86.60	10	Nitronal

Note – Nitronal inj 1 mg per ml, 50 ml vial to be delisted from 1 July 2017.

50 PHENYLEPHRINE HYDROCHLORIDE (delisting)

Inj 10 mg per ml, 1 ml vial	115.50	25	Neosynephrine HCL

Note – Neosynephrine HCL inj 10 mg per ml, 1 ml vial, Pharmacode 2120720, to be delisted from 1 January 2017.

50 PHENYLEPHRINE HYDROCHLORIDE (new listing)

Inj 10 mg per ml, 1 ml ampoule	115.50	25	Neosynephrine HCL

Note – this is the listing of the ampoule with a new Pharmacode, 2341069.

HORMONE PREPARATIONS

66 OESTRADIOL (new listing)

Patch 75 mcg per day – **1% DV Mar-17 to 2019**	7.91	8	**Estradot**

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

Changes to Section H Part II – effective 1 January 2017 (continued)

68 SOMATROPIN (amended restriction – amended criteria shown only)

➔ Inj 5 mg cartridge – **1% DV Jan-15 to 31 Dec 2017**	109.50	1	**Omnitrope**
➔ Inj 10 mg cartridge – **1% DV Jan-15 to 31 Dec 2017**	219.00	1	**Omnitrope**
➔ Inj 15 mg cartridge – **1% DV Jan-15 to 31 Dec 2017**	328.50	1	**Omnitrope**

Restricted
Initiation — Prader-Willi syndrome
Endocrinologist or paediatric endocrinologist
Re-assessment required after 12 months
All of the following:

1 The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and

~~2 The patient's height velocity is < 25th percentile for bone age adjusted for bone age/pubertal status if appropriate as calculated over 6 to 12 months using the standards of Tanner and Davies (1985) or pubertal status over 6 to 12 months; and~~

~~3 Either:~~

~~3.1 The patient is under two years of age and height velocity has been assessed over a minimum six-month period from the age of 12 months, with at least three supine length measurements over this period demonstrating clear and consistent evidence of linear growth failure (with height velocity < 25th percentile); or~~

~~3.2 The patient is aged two years or older; and~~

2 The patient is aged six months or older; and

34 A current bone age is < 14 years (female patients) or < 16 years (male patients); and

45 Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and

56 **Either:**

5.1 Both:

5.1.1 The patient is aged two years or older; and

5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by ≥ 0.5 standard deviations in the preceding 12 months**; or**.

5.2 The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation.

INFECTIONS

88 DIDANOSINE [DDI] (delisting)

➔ Cap 125 mg
➔ Cap 200 mg
➔ Cap 250 mg
➔ Cap 400 mg

Note – Didanosine [DDI] cap 125 mg, 200 mg, 250 mg and 400 mg to be delisted from 1 July 2017.

MUSCULOSKELETAL SYSTEM

100 RISEDRONATE SODIUM (↓ price and addition of HSS)

Tab 35 mg – **1% DV Mar-17 to 2019**	3.80	4	**Risedronate Sandoz**

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

Changes to Section H Part II – effective 1 January 2017 (continued)

103 ALLOPURINOL (HSS added)

Tab 100 mg – **1% DV Jan-17 to 2017**	15.11	1,000	**Allopurinol-Apotex**
Tab 300 mg – **1% DV Jan-17 to 2017**	15.91	500	**Allopurinol-Apotex**

103 ALLOPURINOL (HSS removed)

Tab 100 mg – **1% DV Mar-15 to ~~2017~~ 31 Dec 2016**	15.11	1,000	Apo-Allopurinol
Tab 300 mg – **1% DV Mar-15 to ~~2017~~ 31 Dec 2016**	15.91	500	Apo-Allopurinol

103 BENZBROMARONE (website address amended)

➔ Tab 100 mg	45.00	100	Benzbromaron AL 100

Restricted
Initiation
Any specialist
All of the following:
1 Patient has been diagnosed with gout; and
2 Any of the following:
- 2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
- 2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
- 2.3 Both:
  - 2.3.1 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); and
  - 2.3.2 The patient has a rate of creatinine clearance greater than or equal to 20 ml/min; or
- 2.4 All of the following:
  - 2.4.1 The patient is taking azathioprine and requires urate-lowering therapy; and
  - 2.4.2 Allopurinol is contraindicated; and
  - 2.4.3 Appropriate doses of probenecid are ineffective or probenecid cannot be used due to reduced renal function; and

