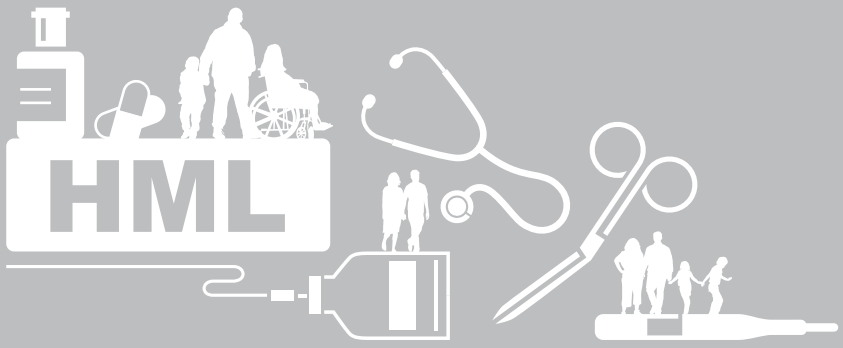
The Hospital Medicines List (HML)

# Section H

## for Hospital Pharmaceuticals

## Update effective 1 February 2016

**Cumulative for December 2015, January and February 2016**




PHARMAC
Pharmaceutical Management Agency

# Contents

## Summary of decisions
### EFFECTIVE 1 FEBRUARY 2016

- Amoxicillin with clavulanic acid (Augmentin) grans for oral liq 25 mg with clavulanic acid 6.25 mg per ml, and 50 mg with clavulanic acid 12.5 mg per ml – price increase
- Desflurane (Suprane) soln for inhalation 100%, 240 ml bottle – price increase
- Dexamethasone phosphate (Max Health) inj 4 mg per ml, 1 ml and 2 ml ampoules – brand name change, price decrease and extension of HSS
- Dimethyl fumarate (Tecfidera) cap 120 mg and 240 mg – new listing
- Etoposide (Rex Medical) inj 20 mg per ml, 5 ml vial – new listing and addition of HSS
- Etoposide (Hospira) inj 20 mg per ml, 5 ml ampoule – to be delisted 1 April 2016
- Glycopyrronium bromide (Max Health) inj 200 mcg per ml, 1 ml ampoule – price decrease and extension of HSS
- Isoflurane (Aerrane) soln for inhalation 100%, 250 ml bottle – price increase
- Levetiracetam (Everet) tab 250 mg, 500 mg, 750 mg and 1,000 mg – new listing
- Levetiracetam (Levetiracetam-Rex) tab 250 mg, 500 mg, and 750 mg – to be delisted 1 August 2016
- Moxifloxacin (Avelox IV 400) inj 1.6 mg per ml, 250 ml bottle – new listing
- Moxifloxacin (Avelox IV 400) inj 1.6 mg per ml, 250 ml bag – to be delisted 1 April 2016
- Neostigmine metilsulfate with glycopyrronium bromide (Max Health) inj 2.5 mg glycopyrronium bromide 0.5 mg per ml, 1 ml ampoule – price decrease and extension of HSS
- Rizatriptan (Rizamelt) tab orodispersible 10 mg, 12 tab pack size – new listing of additional pack
- Sevoflurane (Baxter) soln for inhalation 100%, 250 ml bottle – price increase
- Teriflunomide (Aubagio) tab 14 mg – new listing
- Tetracosactide [tetracosactrin] (Synacthen) inj 250 mcg per ml, 1 ml ampoule, 1 inj pack size – new listing
- Tetracosactide [tetracosactrin] (Synacthen) inj 250 mcg per ml, 1 ml ampoule, 10 inj pack size – to be delisted 1 April 2016

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

# Section H changes to Part II

## Effective 1 February 2016

### ALIMENTARY TRACT AND METABOLISM

15 GLYCOPYRRONIUM BROMIDE (↓ price and extension of HSS)

Inj 200 mcg per ml, 1 ml ampoule – **1% DV Oct-13 to 2019** ~~2016~~ ..... 17.14 | 10 | **Max Health**

### HORMONE PREPARATIONS

60 DEXAMETHASONE PHOSPHATE (brand name change, ↓ price and extension of HSS)

Inj 4 mg per ml, 1 ml ampoule – **1% DV Apr-14 to 2019** ~~2016~~ ..... 14.19 | 10 | **Max Health** ~~Dexamethasone-hameln~~

Inj 4 mg per ml, 2 ml ampoule – **1% DV Apr-14 to 2019** ~~2016~~ ..... 12.59 | 5 | **Max Health** ~~Dexamethasone-hameln~~

62 TETRACOSACTIDE [TETRACOSACTRIN] (pack size change)

Inj 250 mcg per ml, 1 ml ampoule ..... 17.71 | 1 | Synacthen

Note – pack size change from 10 inj to 1 inj pack. The 10 injection pack size to be delisted from 1 April 2016.

### INFECTIONS

72 AMOXICILLIN WITH CLAVULANIC ACID (↑ price)

Grans for oral liq 25 mg with clavulanic acid 6.25 mg per ml..... 3.83 | 100 ml | Augmentin

Grans for oral liq 50 mg with clavulanic acid 12.5 mg per ml..... 4.97 | 100 ml | Augmentin

73 MOXIFLOXACIN (presentation change)

➔ Inj 1.6 mg per ml, 250 ml bottle ..... 70.00 | 1 | Avelox IV 400

Note – this is a presentation change from a bag to bottle. Avelox IV 400 infusion bag will be delisted from 1 April 2016.

### MUSCULOSKELETAL SYSTEM

92 NEOSTIGMINE METILSULFATE WITH GLYCOPYRRONIUM BROMIDE (↓ price and extension of HSS)

Inj 2.5 mg with glycopyrronium bromide 0.5 mg per ml, 1 ml ampoule – **1% DV Nov-13 to 2019** ~~2016~~ ..... 20.90 | 10 | **Max Health**

### NERVOUS SYSTEM

103 DESFLURANE (↑ price)

Soln for inhalation 100%, 240 ml bottle ..... 1,414.50 | 6 | Suprane

103 ISOFLURANE (↑ price)

Soln for inhalation 100%, 250 ml bottle ..... 1,173.00 | 6 | Aerrane

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

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

104 SEVOFLURANE (↑ price)
Soln for inhalation 100%, 250 ml bottle ..... 1,365.00 6 Baxter

114 LEVETIRACETAM
Tab 250 mg ..... 24.03 60 Everet
Tab 500 mg ..... 28.71 60 Everet
Tab 750 mg ..... 45.23 60 Everet
Tab 1,000 mg ..... 59.12 60 Everet
Note – Levetiracetam-Rex tab 250 mg, 500 mg and 750 mg to be delisted from 1 August 2016.

116 RIZATRIPTAN (additional pack size)
Tab orodispersible 10 mg – **1% DV Sep-14 to 2017** ..... 3.24 12 **Rizamelt**

122 DIMETHYL FUMARATE
➔ Cap 120 mg ..... 520.00 14 Tecfidera
➔ Cap 240 mg ..... 2,000.00 56 Tecfidera
Restricted
Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

122 TERIFLUNOMIDE
➔ Tab 14 mg ..... 1,582.62 28 Aubagio
Restricted
Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

## ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

131 ETOPOSIDE
Inj 20 mg per ml, 5 ml vial – **1% DV Apr-16 to 2018** ..... 7.90 1 **Rex Medical**
Note – Hospira etoposide inj 20 mg per ml, 5 ml vial to be delisted from 1 April 2016.

