Pharmaceutical Management Agency

# **Section H Update**for Hospital Pharmaceuticals

# **Effective 1 March 2019**

Cumulative for December 2018, January, February and March 2019



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# Summary of decisions EFFECTIVE 1 MARCH 2019

- Arsenic trioxide (Phenasen) inj 1 mg per ml, 10 ml vial new listing
- Arsenic trioxide (AFT) inj 1 mg per ml, 10 ml vial to be delisted 1 September 2019
- Carmustine (BiCNU) inj 100 mg vial to be delisted 1 July 2019
- Ceftazidime (Ceftazidime Mylan) inj 1 g vial price increase
- Doxepin hydrochloride cap 10 mg, 25 mg and 50 mg restriction added
- Enalapril maleate (Ethics Enalapril) tab 5 mg, 10 mg and 20 mg
   price increase
- Filgrastim (Nivestim) inj 300 mcg and 480 mcg in 0.5 ml prefilled syringe
   new listing and addition of HSS
- Filgrastim (Zarzio) inj 300 mcg and 480 mcg in 0.5 ml prefilled syringe
   to be delisted 1 May 2019
- Hepatitis B recombinant vaccine (Engerix-B) inj 20 mcg per 1 ml prefilled syringe – amended restriction
- Ibuprofen (Ethics) oral liq 20 mg per ml new listing and addition of HSS
- Ibuprofen (Fenpaed) oral liq 20 mg per ml to be delisted 1 May 2019
- Imiglucerase inj 40 iu per ml, 10 ml vial amended restriction and delist date
- Influenza vaccine inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) (Fluarix Tetra) and inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Influvac Tetra) amended restriction
- Influenza vaccine (Influvac) inj 45 mcg in 0.5 ml syringe (trivalent vaccine)
   delisted 1 March 2019
- Latanoprost (Hysite) eye drops 0.005% price decrease
- Magnesium oxide cap 696 mg (420 mg elemental) new listing
- Midazolam (Hypnovel) tab 7.5 mg to be delisted 1 June 2019
- Moroctocog alfa [Recombinant factor VIII] (Xyntha) inj 250 iu, inj 500 iu, inj 1,000 iu, inj 2,000 iu and inj 3,000 iu prefilled syringe amended restriction
- Octocog alfa [Recombinant factor VIII] (Advate) inj 250 iu, inj 500 iu, inj 1,000 iu, inj 1,500 iu, inj 2,000 iu and inj 3,000 iu vial amended restriction
- Octocog alfa [Recombinant factor VIII] (Kogenate FS) inj 250 iu, inj 500 iu, inj 1,000 iu, inj 2,000 iu and inj 3,000 iu vial – amended restriction
- Oxycodone hydrochloride (Oxycodone Sandoz) tab controlled-release 5 mg,
   10 mg, 20 mg, 40 mg and 80 mg new listing and addition of HSS
- $\bullet$  Oxycodone hydrochloride (BNM) tab controlled-release 5 mg, 10 mg, 20 mg, 40 mg and 80 mg to be delisted 1 May 2019

### Summary of decisions – effective 1 March 2019 (continued)

- Sodium fusidate [fusidic acid] (Foban) crm 2% and oint 2% new listing and addition of HSS
- Sodium fusidate [fusidic acid] crm 2% (DP Fusidic Acid Cream) and oint 2% (Foban), 15 g – to be delisted 1 May 2019
- Taliglucerase alfa (Elelyso) inj 200 unit vial amended restriction
- Valganciclovir (Valganciclovir Mylan) tab 450 mg new listing and addition of HSS
- Valganciclovir (Valcyte) tab 450 mg to be delisted 1 May 2019
- Vinorelbine (Navelbine) inj 10 mg per ml, 1 ml and 5 ml vial price increase
- Zoledronic acid (Zoledronic acid Mylan) inj 4 mg per 5 ml, vial price decrease and addition of HSS
- Zoledronic acid (Zometa) inj 4 mg per 5 ml, vial to be delisted 1 May 2019

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

## Section H changes to Part II

Effective 1 March 2019

#### ALIMENTARY TRACT AND METABOLISM

15 IMIGLUCERASE (amended restriction and delist date)

→ Inj 40 iu per ml, 10 ml vial

Restricted

Initiation

Only for use in patients with approval by the Gaucher's Gaucher Treatment Panel.

Note - Imiglucerase inj 40 iu per ml, 10 ml vial delisting amended from 1 March 2019 until 1 September 2019.

17 TALIGLUCERASE ALFA (amended restriction)

Restricted

Initiation

Only for use in patients with approval by the Gaucher's Gaucher Treatment Panel.