3 The patient is receiving monthly liver function tests.

Notes: Benzbromarone has been associated with potentially fatal hepatotoxicity. In chronic renal insufficiency, particularly when the glomerular filtration rate is 30 ml/minute or less, probenecid may not be effective. Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.
The New Zealand Rheumatology Association has developed information for prescribers which can be accessed from its website at **www.rheumatology.org.nz/home/resources-2/**
~~www.rheumatology.org.nz/downloads/Benzbromarone-prescriber-information-NZRA-V2.pdf~~

NERVOUS SYSTEM

115 TRAMADOL HYDROCHLORIDE (new listing)
Oral soln 10 mg per ml

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

Changes to Section H Part II – effective 1 January 2017 (continued)

115 TRAMADOL HYDROCHLORIDE (delisting)
Oral drops 100 mg per ml
Note – Tramadol hydrochloride oral drops 100 mg per ml to be delisted from 1 July 2017.

117 DIAZEPAM (↑ price)

Rectal tubes 5 mg	33.07	5	Stesolid
Rectal tubes 10 mg	40.87	5	Stesolid

121 SUMATRIPTAN (delisting)

Inj 12 mg per ml, 0.5 ml cartridge	13.80	2	Arrow-Sumatriptan

Note – Arrow-Sumatriptan inj 12 mg per ml, 0.5 ml cartridge to be delisted from 1 July 2017.

125 TRIFLUOPERAZINE HYDROCHLORIDE – **Restricted: for continuation only** (restriction added and delisting)
➔ Tab 1 mg
➔ Tab 2 mg
➔ Tab 5 mg
Note: Trifluoperazine hydrochloride tab 1 mg, 2 mg and 5 mg to be delisted from 1 December 2017.

126 FLUPHENAZINE DECANOATE (new listing)
➔ Inj 25 mg per ml, 2 ml ampoule *e.g. Modecate*

132 BUPROPION HYDROCHLORIDE (↑ price)

Tab modified-release 150 mg	11.00	30	Zyban

132 DISULFIRAM (↑ price)

Tab 200 mg	44.30	100	Antabuse

133 NALTREXONE HYDROCHLORIDE (↑ price)

➔ Tab 50 mg	131.00	30	Naltraccord

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

141 ERLOTINIB (↓ price and HSS removed)

➔ Tab 100 mg – **1% DV Jun-15 to ~~2018~~ 31 Dec 2016**	764.00	30	Tarceva
➔ Tab 150 mg – **1% DV Jun-15 to ~~2018~~ 31 Dec 2016**	1,146.00	30	Tarceva

149 ETANERCEPT (new Pharmacode listing)

➔ Inj 50 mg autoinjector	1,599.96	4	Enbrel

Note – Enbrel inj 50 mg autoinjector (Pharmacode 2375729) to be delisted from 1 August 2017.

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

Changes to Section H Part II – effective 1 January 2017 (continued)

166 OBINUTUZUMAB (new listing)

➔ Inj 25 mg per ml, 40 ml vial.....5,910.00 1 Gazyva

Restricted
Initiation
Haematologist
Limited to 6 months treatment
All of the following:

1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
2 The patient is obinutuzumab treatment naive; and
3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance <70mL/min); and
4 Patient has adequate neutrophil and platelet counts (≥1.5 x 10^9/L and platelets ≥75 x 10^9/L) unless the cytopenias are a consequence of marrow infiltration by CLL; and
5 Patient has good performance status; and
6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

Notes: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to <2.

167 PERTUZUMAB (new listing)

➔ Inj 30 mg per ml, 14 ml vial.....3,927.00 1 Perjeta

Restricted
Initiation
Re-assessment required after 12 months
All of the following:

1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 Either:
  2.1 Patient is chemotherapy treatment naïve; or
  2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3 The patient has good performance status (ECOG grade 0-1); and
4 Pertuzumab to be administered in combination with trastuzumab; and
5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
6 Pertuzumab to be discontinued at disease progression.

Continuation
Re-assessment required after 12 months
Both:

1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab.