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

## Changes to Section H Part II – effective 1 January 2016

### ALIMENTARY TRACT AND METABOLISM

14 MESALAZINE (new listing)

| | | | |
|---|---|---|---|
| Tab 800 mg | 85.55 | 90 | Asacol |

### CARDIOVASCULAR SYSTEM

44 EZETIMIBE (Pharmacode change)

| | | | |
|---|---|---|---|
| ➔ Tab 10 mg – **1% DV Aug-15 to 2017** | 3.35 | 30 | **Ezemibe** |

Note – Pharmacode change from a blister pack to bottle. The blister will be delisted from 1 July 2016.

### DERMATOLOGICALS

50 ISOTRETINOIN (HSS suspended)

| | | | |
|---|---|---|---|
| Cap 10 mg – **1% DV Nov-15 to 31/12/15** ~~2018~~ | 12.47 | 100 | Isotane 10 |
| Cap 20 mg – **1% DV Nov-15 to 31/12/15** ~~2018~~ | 19.27 | 100 | Isotane 20 |

50 ISOTRETINOIN (new listing)

| | | | |
|---|---|---|---|
| Cap 10 mg | 14.96 | 120 | Oratane |
| Cap 20 mg | 23.12 | 120 | Oratane |

51 AQUEOUS CREAM

| | | | |
|---|---|---|---|
| Crm 500 g – **1% DV Mar-16 to 2018** | 1.99 | 500 g | **AFT SLS-free** |

**Note: DV limit applies to the pack sizes of greater than 100 g.**

Note – AFT aqueous cream 500 g to be delisted from 1 March 2016.

### INFECTIONS

72 AMOXICILLIN (new listing)

| | | | |
|---|---|---|---|
| Grans for oral liq 125 mg per 5 ml | 2.00 | 100 ml | Ospamox |
| Grans for oral liq 250 mg per 5 ml | 2.00 | 100 ml | Ospamox |

73 CIPROFLOXACIN

| | | | |
|---|---|---|---|
| ➔ Inj 2 mg per ml, 100 ml bag – **1% DV Mar-16 to 2018** | 30.58 | 10 | **Cipflox** |

Note – Aspen Ciprofloxacin inj 2 mg per ml, 100 ml bag to be delisted from 1 March 2016.

79 RIFAMPICIN (discontinuation)

| | | | |
|---|---|---|---|
| ➔ Tab 600 mg – **1% DV Nov-14 to 2017** | 108.70 | 30 | **Rifadin** |

Note – Rifadin tab 600 mg to be delisted from 1 March 2016.

89 VALACICLOVIR

| | | | |
|---|---|---|---|
| ➔ Tab 500 mg – **1% DV Mar-16 to 2018** | 6.42 | 30 | **Vaclovir** |
| ➔ Tab 1,000 mg – **1% DV Mar-16 to 2018** | 12.75 | 30 | **Vaclovir** |

Note – Valtrex tab 500 mg to be delisted from 1 March 2016.

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

### NERVOUS SYSTEM

116 SUMATRIPTAN (HSS suspended)
Inj 12 mg per ml, 0.5 ml cartridge
– **1% DV Sep-13 to 31/12/15** ~~2016~~ ..... 13.80 2 Arrow-Sumatriptan

120 ZIPRASIDONE (restriction removed)
Cap 20 mg – **1% DV Jan-16 to 2018**..... 14.56 60 **Zusdone**
Cap 40 mg – **1% DV Jan-16 to 2018**..... 24.75 60 **Zusdone**
Cap 60 mg – **1% DV Jan-16 to 2018**..... 33.87 60 **Zusdone**
Cap 80 mg – **1% DV Jan-16 to 2018**..... 39.74 60 **Zusdone**

~~Restricted~~
~~1 Patient is suffering from schizophrenia or related psychoses; and~~
~~2 Either:~~
~~2.1 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of unacceptable side effects; or~~
~~2.2 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of inadequate clinical response.~~

### ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

128 BLEOMYCIN SULPHATE (amended presentation description)
Inj 15,000 iu ~~(10 mg)~~ vial – **1% DV Oct-15 to 2018**..... 150.48 1 **DBL Bleomycin Sulfate**

133 OXALIPLATIN
Inj 5 mg per ml, 10 ml vial – **1% DV Mar-16 to 2018**..... 13.32 1 **Oxaliccord**
Inj 5 mg per ml, 20 ml vial – **1% DV Mar-16 to 2018**..... 16.00 1 **Oxaliccord**
Note – Oxaliplatin Actavis 50 inj 50 mg vial and Oxaliplatin Actavis 100 inj 100 mg vial to be delisted from 1 March 2016.

147 ADALIMUMAB (new listing)
➔ Inj 10 mg per 0.2 ml prefilled syringe..... 1,599.96 2 Humira

147 ADALIMUMAB (↓ price)
➔ 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

154 INFLIXIMAB (amended restriction – affected criteria only)
➔ Inj 100 mg – **10% DV Mar-15 to 29 Feb 2020**..... 806.00 1 **Remicade**

Initiation – fistulising Crohn's disease
Gastroenterologist
***Re-assessment required after 4 months*** ~~*Therapy limited to 4 doses*~~
All of the following:
1 Patient has confirmed Crohn's disease; and
2 Either:
2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
2.2 Patient has one or more rectovaginal fistula(e).

Initiation – plaque psoriasis~~, prior TNF use~~

*continued...*

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

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

*continued...*

Dermatologist

**Re-assessment required after** ~~Therapy limited to~~ 3 doses

**Either:**

**1** Both:

**1.**1 The patient has had an initial Special Authority approval for adalimumab or etanercept for severe chronic plaque psoriasis; and

**1.**2 Either:

**1.**2.1 The patient has experienced intolerable side effects from adalimumab or etanercept; or

**1.**2.2 The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept for severe chronic plaque psoriasis; or

**2 All of the following:**

**2.1 Either:**

**2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or**

**2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and**

**2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated):**
**phototherapy, methotrexate, ciclosporin, or acitretin; and**

**2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and**

**2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.**

**Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.**

~~Initiation – plaque psoriasis, treatment-naive~~
~~Dermatologist~~
~~Therapy limited to 3 doses~~
~~All of the following:~~
~~1 Either:~~
~~1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or~~
~~1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and~~
~~2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, thotrexate, ciclosporin, or acitretin; and~~
~~3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and~~
~~4 The most recent PASI assessment is no more than 1 month old at the time of initiation.~~

*continued...*

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

*continued...*

~~Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.~~

### RESPIRATORY SYSTEM AND ALLERGIES

172 ICATIBANT (new listing)

➔ Inj 10 mg per ml, 3 ml prefilled syringe ..... 2,668.00 1 Firazyr

Restricted
Initiation
Clinical immunologist or relevant specialist
*Re-assessment required after 12 months*
Both:
1 Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
2 The patient has undergone product training and has agreed upon an action plan for self-administration.

Continuation
Re-assessment required after 12 months
The treatment remains appropriate and the patient is benefiting from treatment.

