Pharmaceutical Management Agency

Section H Update for Hospital Pharmaceuticals

Effective 1 December 2016

PHARMAC
Pharmaceutical Management Agency

Contents

Summary of decisions
EFFECTIVE 1 DECEMBER 2016

- Adalimumab inj 10 mg per 0.2 ml syringe, 20 mg per 0.4 ml syringe, and 40 mg per 0.8 ml syringe (Humira), and inj 40 mg per 0.8 ml pen (HumiraPen) – amended restriction
- Alglucosidase alfa (Myozyme) inj 50 mg vial – new listing
- Allopurinol (Allopurinol-Apotex) tab 100 mg and 300 mg – new listing
- Allopurinol (Apo-Allopurinol) tab 100 mg and 300 mg – to be delisted from 1 June 2017
- Alprazolam tab 250 mcg, 500 mcg and 1 mg – For continuation only added
- Enfuvirtide (Fuzeon) inj 108 mg vial x 60 – to be delisted 1 February 2017
- Etanercept (Enbrel) inj 25 mg vial, 50 mg autoinjector and 50 mg syringe – amended restriction
- Fat-modified feed (e.g. Monogen) powder 11.4 g protein, 68 g carbohydrate and 11.8 g fat per 100 g, 400 g can – to be delisted 1 February 2017
- Fluphenazine decanoate (Modecate) inj 12.5 mg per 0.5 ml ampoule, 25 mg per ml, 1 ml ampoule, and 100 mg per ml, 1 ml ampoule – For continuation only added
- Hydrocortisone (DermAssist) crm 1%, 30 g – new listing and addition of HSS
- Hydrocortisone (Pharmacy Health) crm 1%, 100 g – to be delisted 1 February 2017
- Idursulfase (Elaprase) inj 2 mg per ml, 3 ml vial – new listing
- Leuprorelin acetate (Lucrin Depot 6-month) inj 30 mg prefilled dual chamber syringe – to be delisted 1 August 2017
- Loratadine (Lorfast) oral liq 1 mg per ml, 120 ml – new listing and addition of HSS
- Loratadine (LoraPaed) oral liq 1 mg per ml, 200 ml – to be delisted 1 February 2017
- Methyldopa (Methyldopa Mylan) tab 250 mg – new listing
- Methyldopa (Prodopa) tab 500 mg – to be delisted 1 June 2017
- Paritaprevir, ritonavir and oimbitasvir with dasabuvir (Viekira Pak) tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56), with dasabuvir tab 250 mg (56) – website address amended
- Paritaprevir, ritonavir and ombitasvir with dasabuvir and ribavirin (Viekira Pak-RBV) 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) – website address amended
- Prednisone (Apo-Prednisone S29) tab 1 mg – to be delisted 1 December 2016

Summary of decisions – effective 1 December 2016 (continued)

- Rituximab (Mabthera) inj 10 mg per ml, 10 ml and 50 ml vials – amended restriction
- Temozolomide (Orion Temozolomide) cap 5 mg, 20 mg, 100 mg and 250 mg – new listing and addition of HSS
- Temozolomide (Temaccord) cap 5 mg, 20 mg, 100 mg and 250 mg to be delisted 1 February 2017
- Terazosin (Apo-Terazosin) tab 5 mg – new listing and addition of HSS
- Terazosin (Arrow) tab 5 mg – to be delisted 1 February 2017
- Tobramycin (Tobramycin Mylan) inj 40 mg per ml, 2 ml vial – new listing and addition of HSS
- Tobramycin (DBL Tobramycin) inj 40 mg per ml, 2 ml vial – to be delisted 1 February 2017
- Tocilizumab (Actemra) inj 20 mg per ml, 4 ml, 10 ml and 20 ml vials – amended restriction

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

Section H changes to 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

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

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...

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

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.

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...

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

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	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.

➔ Restriction

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

Index
Pharmaceuticals and brands

New Zealand Government

New Zealand
Permit No. 478

Permit

Email: enquiry@pharmac.govt.nz

www.pharmac.govt.nz/medicines/hospital-pharmaceuticals

Pharmaceutical Management Agency
Level 9, 40 Mercer Street, PO Box 10254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

ISSN 1172-3694 (Print) - ISSN 1179-3708 (Online)

If Undelivered, Return To: PO Box 10254, Wellington 6143, New Zealand