➔ 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 January 2017 (continued)

167 RITUXIMAB (amended restriction – amended criteria shown only)

➔ Inj 10 mg per ml, 10 ml vial	1,075.50	2	Mabthera
➔ Inj 10 mg per ml, 50 ml vial	2,688.30	1	Mabthera

Restricted

Initiation — indolent, low-grade lymphomas **or hairy cell leukaemia***

Re-assessment required after 9 months

Either:

1 Both:
   1.1 The patient has indolent low grade NHL **or hairy cell leukaemia*** with relapsed disease following prior chemotherapy; and
   1.2 To be used for a maximum of 6 treatment cycles; or
2 Both:
   2.1 The patient has indolent, low grade lymphoma **or hairy cell leukaemia*** requiring first-line systemic chemotherapy; and
   2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/ Waldenstrom macroglobulinaemia. ***Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.**

Continuation — indolent, low-grade lymphomas **or hairy cell leukaemia***

Re-assessment required after 9 months

All of the following:

1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has indolent, low-grade NHL **or hairy cell leukaemia*** with relapsed disease following prior chemotherapy; and
3 To be used for no more than 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/ Waldenstrom macroglobulinaemia. ***Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.**

Continuation – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

All of the following:

1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
2 The patient has had a rituximab treatment–free interval of 36 months or more; and
3 The patient does not have chromosome 17p deletion CLL; and
4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration); and
5 Rituximab to be administered in combination with fludarabine and cyclophosphamide for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

Initiation – ANCA associated vasculitis

Re-assessment required after 4 weeks

All of the following:

1 Patient has been diagnosed with ANCA associated vasculitis*; and
~~2 Either:~~
   ~~2.1 Patient does not have MPO-ANCA positive vasculitis*; or~~
   ~~2.2 Mycophenolate mofetil has not been effective in those patients who have MPO-ANCA positive vasculitis*; and~~

continued...

Changes to Section H Part II – effective 1 January 2017 (continued)

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2~~3~~ The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks; and

3~~4~~ Any of the following:

3~~4~~.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve ~~complete absence~~ **significant improvement** of disease after at least 3 months; or

3~~4~~.2 Patient has previously had a cumulative dose of cyclophosphamide >15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose >15 g; or

3~~4~~.3 Cyclophosphamide and methotrexate are contraindicated; or

3~~4~~.4 Patient is a female of child-bearing potential; or

3~~4~~.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with * are Unapproved Indications.

175 TOCILIZUMAB (amended restriction – amended criteria shown only)

➔ Inj 20 mg per ml, 4 ml vial	220.00	1	Actemra
➔ Inj 20 mg per ml, 10 ml vial	550.00	1	Actemra
➔ Inj 20 mg per ml, 20 ml vial	1,100.00	1	Actemra

Restricted
Initiation — Rheumatoid Arthritis
Rheumatologist
Re-assessment required after 6 months
Either:

1 All of the following:
- 1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- **1.3 Either:**
  - **1.3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or**
  - **1.3.2 Both:**
    - **1.3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital in accordance with the Section H rules; and**
    - **1.3.2.1 Either:**
      - **1.3.2.1.1 The patient has experienced intolerable side effects from rituximab; or**
      - **1.3.2.1.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis; or**
- ~~1.3 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital in accordance with the Section H rules; and~~
- ~~1.4 Either:~~
  - ~~1.4.1 The patient has experienced intolerable side effects from rituximab; or~~
  - ~~1.4.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria 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 Tocilizumab is to be used as monotherapy; and
- 2.3 Either:

continued...

Changes to Section H Part II – effective 1 January 2017 (continued)

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2.3.1 Treatment with methotrexate is contraindicated; or
2.3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
2.4 Either:
2.4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of cyclosporin alone or in combination with another agent; or
2.4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
2.5 Either:
2.5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
2.5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
2.6 Either:
2.6.1 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
2.6.2 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.

Initiation – polyarticular juvenile idiopathic arthritis
Rheumatologist
Re-assessment required after 4 months.
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for juvenile idiopathic arthritis (JIA); and
1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or
2 All of the following:
2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
2.2 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m^2 weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
2.4 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.5 Both:
2.5.1 Either:
2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
2.5.2 Physician's global assessment indicating severe disease.