### SENSORY ORGANS

178 CHLORAMPHENICOL (↑ price)

Eye oint 1% ..... 3.19 4 g Chlorsig

180 MIXED SALT SOLUTION FOR EYE IRRIGATION (Pharmacode change)

Eye irrigation solution calcium chloride 0.048% with magnesium chloride 0.03%, potassium chloride 0.075%, sodium acetate 0.39%, sodium chloride 0.64% and sodium citrate 0.17%, 500 ml bottle
**– 1% DV Jan-16 to 2018** ..... 10.50 500 ml **Balanced Salt Solution**

Note – Pharmacode change from 500615 to 286850. Pharmacode 500615 to be delisted from 1 January 2016.

### EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS

193 GLYCERIN WITH SODIUM SACCHARIN (↓ price)

Suspension ..... 32.50 473 ml Ora-Sweet SF

193 GLYCERIN WITH SUCROSE (↓ price)

Suspension ..... 32.50 473 ml Ora-Sweet

193 METHYLCELLULOSE (↓ price)

Suspension ..... 32.50 473 ml Ora-Plus

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

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

193 METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN (↓ price)
Suspension ..... 32.50 473 ml Ora-Blend SF

193 METHYLCELLULOSE WITH GLYCERIN AND SUCROSE (↓ price)
Suspension ..... 32.50 473 ml Ora-Blend

## SPECIAL FOODS

203 EXTENSIVELY HYDROLYSED FORMULA
➔ Powder 14 g protein, 53.4 g carbohydrate and 27.3 g fat per 100 g, 450 g can — *e.g. Aptamil Gold+ Pepti Junior*

Restricted
Initiation ~~- new patients~~
Any of the following:
1 Both:
1.1 Cows' milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
1.2 Either:
1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
2 Severe malabsorption; or
3 Short bowel syndrome; or
4 Intractable diarrhoea; or
5 Biliary atresia; or
6 Cholestatic liver diseases causing malsorption; or
7 Cystic fibrosis; or
8 Proven fat malabsorption; or
9 Severe intestinal motility disorders causing significant malabsorption; or
10 Intestinal failure**; or**
**11 For step down from Amino Acid Formula.**
Note: A reasonable trial is defined as a 2-4 week trial**, or signs of an immediate IgE mediated allergic reaction**.

~~Initiation - step down from amino acid formula~~
~~Both:~~
~~1 The infant is currently receiving funded amino acid formula; and~~
~~2 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula.~~

Continuation
Both:
1 An assessment as to whether the infant can be transitioned to a cows' milk protein or soy infant formula has been undertaken; and
2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula.


➔ 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 December 2015

### ALIMENTARY TRACT AND METABOLISM

24 NYSTATIN (new listing)
Oral liquid 100,000 u per ml – **1% DV Feb-16 to 2017**.....2.55 24 ml **m-Nystatin**
Note – Nilstat oral liquid 100,000 u per ml to be delisted from 1 February 2016

24 ~~NYSTATIN (↓ price and delisting)~~ – Decision recinded
~~Oral liquid 100,000 u per ml .....2.55 24 ml Nilstat~~

### BLOOD AND BLOOD FORMING ORGANS

31 RIVAROXABAN (amended restriction)
➔ Tab 10 mg.....153.00 15 Xarelto
Restricted
~~Either:~~
~~1 Limited to five weeks' treatment for the prophylaxis of venous thromboembolism following a total hip replacement; or~~
~~2 Limited to two weeks' treatment for the prophylaxis of venous thromboembolism following a total knee replacement.~~

**Initiation — total hip replacement**
***Therapy limited to 5 weeks***
**For the prophylaxis of venous thromboembolism.**

**Initiation — total knee replacement**
***Therapy limited to 2 weeks***
**For the prophylaxis of venous thromboembolism.**

### INFECTIONS

73 DEMECLOCYCLINE HYDROCHLORIDE (new listing)
Tab 150 mg

73 MOXIFLOXACIN (amended restriction)
➔ Tab 400 mg.....52.00 5 Avelox
➔ Inj 1.6 mg per ml, 250 ml bottle .....70.00 1 Avelox IV 400
Restricted
Initiation — Mycobacterium infection
Infectious disease specialist, clinical microbiologist or respiratory specialist
Either:
1 **Both:**
**1.1** Active tuberculosis**; and** ~~, with~~
**1.2** any of the following:
**1.2.1** ~~1.1~~ Documented resistance to one or more first-line medications; or
**1.2.2** ~~1.2~~ Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or
**1.2.3** ~~1.3~~ Impaired visual acuity (considered to preclude ethambutol use); or
**1.2.4** ~~1.4~~ Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
**1.2.5** ~~1.5~~ Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.

Initiation — Pneumonia
Infectious disease specialist or clinical microbiologist
**Either:**
1 Immunocompromised patient with pneumonia that is unresponsive to first-line treatment; or
2 Pneumococcal pneumonia or other invasive pneumococcal disease highly resistant to other antibiotics.

Initiation — Penetrating eye injury
Ophthalmologist
Five days treatment for patients requiring prophylaxis following a penetrating eye injury.

Initiation — Mycoplasma genitalium
All of the following:
1 Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium; and
2 Has tried and failed to clear infection using azithromycin; and
3 Treatment is only for 7 days.

85 ADEFOVIR DIPIVOXIL (amended restriction)
➔ Tab 10 mg ..... 670.00 30 Hepsera
Restricted
Gastroenterologist or infectious disease specialist
All of the following:
1 Patient has confirmed Hepatitis B infection (HBsAg+); and
Documented resistance to lamivudine, defined as:
**2**~~1~~ Patient has raised serum ALT (> 1 × ULN); and
**3**~~2~~ Patient has HBV DNA greater than 100,000 copies per mL, or viral load ≥ 10-fold over nadir; and
**4**~~3~~ Detection of M204I or M204V mutation; and
**5**~~4~~ Either:
**5**.1 Both:
**5**.1.1 Patient is cirrhotic; and
**5**.1.2 Adefovir dipivoxil to be used in combination with lamivudine; or
**5**.2 Both:
**5**.2.1 Patient is not cirrhotic; and
**5**.2.2 Adefovir dipivoxil to be used as monotherapy.

89 VALACICLOVIR (amended restriction)
➔ Tab 500 mg ..... 102.72 30 Valtrex
Restricted
**Initiation – Immunocompetent patients**
Any of the following:
1 Patient has genital herpes with 2 or more breakthrough episodes in any 6 month period while treated with aciclovir 400 mg twice daily; or
2 Patient has previous history of ophthalmic zoster and the patient is at risk of vision impairment; or
3 Patient has undergone organ transplantation.

**Initiation** – Immunocompromised patients
*Limited to 7 days treatment*
Both:
1 Patient is immunocompromised; and
2 Patient has herpes zoster.

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

90 PEGYLATED INTERFERON ALFA-2A (amended restriction)

| | | | |
|---|---|---|---|
| ➔ Inj 135 mcg prefilled syringe | | | |
| ➔ Inj 135 mcg prefilled syringe (4) with ribavirin tab 200 mg (112) | | | |
| ➔ Inj 135 mcg prefilled syringe (4) with ribavirin tab 200 mg (168) | | | |
| ➔ Inj 180 mcg prefilled syringe | 900.00 | 4 | Pegasys |
| ➔ Inj 180 mcg prefilled syringe (4) with ribavirin tab 200 mg (112) | 1,159.84 | 1 | Pegasys RBV Combination Pack |
| ➔ Inj 180 mcg prefilled syringe (4) with ribavirin tab 200 mg (168) | 1,290.00 | 1 | Pegasys RBV Combination Pack |

Restricted

Initiation – Chronic hepatitis C – genotype 1, 4, 5 or 6 infection or co-infection with HIV or genotype 2 or 3 post liver transplant

***Therapy limited to 48 weeks***

~~Both:~~

~~1~~ Any of the following:

~~1.~~1 Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or

~~1.~~2 Patient has chronic hepatitis C and is co-infected with HIV; or

~~1.~~3 Patient has chronic hepatitis C genotype 2 or 3 and has received a liver transplant.