Continuation – polyarticular juvenile idiopathic arthritis
Rheumatologist
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

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

Changes to Section H Part II – effective 1 January 2017 (continued)

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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 – idiopathic multicentric Castleman's disease
Haematologist or rheumatologist
Re-assessment required after 6 months
All of the following:
1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease; and
2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
3 Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks.

Continuation – idiopathic multicentric Castleman's disease
Haematologist or rheumatologist
Re-assessment required after 12 months
The treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status.

177 TRASTUZUMAB (amended restriction – amended criteria shown only)

➔ Inj 150 mg vial	1,350.00	1	Herceptin
➔ Inj 440 mg vial	3,875.00	1	Herceptin

Initiation — metastatic breast cancer (trastuzumab-naive patients)
Limited to 12 months treatment
All of the following:
1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 Either:
2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
2.2 Both:
2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
2.2.2 The cancer did not progress whilst on lapatinib; and
3 Either:
3.1 Trastuzumab will not be given in combination with pertuzumab; or
3.2 All of the following:
3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3.2.3 The patient has good performance status (ECOG grade 0-1); and
4 Trastuzumab not to be given in combination with lapatinib; and
5 Trastuzumab to be discontinued at disease progression.
~~Either:~~
~~1 All of the following:~~
~~1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and~~
~~1.2 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; and~~
~~1.3 Trastuzumab not to be given in combination with lapatinib; and~~
~~1.4 Trastuzumab to be discontinued at disease progression; or~~

continued...

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

Changes to Section H Part II – effective 1 January 2017 (continued)

continued...

~~2 All of the following:~~
~~2.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and~~
~~2.2 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and~~
~~2.3 The cancer did not progress whilst on lapatinib; and~~
~~2.4 Trastuzumab not to be given in combination with lapatinib; and~~
~~2.5 Trastuzumab to be discontinued at disease progression.~~

Initiation — metastatic breast cancer (patients previously treated with trastuzumab)
Limited to 12 months treatment
All of the following:
1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 Either:
2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
2.2 Both:
2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
2.2.2 The cancer did not progress whilst on lapatinib; and
3 Either:
3.1 Trastuzumab will not be given in combination with pertuzumab; or
3.2 All of the following:
3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3.2.3 The patient has good performance status (ECOG grade 0-1); and
4 Trastuzumab not to be given in combination with lapatinib; and
5 Trastuzumab to be discontinued at disease progression.

~~All of the following:~~
~~1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and~~
~~2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and~~
~~3 Any of the following:~~
~~3.1 All of the following:~~
~~3.1.1 The patient has not previously received lapatinib treatment for metastatic breast cancer; and~~
~~3.1.2 Trastuzumab not to be given in combination with lapatinib; and~~
~~3.1.3 Trastuzumab to be discontinued at disease progression; or~~
~~3.2 All of the following:~~
~~3.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and~~
~~3.2.2 The cancer did not progress whilst on lapatinib; and~~
~~3.2.3 Trastuzumab not to be given in combination with lapatinib; and~~
~~3.2.4 Trastuzumab to be discontinued at disease progression; or~~
~~3.3 All of the following:~~
~~3.3.1 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and~~
~~3.3.2 Trastuzumab not to be given in combination with lapatinib; and~~
~~3.3.3 Trastuzumab to be discontinued at disease progression.~~

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

Changes to Section H Part II – effective 1 January 2017 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

186 PIRFENIDONE (new listing)

➔ Cap 267 mg	3,645.00	270	Esbriet

Restricted
Initiation
Respiratory specialist
Re-assessment required after 12 months
All of the following:
1 Patient has been diagnosed with idiopathic pulmonary fibrosis as confirmed by histology, CT or biopsy; and
2 Forced vital capacity is between 50% and 80% predicted; and
3 Pirfenidone is to be discontinued at disease progression (See Notes).

Continuation
Respiratory specialist
Re-assessment required after 12 months
Both:
1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Pirfenidone is to be discontinued at disease progression (See Notes).