~~2 Maximum of 48 weeks therapy.~~

Notes:

Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.

Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400,000IU/ml.

Continuation – (Chronic hepatitis C – genotype 1 infection)

Gastroenterologist, infectious disease specialist or general physician

***Therapy limited to 48 weeks***

All of the following:

1 Patient has chronic hepatitis C, genotype 1; and

2 Patient has had previous treatment with pegylated interferon and ribavirin; and

3 Either:

3.1 Patient has responder relapsed; or

3.2 Patient was a partial responder; and

4 Patient is to be treated in combination with boceprevir~~; and~~

~~5 Maximum of 48 weeks therapy.~~

Initiation (Chronic Hepatitis C – genotype 1 infection treatment more than 4 years prior)

Gastroenterologist, infectious disease specialist or general physician

***Therapy limited to 48 weeks***

All of the following:

1 Patient has chronic hepatitis C, genotype 1; and

2 Patient has had previous treatment with pegylated interferon and ribavirin; and

3 Any of the following:

3.1 Patient has responder relapsed; or

3.2 Patient was a partial responder; or

3.3 Patient received interferon treatment prior to 2004; and

4 Patient is to be treated in combination with boceprevir~~; and~~

~~5 Maximum of 48 weeks therapy~~.

*continued...*

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

Initiation – Chronic hepatitis C – genotype 2 or 3 infection without co-infection with HIV

***Therapy limited to 6 months***

~~Both:~~

~~1~~ Patient has chronic hepatitis C, genotype 2 or 3 infection~~; and~~

~~2 Maximum of 6 months therapy~~.

Initiation – Hepatitis B

Gastroenterologist, infectious disease specialist or general physician

***Therapy limited to 48 weeks***

All of the following:

1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
2 Patient is Hepatitis B treatment-naive; and
3 ALT > 2 times Upper Limit of Normal; and
4 HBV DNA < 10 log10 IU/ml; and
5 Either:
  5.1 HBeAg positive; or
  5.2 Serum HBV DNA ≥ 2,000 units/ml and significant fibrosis (≥ Metavir Stage F2 or moderate fibrosis); and
6 Compensated liver disease; and
7 No continuing alcohol abuse or intravenous drug use; and
8 Not co-infected with HCV, HIV or HDV; and
9 Neither ALT nor AST > 10 times upper limit of normal; and
10 No history of hypersensitivity or contraindications to pegylated interferon~~; and~~
~~11 Maximum of 48 weeks therapy~~.

Notes:

Approved dose is 180 mcg once weekly.

The recommended dose of Pegylated Interferon alfa-2a is 180 mcg once weekly.

In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon alfa-2a dose should be reduced to 135 mcg once weekly.

In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.

Pegylated Interferon alfa-2a is not approved for use in children.

## MUSCULOSKELETAL SYSTEM

92 ALENDRONATE SODIUM (amended restriction)

➔ Tab 40 mg ..... 133.00 30 Fosamax

Restricted

**Initiation – Paget's disease**

Both:

1 Paget's disease; and
2 Any of the following:
  2.1 Bone or articular pain; or
  2.2 Bone deformity; or
  2.3 Bone, articular or neurological complications; or
  2.4 Asymptomatic disease, but risk of complications due to site (base of skull, spine, long bones of lower limbs); or
  2.5 Preparation for orthopaedic surgery.

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

92 ALENDRONATE SODIUM (amended restriction – affected criterion only)

➔ Tab 70 mg ..... 12.90 4 Fosamax

Restricted

Initiation — Osteoporosis

Any of the following:

1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≥ -2.5) (see Note); or
2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
3 History of two significant osteoporotic fractures demonstrated radiologically; or
4 Documented T-Score ≤ -3.0 (see Note); or
5 A 10-year risk of hip fracture ≥ 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
6 Patient has had a Special Authority approval for zoledronic acid (**underlying cause** – osteoporosis) or raloxifene.

93 ALENDRONATE SODIUM WITH CHOLECALCIFEROL (amended restriction – affected criterion only)

➔ Tab 70 mg with cholecalciferol 5,600 iu ..... 12.90 4 Fosamax Plus

Restricted

Initiation — Osteoporosis

Any of the following:

1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≥ -2.5) (see Note); or
2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
3 History of two significant osteoporotic fractures demonstrated radiologically; or
4 Documented T-Score ≤ -3.0 (see Note); or
5 A 10-year risk of hip fracture ≥ 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
6 Patient has had a Special Authority approval for zoledronic acid (**underlying cause** – osteoporosis) or raloxifene.

97 TERIPARATIDE (amended restriction)

➔ Inj 250 mcg per ml, 2.4 ml cartridge ..... 490.00 1 Forteo

Restricted

*Limited to 18 months' treatment*

All of the following:

1 The patient has severe, established osteoporosis; and
2 The patient has a documented T-score less than or equal to -3.0 (see Notes); and
3 The patient has had two or more fractures due to minimal trauma; and
4 The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes).

Notes:

1 The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
2 Antiresorptive agents and their adequate doses for the purposes of this **restriction** ~~Special Authority~~

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

are defined as: alendronate sodium tab 70 mg or tab 70 mg with cholecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.

3 A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

100 MELOXICAM (amended restriction)

➔ Tab 7.5 mg

Restricted

Either:

~~1 Haemophilic arthropathy, with both of the following:~~

**1 All of the following:**

**1.1 Haemophilic arthropathy; and**

**1.2** ~~1.1~~ The patient has moderate to severe haemophilia with less than or equal to 5% of normal circulating functional clotting factor; and

**1.3** ~~1.2~~ Pain and inflammation associated with haemophilic arthropathy is inadequately controlled by alternative funded treatment options, or alternative funded treatment options are contraindicated; or

2 For preoperative and/or postoperative use for a total of up to 8 days' use.

## NERVOUS SYSTEM

103 DESFLURANE (Pharmacode change)

| | | | |
|---|---|---|---|
| Soln for inhalation 100%, 240 ml bottle | 1,230.00 | 6 | Suprane |

Note – Suprane bottle presentation changed, so Pharmacode change from 2331551 to 2490293. Pharmacode 2331551 to be delisted from 1 February 2016.

109 OXYCODONE HYDROCHLORIDE

| | | | |
|---|---|---|---|
| Inj 10 mg per ml, 1 ml ampoule – **1% DV Feb-16 to 2018** | 8.57 | 5 | **OxyNorm** |
| Inj 10 mg per ml, 2 ml ampoule – **1% DV Feb-16 to 2018** | 16.89 | 5 | **OxyNorm** |

Note – Oxycodone Orion inj 10 mg per ml, 1 ml and 2 ml ampoules to be delisted from 1 February 2016.