Notes: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

VARIOUS

198 IODISED OIL (↑ price)

Inj 38% w/w (480 mg per ml), 10 ml ampoule	230.00	1	Lipiodol Ultra Fluid

SPECIAL FOODS

216 PAEDIATRIC ORAL FEED (↑ price)

➔ Powder 14.9 g protein, 54.3 g carbohydrate and 24.7 g fat per 100 g, can	28.00	850 g	Pediasure (Vanilla)

219 ORAL FEED (↑ price)

➔ Powder 15.9 g protein, 57.4 g carbohydrate and 14 g fat per 100 g, can	26.00	850 g	Ensure (Chocolate) Ensure (Vanilla)
➔ Powder 16 g protein, 59.8 g carbohydrate and 14 g fat per 100 g, can	26.00	850 g	Ensure (Chocolate) Ensure (Vanilla)

Changes to Section H Part II – effective 1 January 2017 (continued)

VACCINES

225 HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV] (new listing)
➔ Inj 270 mcg in 0.5 ml syringe – **0% DV Jul-17 to 2020** ..... 0.00 10 **Gardasil 9**

Restricted
Initiation – children aged 14 years and under
Therapy limited to 2 doses
Children aged 14 years and under.

Initiation – other conditions
Either:
1 Up to 3 doses for people aged 15 to 26 years inclusive; or
2 Both:
2.1 People aged 9 to 26 years inclusive; and
2.2 Any of the following:
2.2.1 Up to 3 doses for confirmed HIV infection; or
2.2.2 Up to 3 doses for transplant (including stem cell) patients: or
2.2.3 Up to 4 doses for Post chemotherapy.

225 HUMAN PAPILLOMAVIRUS (6, 11, 16 AND 18) VACCINE [HPV] (delisting)
➔ Inj 120 mcg in 0.5 ml syringe – **1% DV Jul-14 to 2017** ..... 0.00 10 **Gardasil**
Note – Gardasil inj 120 mcg in 0.5 ml syringe to be delisted from 1 October 2017.

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

Changes to Section H Part II – effective 1 December 2016

ALIMENTARY TRACT AND METABOLISM

20 ALGLUCOSIDASE ALFA

➔ Inj 50 mg vial ..... 1,142.60 1 Myozyme

Restricted
Initiation
Metabolic physician
Re-assessment required after 12 months
All of the following:
1 The patient is aged up to 24 months at the time of initial application and has been diagnosed with infantile Pompe disease; and
2 Any of the following:
  2.1 Diagnosis confirmed by documented deficiency of acid alpha-glucosidase by prenatal diagnosis using chorionic villus biopsies and/or cultured amniotic cells; or
  2.2 Documented deficiency of acid alpha-glucosidase, and urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides; or
  2.3 Documented deficiency of acid alpha-glucosidase, and documented molecular genetic testing indicating a disease-causing mutation in the acid alpha-glucosidase gene (GAA gene); or
  2.4 Documented urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides, and molecular genetic testing indicating a disease-causing mutation in the GAA gene; and
3 Patient has not required long-term invasive ventilation for respiratory failure prior to starting enzyme replacement therapy (ERT); and
4 Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by ERT or might reasonably be expected to compromise a response to ERT; and
5 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks.

Continuation
Metabolic physician
Re-assessment required after 12 months
All of the following:
1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and
2 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks; and
3 Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
4 Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by ERT; and
5 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
6 There is no evidence of life threatening progression of respiratory disease as evidenced by the needed for >14 days of invasive ventilation.
7 There is no evidence of new or progressive cardiomyopathy.

21 IDURSULFASE

➔ Inj 2 mg per ml, 3 ml vial ..... 4,608.30 1 Elaprase

Restricted
Metabolic physician.
Limited to 24 weeks treatment
All of the following:
1 The patient has been diagnosed with Hunter Syndrome (mucopolysacchardosis II); and
2 Either:

continued...

Changes to Section H Part II – effective 1 December 2016 (continued)

continued...

2.1 Diagnosis confirmed by demonstration of iduronate 2-sulfatase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts or

2.2 Detection of a disease causing mutation in the iduronate 2-sulfatase gene; and

3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with idursulfase would be bridging treatment to transplant; and.

4 Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT); and

5 Idursulfase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 weeks post-HSCT) at doses no greater than 0.5 mg/kg every week.