112 GABAPENTIN (amended restriction – affected criteria only)

| | | | |
|---|---|---|---|
| ➔ Cap 100 mg | 7.16 | 100 | Arrow-Gabapentin<br>Neurontin<br>Nupentin |
| ➔ Cap 300 mg | 11.00 | 100 | Arrow-Gabapentin<br>Neurontin<br>Nupentin |
| ➔ Cap 400 mg | 13.75 | 100 | Arrow-Gabapentin<br>Neurontin<br>Nupentin |

Restricted

~~1 For preoperative and/or postoperative use for up to a total of 8 days' use; or~~

~~2 For the pain management of burns patients with monthly review.~~

**Initiation — preoperative and/or postoperative use**

***Therapy limited to 8 days***

**Initiation — pain management of burns patients**

***Re-assessment required after 1 month***

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

**Continuation – pain management of burns patients**
***Re-assessment required after 1 month***
**The treatment remains appropriate and the patient is benefiting from the treatment.**

115 VIGABATRIN (amended restriction)
➔ Tab 500 mg
Restricted
**Initiation**
***Re-assessment required after 15 months***
Both:
1 Either:
1.1 Patient has infantile spasms; or
1.2 Both:
1.2.1 Patient has epilepsy; and
1.2.2 Either:
1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and
2 Either:
2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

Notes:
"Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.
Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

**Continuation**
**Both:**
**1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and**
**2 Either:**
**2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or**
**2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.**

**Notes: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.**
**Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.**

116 PIZOTIFEN (new listing)
Tab 500 mcg – **1% DV Sep-15 to 2018**.....23.21 100 **Sandomigran**
Note – this is the listing of the bottle presentation. The blister pack also remains listed.

## Changes to Section H Part II – effective 1 December 2015 (continued)

124 DEXAMFETAMINE SULFATE (amended restriction)

➔ Tab 5 mg – **1% DV Dec-15 to 2018** ..... 17.00 | 100 | **PSM**

Restricted

**Initiation** – ADHD

Paediatrician or psychiatrist

Patient has ADHD (Attention Deficit and Hyperactivity Disorder), diagnosed according to DSM-IV or ICD 10 criteria

**Initiation** – Narcolepsy

Neurologist or respiratory specialist

***Re-assessment required after 24 months***

Patient suffers from narcolepsy

**Continuation – Narcolepsy**

**Neurologist or respiratory specialist**

***Re-assessment required after 24 months***

**The treatment remains appropriate and the patient is benefiting from the treatment.**

125 METHYLPHENIDATE HYDROCHLORIDE (amended restriction – affected criteria only)

| | | | |
|---|---|---|---|
| ➔ Tab extended-release 18 mg | 58.96 | 30 | Concerta |
| ➔ Tab extended-release 27 mg | 65.44 | 30 | Concerta |
| ➔ Tab extended-release 36 mg | 71.93 | 30 | Concerta |
| ➔ Tab extended-release 54 mg | 86.24 | 30 | Concerta |
| ➔ Tab immediate-release 5 mg | 3.20 | 30 | Rubifen |
| ➔ Tab immediate-release 10 mg | 3.00 | 30 | Ritalin |
| | | | Rubifen |
| ➔ Tab immediate-release 20 mg | 7.85 | 30 | Rubifen |
| ➔ Tab sustained-release 20 mg | 10.95 | 30 | Rubifen SR |
| | 50.00 | 100 | Ritalin SR |
| ➔ Cap modified-release 10 mg | 15.60 | 30 | Ritalin LA |
| ➔ Cap modified-release 20 mg | 20.40 | 30 | Ritalin LA |
| ➔ Cap modified-release 30 mg | 25.52 | 30 | Ritalin LA |
| ➔ Cap modified-release 40 mg | 30.60 | 30 | Ritalin LA |

Restricted

**Initiation** — Narcolepsy (immediate-release and sustained-release formulations)

Neurologist or respiratory specialist

***Re-assessment required after 24 months***

Patient suffers from narcolepsy.

**Continuation – Narcolepsy (immediate-release and sustained-release formulations)**

**Neurologist or respiratory specialist**

***Re-assessment required after 24 months***

**The treatment remains appropriate and the patient is benefiting from the treatment.**

125 MODAFINIL (amended restriction)

➔ Tab 100 mg

Restricted

**Initiation**

Neurologist or respiratory specialist

***Re-assessment required after 24 months***

All of the following:

1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and

2 Either:

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
3 Either:
3.1 An effective dose of a listed formulation of methylphenidate or dexamphetamine has been trialled and discontinued because of intolerable side effects; or
3.2 Methylphenidate and dexamphetamine are contraindicated.

**Continuation – Narcolepsy**
**Neurologist or respiratory specialist**
***Re-assessment required after 24 months***
**The treatment remains appropriate and the patient is benefiting from the treatment.**

## ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

128 DOXORUBICIN HYDROCHLORIDE (new listing)

| | | | |
|---|---|---|---|
| Inj 2 mg per ml, 25 ml vial – **1% DV Feb-16 to 2018** | 11.50 | 1 | **Doxorubicin Ebewe** |
| Inj 2 mg per ml, 50 ml vial – **1% DV Feb-16 to 2018** | 23.00 | 1 | **Doxorubicin Ebewe** |
| Inj 2 mg per ml, 100 ml vial – **1% DV Feb-16 to 2018** | 46.00 | 1 | **Doxorubicin Ebewe** |

Note – Arrow-Doxorubicin inj 2 mg per ml, 25 ml and 100 ml vials to be delisted from 1 February 2016.

128 DOXORUBICIN HYDROCHLORIDE (delisting)
Inj 50 mg vial
Note – Doxorubicin hydrochloride inj 50 mg vial to be delisted from 1 February 2016.

129 AZACITIDINE (amended restriction)

| | | | |
|---|---|---|---|
| ➔ Inj 100 mg vial | 605.00 | 1 | Vidaza |

Restricted
Initiation
Haematologist
*Re-assessment required after 12 months*
All of the following:
1 Any of the following:
1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
2 The patient has performance status (WHO/ECOG) grade 0-2; and
3 The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
4 The patient has an estimated life expectancy of at least 3 months.

~~Notes: Indication marked with a * is an Unapproved Indication. Studies of temozolomide show that its benefit is predominantly in those patients with a good performance status (WHO grade 0 or 1 or Karnofsky score >80), and in patients who have had at least a partial resection of the tumour.~~

Continuation
Haematologist
*Re-assessment required after 12 months*
Both:
1 No evidence of disease progression, and
2 The treatment remains appropriate and patient is benefitting from treatment.

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

130 BORTEZOMIB (amended restriction)

➔ Inj 1 mg vial ..... 540.70 1 Velcade

➔ Inj 3.5 mg vial ..... 1,892.50 1 Velcade

Restricted

Initiation – treatment naive multiple myeloma/amyloidosis

***Re-assessment required after 15 months***

Both:

1 Either:
   1.1 The patient has treatment-naive symptomatic multiple myeloma; or
   1.2 The patient has treatment-naive symptomatic systemic AL amyloidosis *; and
2 Maximum of 9 treatment cycles.

~~Note: Indications marked with * are Unapproved Indications.~~

Initiation – relapsed/refractory multiple myeloma/amyloidosis

***Re-assessment required after 8 months***

All of the following:

1 Either:
   1.1 The patient has relapsed or refractory multiple myeloma; or
   1.2 The patient has relapsed or refractory systemic AL amyloidosis *; and
2 The patient has received only one prior front line chemotherapy for multiple myeloma or amyloidosis; and
3 The patient has not had prior publicly funded treatment with bortezomib; and
4 Maximum of 4 treatment cycles.

~~Note: Indications marked with * are Unapproved Indications.~~

Continuation – relapsed/refractory multiple myeloma/amyloidosis

***Re-assessment required after 8 months***

Both:

1 The patient's disease obtained at least a partial response from treatment with bortezomib at the completion of cycle 4; and
2 Maximum of 4 further treatment cycles (making a total maximum of 8 consecutive treatment cycles).

Notes: Responding relapsed/refractory multiple myeloma patients should receive no more than 2 additional cycles of treatment beyond the cycle at which a confirmed complete response was first achieved. A line of therapy is considered to comprise either:

1 A known therapeutic chemotherapy regimen and supportive treatments; or
2 A transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.

Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.

132 TEMOZOLOMIDE (amended restriction)

➔ Cap 5 mg – **1% DV Sep-13 to 2016** ..... 8.00 5 **Temaccord**

➔ Cap 20 mg – **1% DV Sep-13 to 2016** ..... 36.00 5 **Temaccord**

➔ Cap 100 mg – **1% DV Sep-13 to 2016** ..... 175.00 5 **Temaccord**

➔ Cap 250 mg – **1% DV Sep-13 to 2016** ..... 410.00 5 **Temaccord**

Restricted

All of the following:

1 Either:
   1.1 Patient has newly diagnosed glioblastoma multiforme; or
   1.2 Patient has newly diagnosed anaplastic astrocytoma*; and
2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
3 Following concomitant treatment temozolomide is to be used for a maximum of six cycles of 5 days treatment, at a maximum dose of 200 mg/m$^2$.

Notes: Indication marked with a * is an Unapproved Indication. **Temozolomide is not funded for the treatment of relapsed glioblastoma multiforme. Reapplications will not be approved.** Studies of temozolomide

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

show that its benefit is predominantly in those patients with a good performance status (WHO grade 0 or 1 or Karnofsky score >80), and in patients who have had at least a partial resection of the tumour.

133 THALIDOMIDE (amended restriction)

➔ Cap 50 mg..... 378.00 28 Thalomid

➔ Cap 100 mg..... 756.00 28 Thalomid

Restricted

Initiation

***Re-assessment required after 12 months***

Any of the following:

1 The patient has multiple myeloma; or
2 The patient has systemic AL amyloidosis*; or
3 The patient has erythema nodosum leprosum.

Continuation

Patient has obtained a response from treatment during the initial approval period.

Notes: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier.
Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen.
Indication marked with * is an Unapproved Indication

134 ERLOTINIB (amended restriction)

➔ Tab 100 mg – **1% DV Jun-15 to 2018** ..... 1,000.00 30 **Tarceva**

➔ Tab 150 mg – **1% DV Jun-15 to 2018** ..... 1,500.00 30 **Tarceva**

Restricted

Initiation

*Re-assessment required after **4** ~~3~~ months*

***Therapy limited to 3 months***

Either:

1 All of the following:
   1.1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
   1.2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
   1.3 Any of the following:
      1.3.1 Patient is treatment naive; or
      1.3.2 Both:
         1.3.2.1 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and
         1.3.2.2 Patient has not received prior treatment with gefitinib; or
      1.3.3 Both:
         1.3.3.1 The patient has discontinued getitinib within 6 weeks of starting treatment due to intolerance; and
         1.3.3.2 The cancer did not progress while on gefitinib; ~~and~~ **or**
   ~~1.4 Erlotinib is to be given for a maximum of 3 months, or~~
2 The patient received funded erlotinib prior to 31 December 2013 and radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

Continuation

*Re-assessment required after 6 months*

***Therapy limited to 3 months***

Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

134 GEFITINIB (amended restriction)

➔ Tab 250 mg ..... 1,700.00 30 Iressa

Restricted

Initiation

*Re-assessment required after **4** 3 months*

***Therapy limited to 3 months***

All of the following:

1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and

2 Either:

2.1 Patient is treatment naive; or

2.2 Both:

2.2.1 The patient has discontinued erlotinib within 6 weeks of starting treatment due to intolerance; and

2.2.2 The cancer did not progress whilst on erlotinib; and

3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase.

Continuation

*Re-assessment required after 6 months*

***Therapy limited to 3 months***

Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

134 IMATINIB MESILATE (amended restriction)

Note: Imatinib-AFT is not a registered for the treatment of Gastro Intestinal Stromal Tumours (GIST). The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST, see SA1460 in Section B of the Pharmaceutical Schedule.

➔ Tab 100 mg ..... 2,400.00 60 Glivec

Restricted

Initiation

*Re-assessment required after 12 months*

Both:

1 Patient has diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST); and

2 Maximum dose of 400 mg/day.

Continuation

*Re-assessment required after 12 months*

Adequate clinical response to treatment with imatinib (prescriber determined).

**Note: The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST, see SA1460 in Section B of the Pharmaceutical Schedule.**

137 SUNITINIB (amended restriction – affected criteria only)

➔ Cap 12.5 mg ..... 2,315.38 28 Sutent

➔ Cap 25 mg ..... 4,630.77 28 Sutent

➔ Cap 50 mg ..... 9,261.54 28 Sutent

Restricted

Initiation – RCC

*Re-assessment required after 3 months*

1 The patient has metastatic renal cell carcinoma; and

2 Any of the following:

2.1 The patient is treatment naive; or

2.2 The patient has only received prior cytokine treatment; or

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or
2.4 Both:
2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
2.4.2 The cancer did not progress whilst on pazopanib; and
3 The patient has good performance status (WHO/ECOG grade 0-2); and
4 The disease is of predominant clear cell histology; and
5 The patient has intermediate or poor prognosis defined as any of the following:
5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
5.2 Haemoglobin level < lower limit of normal; or
5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
5.5 Karnofsky performance score of ≤ 70; or
5.6 ≥ 2 sites of organ metastasis; and
6 Sunitinib to be used for a maximum of 2 cycles.

**Notes: RCC – Sunitinib treatment should be stopped if disease progresses.**
**Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.**

Continuation – GIST
*Re-assessment required after 6 months*
Both:
The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:
1 Any of the following:
1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
1.2 The patient has had a partial response (a decrease in size of ≥ 10% or decrease in tumour density in Hounsfield Units (HU) of ≥ 15% on CT and no new lesions and no obvious progression of non-measurable disease); or
1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
2 The treatment remains appropriate and the patient is benefiting from treatment.

Notes: ~~RCC – Sunitinib treatment should be stopped if disease progresses.~~
~~Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.~~

GIST – It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of ≥ 10% and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

141 ETANERCEPT (amended restriction – affected criteria 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 – 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 2015 (continued)

*continued...*

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** ~~HML~~ rules; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab 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, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and

2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

147 ADALIMUMAB (amended restriction – affected criteria only)

| | | | |
|---|---|---|---|
| ➔ Inj 20 mg per 0.4 ml syringe | 1,799.92 | 2 | Humira |
| ➔ Inj 40 mg per 0.8 ml pen | 1,799.92 | 2 | HumiraPen |
| ➔ Inj 40 mg per 0.8 ml syringe | 1,799.92 | 2 | Humira |

Restricted

Continuation – rheumatoid arthritis

Rheumatologist

*Re-assessment required after 6 months*

All of the following:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2 Either:

2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and

3 Adalimumab to be administered at doses no greater than **40 mg every 14 days** ~~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** ~~HML~~ 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, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and

2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

## Changes to Section H Part II – effective 1 December 2015 (continued)

154 INFLIXIMAB (amended restriction – affected criteria only)
➔ Inj 100 mg – **10% DV Mar-15 to 29 Feb 2020** ..... 806.00 1 **Remicade**
Restricted
Initiation – rheumatoid arthritis
Rheumatologist
*Re-assessment required after **4** ~~3-4~~ months*
All of the following:
1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

Initiation – psoriatic arthritis
Rheumatologist
*Re-assessment required after **4** ~~3-4~~ months*
Both:
1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for psoriatic arthritis; and
2 Either:
2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for psoriatic arthritis.