CARDIOVASCULAR SYSTEM

42	TERAZOSIN (brand change)			
	Tab 5 mg – **1% DV Feb-17 to 2019**	10.90	500	**Apo-Terazosin**
	Note – Arrow terazosin tab 5 mg to be delisted from 1 February 2017.			
46	METHYLDOPA (new listing)			
	Tab 250 mg	15.10	100	Methyldopa Mylan
46	METHYLDOPA (delisting)			
	Tab 500 mg	23.15	100	Prodopa
	Note – Prodopa tab 500 mg to be delisted from 1 June 2017.			

DERMATOLOGICALS

56	HYDROCORTISONE (new listing)			
	Crm 1%, 30 g – **1% DV Feb-17 to 2019**	1.11	30 g	**DermAssist**
	Note: DV limit applies to the pack sizes of less than or equal to 100 g.			
56	HYDROCORTISONE (delisting)			
	Crm 1%, 100 g	3.75	100 g	Pharmacy Health
	Note – Pharmacy Health crm 1%, 100 g to be delisted from 1 February 2017.			

HORMONE PREPARATIONS

66	PREDNISONE (delisting)			
	Tab 1 mg	2.13	100	Apo-Prednisone S29
	Note – Apo-Prednisone S29 tab 1 mg to be delisted from 1 December 2016.			
68	LEUPRORELIN ACETATE (delisting)			
	Inj 30 mg prefilled dual chamber syringe	1,109.40	1	Lucrin Depot 6-month
	Note – Lucrin Depot 6-month inj 30 mg prefilled dual chamber syringe to be delisted from 1 August 2017.			

INFECTIONS

74	TOBRAMYCIN (brand change)			
	➔ Inj 40 mg per ml, 2 ml vial – **1% DV Feb-17 to 2018**	15.00	5	**Tobramycin Mylan**
	Note – DBL Tobramycin inj 40 mg per ml, 2 ml vial to be delisted from 1 February 2017.			

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

Changes to Section H Part II – effective 1 December 2016 (continued)

86 ENFUVIRTIDE (delisting)
➔ Inj 108 mg vial x 60 ..... 2,380.00 1 Fuzeon
Note – Fuzeon inj 108 mg vial x 60 to be delisted from 1 February 2017.

94 PARITAPREVIR, RITONAVIR AND OIMBITASVIR WITH DASABUVIR (website address amended)
Note: Only for use in patients who have received supply of treatment via PHARMAC's approved direct distribution supply.
Application details for accessing treatment may be obtained from PHARMAC's website **http://www.pharmac.govt.nz/hepatitis-c-treatments/** ~~http://www.pharmac.govt.nz~~.
Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56), with dasabuvir tab 250 mg (56)..... 16,500.00 1 Viekira Pak

94 PARITAPREVIR, RITONAVIR AND OMBITASVIR WITH DASABUVIR AND RIBAVIRIN (website address amended)
Note: Only for use in patients who have received supply of treatment via PHARMAC's approved direct distribution supply.
Application details for accessing treatment may be obtained from PHARMAC's website **http://www.pharmac.govt.nz/hepatitis-c-treatments/** ~~http://www.pharmac.govt.nz~~.
Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56) with dasabuvir tab 250 mg (56) and ribavirin tab 200 mg (168) ..... 16,500.00 1 Viekira Pak-RBV

MUSCULOSKELETAL SYSTEM

103 ALLOPURINOL (new listing)
Tab 100 mg ..... 15.11 1,000 Allopurinol-Apotex
Tab 300 mg ..... 15.91 500 Allopurinol-Apotex

103 ALLOPURINOL (delisting)
Tab 100 mg – **1% DV Mar-15 to 2017** ..... 15.11 1,000 **Apo-Allopurinol**
Tab 300 mg – **1% DV Mar-15 to 2017** ..... 15.91 500 **Apo-Allopurinol**
Note – Apo-Allopurinol tab 100 mg and 300 mg to be delisted from 1 June 2017.