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

Continuation – Crohn's disease (children)
Gastroenterologist
*Re-assessment required after 6 months*
**Both** ~~All of the following~~:
1 **Any** ~~One~~ of the following:
1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
1.2 PCDAI score is 15 or less; or

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and

2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle~~; and~~

~~3 Patient must be reassessed for continuation after further 6 months~~.

Initiation – fistulising Crohn's disease
Gastroenterologist
***Therapy limited to 4 doses***
**Both** ~~All of the following~~:
1 Patient has confirmed Crohn's disease; and
2 Either:
2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
2.2 Patient has one or more rectovaginal fistula(e~~); and~~
~~3 Patient must be reassessed for continuation after 4 months of therapy~~

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

Initiation – acute severe fulminant ulcerative colitis
Gastroenterologist
***Re-assessment required after 6 weeks***
**Both** ~~All of the following~~:
1 Patient has acute, severe fulminant ulcerative colitis; and
2 Treatment with intravenous or high dose oral corticosteroids has not been successful~~; and~~
~~3 Patient must be reassessed for continuation after 6 weeks of therapy~~.

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

Initiation – severe ulcerative colitis
Gastroenterologist

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

***Re-assessment required after 3 months***

All of the following:

1 Patient has histologically confirmed ulcerative colitis; and

2 Either:

2.1 Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is ≥ 4; or

2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is ≥ 65; and

3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and

4 Surgery (or further surgery) is considered to be clinically inappropriate~~; and~~

~~5 Patient must be reassessed for continuation after 3 months of therapy~~.

Continuation – severe ulcerative colitis

Gastroenterologist

***Re-assessment required after 6 months***

All of the following:

1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and

2 Either:

2.1 Patient is 18 years or older and the SCCAI score has reduced by ≥ 2 points from the SCCAI score when the patient was initiated on infliximab; or

2.2 Patient is under 18 years and the PUCAI score has reduced by ≥ 30 points from the PUCAI score when the patient was initiated on infliximab; and

3 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

Initiation – plaque psoriasis, prior TNF use

Dermatologist

***Therapy limited to 3 doses*** ~~*Re-assessment required after 3 doses*~~

Both:

1 The patient has had an initial Special Authority approval for adalimumab or etanercept for severe chronic plaque psoriasis; and

2 Either:

2.1 The patient has experienced intolerable side effects from adalimumab or etanercept; or

2.2 The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept for severe chronic plaque psoriasis.

160 RITUXIMAB (amended restriction – affected criteria 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 – prior TNF inhibitor use

Rheumatologist

*Re-assessment required after* ***4 months*** ~~*2 doses*~~

All of the following:

1 Both:

1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or

1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and

*continued...*

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

2 Either:
  2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initiation – rheumatoid arthritis – TNF inhibitors contraindicated
Rheumatologist
*Re-assessment required after **4 months** ~~2 doses~~*
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 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 ciclosporin; 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.

Continuation – rheumatoid arthritis – re-treatment in 'partial responders' to rituximab
Rheumatologist
*Re-assessment required after **4 months** ~~2 doses~~*
All of the following:
1 Either:
  1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
  3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis – re-treatment in 'responders' to rituximab
Rheumatologist
*Re-assessment required after **4 months** ~~2 doses~~*
All of the following:
1 Either:
  1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
  3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

166 TOCILIZUMAB (amended restriction – affected criteria 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** ~~HML~~ 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 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

*continued...*

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

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 ciclosporin 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 The patient has had an initial Special Authority approval for **adalimumab and/or** etanercept for adult-onset Still's disease (AOSD); 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, 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

174 SODIUM CHLORIDE (amended presentation)
Aqueous nasal spray **isotonic** ~~7.4 mg per ml~~

175 MONTELUKAST (amended restriction – affected criterion only)

| | | | |
|---|---|---|---|
| ➔ Tab 4 mg | 18.48 | 28 | Singulair |
| ➔ Tab 5 mg | 18.48 | 28 | Singulair |
| ➔ Tab 10 mg | 18.48 | 28 | Singulair |

Initiation – Pre-school wheeze
Both:
1 To be used for the treatment of intermittent severe wheezing (possibly viral) **in children under 5 years**; and
2 The patient has had at least three episodes in the previous 12 months of acute wheeze severe enough to seek medical attention.

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

117 DORNASE ALFA (amended restriction)

➔ Nebuliser soln 2.5 mg per 2.5 ml ampoule ..... 250.00 6 Pulmozyme

Restricted

~~Any of the following:~~

~~1 Cystic fibrosis and the patient has been approved by the Cystic Fibrosis Panel; and/or~~

~~2 Significant mucus production and meets the following criteria~~

~~3 Treatment for up to four weeks for patients meeting the following:~~

~~3.1 Patient is an in-patient; and~~

~~3.2 The mucus production cannot be cleared by first line chest techniques; or~~

~~4 Treatment for up to three days for patients diagnosed with empyema.~~

**Initiation – cystic fibrosis**

**The patient has cystic fibrosis and has been approved for funding by the Cystic Fibrosis Panel.**

**Initiation – significant mucus production**

***Therapy limited to 4 weeks***

**Both:**

**1 Patient is an inpatient; and**

**2 The mucus production cannot be cleared by first line techniques.**

**Initiation – pleural empyema**

***Therapy limited to 3 days***

**Both:**

**1 Patient is an inpatient; and**

**2 Patient diagnosed with pleural empyema.**

## VARIOUS

185 DESFERRIOXAMINE MESILATE

Inj 500 mg vial – **1% DV Feb-16 to 2018**..... 51.52 10 **Desferal**

Note – Hospira desferrioxamine mesilate inj 500 mg vial to be delisted from 1 February 2016.

## SPECIAL FOODS

201 PEPTIDE-BASED ORAL FEED (new listing)

➔ Liquid 6.75 g protein, 18.4 g carbohydrate and 5.5 g fat per 100 ml, bottle ..... 18.06 1,000 ml Vital

201 PEPTIDE-BASED ORAL FEED (delisting)

➔ Powder 12.5 g protein, 55.4 g carbohydrate and 3.25 g fat per sachet..... 4.40 79 g Vital HN

Note – Vital HN powder, 79 g sachet to be delisted from 1 February 2016.

203 EXTENSIVELY HYDROLYSED FORMULA (amended example brand)

➔ Powder 14 g protein, 53.4 g carbohydrate and 27.3 g fat per 100 g, 450 g can ..... **Aptamil Gold+ Pepti Junior** ~~Gold Pepti Junior~~ ~~Karicare Aptamil~~

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

## VACCINES

210 BACILLUS CALMETTE-GUERIN VACCINE (amended restriction)
➔ Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial Danish strain 1331, live attenuated, vial with diluent – **1% DV Oct-14 to 2017**..... 0.00 10 **BCG Vaccine**
Restricted
**All of the following:**
For infants at increased risk of tuberculosis **defined as:**
~~Note: increased risk is defined as:~~
1 Living in a house or family with a person with current or past history of TB; or
2 Having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
3 During their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000.