NERVOUS SYSTEM

126 FLUPHENAZINE DECANOATE – **Restricted: For continuation only** (addition of restriction)
Inj 12.5 mg per 0.5 ml ampoule ..... 17.60 5 Modecate
Inj 25 mg per ml, 1 ml ampoule ..... 27.90 5 Modecate
Inj 100 mg per ml, 1 ml ampoule ..... 154.50 5 Modecate

127 ALPRAZOLAM – **Restricted: For continuation only** (addition of restriction)
Tab 1 mg
Tab 250 mcg
Tab 500 mcg

Changes to Section H Part II – effective 1 December 2016 (continued)

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

139 TEMOZOLOMIDE (brand change)

➔ Cap 5 mg – **1% DV Feb-17 to 2019**	10.20	5	**Orion Temozolomide**
➔ Cap 20 mg – **1% DV Feb-17 to 2019**	18.30	5	**Orion Temozolomide**
➔ Cap 100 mg – **1% DV Feb-17 to 2019**	40.20	5	**Orion Temozolomide**
➔ Cap 250 mg – **1% DV Feb-17 to 2019**	96.80	5	**Orion Temozolomide**

Note – Temaccord cap 5 mg, 20 mg, 100 mg and 250 mg to be delisted 1 February 2017.

147 ETANERCEPT (amended criteria shown only)

➔ Inj 25 mg vial	799.96	4	Enbrel
➔ Inj 50 mg autoinjector	1,599.96	4	Enbrel
➔ Inj 50 mg syringe	1,599.96	4	Enbrel

Restricted
Initiation — juvenile idiopathic arthritis
Rheumatologist or named specialist
*Re-assessment required after **6** 4 months*
Either:
1 Both:
- 1.1 The patient has had an initial Special Authority approval for adalimumab for juvenile idiopathic arthritis (JIA); 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 adalimumab to meet the renewal criteria for adalimumab for JIA; or

2 All of the following:
- 2.1 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and
- 2.2 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 had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m2 weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
- 2.5 Both:
  - 2.5.1 Either:
    - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
    - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
  - 2.5.2 Physician's global assessment indicating severe disease.

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 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 adalimumab to meet the renewal criteria for adalimumab for rheumatoid arthritis; or

continued...

Changes to Section H Part II – effective 1 December 2016 (continued)

continued...

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 sulphasalazine 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
- 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.

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 adalimumab for ankylosing spondylitis; 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 adalimumab to meet the renewal criteria for adalimumab 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 ~~an~~ **a regular** exercise regime**n for ankylosing spondylitis** ~~supervised by a physiotherapist~~; 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

continued...

Changes to Section H Part II – effective 1 December 2016 (continued)

continued...

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.

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 of etanercept treatment,~~ **Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in** BASDAI ~~has improved by~~ **of** 4 or more points from pre-treatment baseline on a 10 point scale, or **an improvement in BASDAI of** ~~by~~ 50%, whichever is less; and
2 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

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
  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 adalimumab 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 anti-inflammatory drugs (NSAIDs) and methotrexate; and
  2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

Changes to Section H Part II – effective 1 December 2016 (continued)

153 ADALIMUMAB (amended criteria shown only)

➔ Inj 10 mg per 0.2 ml prefilled syringe	1,599.96	2	Humira
➔ Inj 20 mg per 0.4 ml syringe	1,599.96	2	Humira
➔ Inj 40 mg per 0.8 ml pen	1,599.96	2	HumiraPen
➔ Inj 40 mg per 0.8 ml syringe	1,599.96	2	Humira

Restricted
Initiation — juvenile idiopathic arthritis
Rheumatologist or named specialist
*Re-assessment required after **6** 4 months*
Either:
1 Either:
  1.1 Both:
    1.1.1 The patient has had an initial Special Authority approval for etanercept for juvenile idiopathic arthritis (JIA); and
    1.1.2 Either:
      1.1.2.1 The patient has experienced intolerable side effects from etanercept; or
      1.1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for JIA; or
2 All of the following:
  2.1 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and
  2.2 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 had severe active polyarticular course JIA for 6 months duration or longer; and
  2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m^2 weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
  2.5 Both:
    2.5.1 Either:
      2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
      2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
    2.5.2 Physician's global assessment indicating severe disease.

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

continued...

Changes to Section H Part II – effective 1 December 2016 (continued)

continued...

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 sulphasalazine 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
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.

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 ~~an~~ **a regular** exercise regime**n for ankylosing spondylitis** ~~supervised by a physiotherapist~~; 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.

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:

continued...