Note: A list of countries with high rates of TB are available at http://www.health.govt.nz/tuberculosis (Search for Downloads) or www.bcgatlas.org/index.php

210 HAEMOPHILUS INFLUENZAE TYPE B VACCINE (amended restriction)
➔ Inj 10 mcg vial with diluent syringe – **1% DV Jul-14 to 2017**.... 0.00 1 **Act-HIB**
Restricted
***Therapy limited to 1 dose***
**Any of the following:**
~~One dose for patients meeting any of the following:~~
1 For primary vaccination in children; or
2 An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or
3 For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

212 HUMAN PAPILLOMAVIRUS (6, 11, 16 AND 18) VACCINE [HPV] (amended restriction)
➔ Inj 120 mcg in 0.5 ml syringe – **1% DV Jul-14 to 2017**.....0.00 10 **Gardasil**
Restricted
***Therapy limited to 3 doses***
**Any of the following:**
~~Maximum of three doses for patient meeting any of the following criteria:~~
1 Females aged under 20 years old; or
2 Patients aged under 26 years old with confirmed HIV infection; or
3 For use in transplant (including stem cell) patients; or
4 An additional dose for patients under 26 years of age post chemotherapy.

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

213 INFLUENZA VACCINE (amended restriction)

➔ Inj 45 mcg in 0.5 ml syringe..... 90.00 10 Fluarix
Influvac

Restricted

**Initiation – People over 65**

**The patient is 65 years of age or over.**

**Initiation – cardiovascular disease**

Any of the following:

~~1 All people 65 years of age and over; or~~

~~2 People under 65 years of age who:~~

~~2.1 Have any of the following cardiovascular diseases:~~

~~2.1.~~1 Ischaemic heart disease; or

~~2.1.~~2 Congestive heart failure; or

~~2.1.~~3 Rheumatic heart disease; or

~~2.1.~~4 Congenital heart disease; or

~~2.1.~~5 Cerebro-vascular disease. ~~; or~~

**Note: hypertension and/or dyslipidaemia without evidence of end-organ disease is excluded from funding.**

**Initiation – chronic respiratory disease**

**Either:**

~~2.2 Have any of the following chronic respiratory diseases:~~

~~2.2.~~1 Asthma, if on a regular preventative therapy; or

~~2.2.~~2 Other chronic respiratory disease with impaired lung function. ~~; or~~

**Note: asthma not requiring regular preventative therapy is excluded from funding.**

**Initiation – other conditions**

**Either:**

**1 Any of the following:**

**1.1** ~~2.3~~ ~~Have~~ diabetes; or

**1.2** ~~2.4~~ ~~Have~~ chronic renal disease; or

**1.3** ~~2.5~~ ~~Have~~ any cancer, excluding basal and squamous skin cancers if not invasive; or

~~2.6~~ ~~Have any of the following other conditions:~~

**1.4** ~~2.6.1~~ Autoimmune disease; or

**1.5** ~~2.6.2~~ Immune suppression or immune deficiency; or

**1.6** ~~2.6.3~~ HIV; or

**1.7** ~~2.6.4~~ Transplant recipients; or

**1.8** ~~2.6.5~~ Neuromuscular and CNS diseases/ disorders; or

**1.9** ~~2.6.6~~ Haemoglobinopathies; or

**1.10** ~~2.6.7~~ ~~Are children~~ **Is a child** on long term aspirin; or

**1.11** ~~2.6.8~~ ~~Have~~ **Has** a cochlear implant; or

**1.12** ~~2.6.9~~ Errors of metabolism at risk of major metabolic decompensation; or

**1.13** ~~2.6.10~~ Pre and post splenectomy; or

**1.14** ~~2.6.11~~ Down syndrome; or

**1.15** ~~2.7~~ ~~Are~~ **Is** pregnant, or

**1.16** ~~2.8~~ ~~Are children~~ **Is a child** aged four and under who **has** ~~have~~ been hospitalised for respiratory illness or **has** ~~have~~ a history of significant respiratory illness: or

**2** ~~3~~Patients who are compulsorily detained long-term in a forensic unit within a DHB hospital ~~in the 2015 season~~.

~~Note: The following conditions are excluded from funding:~~

~~• asthma not requiring regular preventative therapy; and~~

~~• hypertension and/or dyslipidaemia without evidence of end-organ disease.~~

## Changes to Section H Part II – effective 1 December 2015 (continued)

213 MEASLES, MUMPS AND RUBELLA VACCINE (amended restriction)
➔ Inj 1000 TCID50 measles, 12500 TCID50 mumps and 1000 TCID50 rubella vial with diluent – **1% DV Jul-14 to 2017**..... 0.00 10 **M-M-R-II**
Restricted
~~A maximum of two doses for any patient meeting the following criteria:~~
**Initiation – first dose prior to 12 months**
***Therapy limited to 3 doses***
**Any of the following:**
1 For primary vaccination in children; or
2 For revaccination following immunosuppression; or
3 For any individual susceptible to measles, mumps or rubella. ~~; or~~
~~4 A maximum of three doses for children who have had their first dose prior to 12 months.~~

**Initiation – first dose after 12 months**
***Therapy limited to 2 doses***
**Any of the following:**
**1 For primary vaccination in children; or**
**2 For revaccination following immunosuppression; or**
**3 For any individual susceptible to measles, mumps or rubella.**
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

214 POLIOMYELITIS VACCINE (amended restriction)
➔ Inj 80 D-antigen units in 0.5 ml syringe – **1% DV Jul-14 to 2017**..... 0.00 1 **IPOL**
Restricted
~~Up to three doses for patients meeting either of the following:~~
**Therapy limited to 3 doses**
**Either:**
1 For partially vaccinated or previously unvaccinated individuals; or
2 For revaccination following immunosuppression.
Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

214 ROTAVIRUS LIVE REASSORTANT ORAL VACCINE (amended restriction)
➔ Oral susp G1, G2, G3, G4, P1(8) 11.5 million CCID50 units per 2 ml, tube – **1% DV Jul-14 to 2017** ..... 0.00 10 **RotaTeq**
Restricted
~~Maximum of three doses for patients meeting the following:~~
**Therapy limited to 3 doses**
**Both:**
1 First dose to be administered in infants aged under 15 weeks of age; and
2 No vaccination being administered to children aged 8 months or over.

214 VARICELLA VACCINE [CHICKEN POX VACCINE] (amended restriction)
➔ Inj 2,000 PFU vial with diluent – **1% DV Jul-14 to 2017**..... 0.00 1 **Varilrix**
Restricted
~~Maximum of two doses for any of the following:~~
**Therapy limited to 2 doses**
**Any of the following:**
1 For non-immune patients:
1.1 With chronic liver disease who may in future be candidates for transplantation; or
1.2 With deteriorating renal function before transplantation; or
1.3 Prior to solid organ transplant; or

*continued...*

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

## Changes to Section H Part II – effective 1 December 2015 (continued)

*continued...*

1.4 Prior to any elective immunosuppression*.

2 For patients at least 2 years after bone marrow transplantation, on advice of their specialist.

3 For patients at least 6 months after completion of chemotherapy, on advice of their specialist.

4 For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.

5 For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella.

6 For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

7 For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella

* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days.

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