Changes to Section H Part II – effective 1 December 2016 (continued)

continued...

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 of adalimumab treatment,~~ **Following 12 weeks' initial treatment and subsequent renewals, treatment has resulted in an improvement in** BASDAI ~~has improved by~~ **of** 4 or more points from pre-treatment baseline on a 10 point scale, or **an improvement in BASDAI of** ~~by~~ 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 — 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
  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 anti-inflammatory drugs (NSAIDs) and methotrexate; and
  2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

Changes to Section H Part II – effective 1 December 2016 (continued)

167 RITUXIMAB (amended criteria shown only)

➔ Inj 10 mg per ml, 10 ml vial	1,075.50	2	Mabthera
➔ Inj 10 mg per ml, 50 ml vial	2,688.30	1	Mabthera

Restricted
Initiation — rheumatoid arthritis - TNF inhibitors contraindicated
Rheumatologist
Limited to 4 months treatment
All of the following:

1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 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
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
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulphasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
  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 cyclosporin; or
  5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  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
6 Either:
  6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  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
7 Either:
  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
  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; and
8 Either:
  8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

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

Changes to Section H Part II – effective 1 December 2016 (continued)

174 TOCILIZUMAB (amended criteria shown only)

➔ Inj 20 mg per ml, 4 ml vial	220.00	1	Actemra
➔ Inj 20 mg per ml, 10 ml vial	550.00	1	Actemra
➔ Inj 20 mg per ml, 20 ml vial	1,100.00	1	Actemra

Restricted
Initiation — Rheumatoid Arthritis
Rheumatologist
Re-assessment required after 6 months
Either:
1 All of the following:
- 1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 1.3 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital in accordance with the Section H rules; and
- 1.4 Either:
  - 1.4.1 The patient has experienced intolerable side effects from rituximab; or
  - 1.4.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria 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 Tocilizumab is to be used as monotherapy; and
- 2.3 Either:
  - 2.3.1 Treatment with methotrexate is contraindicated; or
  - 2.3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
- 2.4 Either:
  - 2.4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of cyclosporin alone or in combination with another agent; or
  - 2.4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
- 2.5 Either:
  - 2.5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
  - 2.5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.6 Either:
  - 2.6.1 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
  - 2.6.2 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.

Initiation — adult-onset Still's disease
Rheumatologist
Re-assessment required after 6 months
Either:
1 Both:
- 1.1 Either:

continued...

Changes to Section H Part II – effective 1 December 2016 (continued)

continued...

1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or 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 HML rules; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept 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 anti-inflammatory drugs (NSAIDs) and methotrexate; and
2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

RESPIRATORY SYSTEM AND ALLERGIES

183 CETIRIZINE HYDROCHLORIDE (↓ price and delayed delisting)
Tab 10 mg ..... 1.01 100 Zetop
Note – Zetop tab 10 mg delisting delayed from 1 December 2016 until 1 March 2017.

183 CETIRIZINE HYDROCHLORIDE (HSS start date delayed)
Tab 10 mg – **1% DV** ~~Dec-16~~ **Mar-17 to 2019** ..... 1.01 100 **Zista**

183 LORATADINE (brand change)
Oral liq 1 mg per ml – **1% DV Feb-17 to 2019** ..... 2.15 120 ml **Lorfast**
Note – LoraPaed oral liq 1 mg per ml to be delisted from 1 February 2017.

SPECIAL FOODS

212 FAT-MODIFIED FEED (delisting)
➔ Powder 11.4 g protein, 68 g carbohydrate and 11.8 g fat per 100 g, 400 g can e.g. Monogen
Note – Monogen powder (old formulation) to be delisted from 1 February 2017. The new formulation remains listed.

Effective 22 November 2016

BLOOD AND BLOOD FORMING ORGANS

39 POTASSIUM CHLORIDE (HSS suspended)
Tab long-acting 600 mg (8 mmol)
– **1% DV Sep-15 to** ~~2018~~ **22 Nov 2016** ..... 7.42 200 Span-K

39 SODIUM BICARBONATE (new Pharmacode isting)
Cap 840 mg ..... 8.52 100 Sodibic
Note – Pharmacode 2513447 listed from 22 November 2016.

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Pharmaceuticals and brands

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