18 MAGNESIUM OXIDE (new listing) Cap 696 mg (420 mg elemental)

#### **BLOOD AND BLOOD FORMING ORGANS**

27 MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] (amended restriction)

→ Inj 250 iu prefilled syringe	210.00	1	Xyntha
→ Inj 500 iu prefilled syringe	420.00	1	Xyntha
→ Inj 1,000 iu prefilled syringe	840.00	1	Xyntha
→ Inj 2,000 iu prefilled syringe	1,680.00	1	Xyntha
→ Inj 3,000 iu prefilled syringe	2,520.00	1	Xyntha

Initiation

Note: Preferred Brand of recombinant factor VIII from 1 March 2016 until 28 February 2019. When used in the treatment of haemophilia, funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

28 OCTOCOG ALFA (RECOMBINANT FACTOR VIII) (ADVATE) (amended restriction)

→ Inj 250 iu vial	287.50	1	Advate
→ Inj 500 iu vial	575.00	1	Advate
→ Inj 1,000 iu vial	1,150.00	1	Advate
	1,725.00	1	Advate
	2,300.00	1	Advate
→ Inj 3,000 iu vial	3,450.00	1	Advate

Initiation

Notes: Rare Clinical Circumstances Brand of recombinant factor VIII from 1 March 2016 until 28 February 2019. When used in the treatment of haemophilia, access to funded treatment by application to the Haemophilia Treatments Panel. Application details may be obtained from PHARMAC.s website http://www.pharmac.govt.nz or:

The Co-ordinator, Haemophilia Treatments Panel

PHARMAC PO Box 10 254

Wellington

Phone: 0800 023 588 Option 2 Facsimile: (04) 974 4881 Email: haemophilia@pharmac.govt.nz

		Price		Brand or
		(ex man. Excl. G	ST) Per	Generic Manufacturer
Chai	nges to Section H Part II – effective 1 March	h 2019 (continued	)	
28	OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGE			
20	→ Inj 250 iu vial	237 50	1	Kogenate FS
	→ Inj 500 iu vial		1	Kogenate FS
	→ Inj 1,000 iu vial		1	Kogenate FS
	→ lnj 2,000 iu vial		1	Kogenate FS
	→ Inj 3,000 iu vialInitiation		1	Kogenate FS
	Notes: Second Brand of recombinant factor VIII from 1 treatment of haemophilia, access to funded treatment Application details may be obtained from PHARMAC.s The Co-ordinator, Haemophilia Treatments Panel	by application to the I website http://www.p	Haemophilia bharmac.go	a Treatments Panel.
	PHARMAC PO Box 10 254		ile: (04) 97	
	Wellington			a@pharmac.govt.nz
32	FILGRASTIM (brand change)  → Inj 300 mcg in 0.5 ml prefilled syringe			
	- 1% DV May-19 to 2021	06.22	10	Nivestim
	→ Inj 480 mcg in 0.5 ml prefilled syringe	90.22	10	MIAG2IIII
	– 1% DV Mav-19 to 2021	161 50	10	Nivestim
	Note – Zarzio inj 300 mcg in 0.5 ml prefilled syringe ar 1 May 2019.			
CAR	DIOVASCULAR SYSTEM			
36	ENALAPRIL MALEATE († price)			
	Tab 5 mg		100	Ethics Enalapril
	Tab 10 mg		100	Ethics Enalapril
	Tab 20 mg	7.12	100	Ethics Enalapril
DER	MATOLOGICALS			
51	SODIUM FUSIDATE [FUSIDIC ACID] (brand change)	1.50	F ~	Fahan
	Crm 2% – 1% DV May-19 to 2021 Oint 2% – 1% DV May-19 to 2021		5 g 5 g	Foban Foban
	Note – DP Fusidic Acid Cream crm 2% and Foban oint			
10R	MONE PREPARATIONS			
33	ZOLEDRONIC ACID (↓ price and addition of HSS)  → Inj 4 mg per 5 ml, vial – 1% DV May-19 to 2021	20.02	1	Zoledronic acid Mylan
	Note – Zometa inj 4 mg per 5 ml, vial to be delisted fro		'	Zoieuronic aciu myian
NFE	CTIONS			
73	CEFTAZIDIME († price)	24.00	F	Coftoridime Mules
	→ Inj 1 g vial	34.00	5	Ceftazidime Mylan
89	VALGANCICLOVIR (brand change)  → Tab 450 mg – 1% DV May-19 to 2021  Note – Valcyte tab 450 mg to be delisted from 1 May 2		60	Valganciclovir Mylan

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

## Changes to Section H Part II - effective 1 March 2019 (continued)

MUSCUL	OSKELETAL	SYSTEM

MOSC	OLUSKELETAL STSTEM		
104	IBUPROFEN (brand change) Oral liq 20 mg per ml – 1% DV May-19 to 2021	200 ml	Ethics
NERV	OUS SYSTEM		
113	DOXEPIN HYDROCHLORIDE – <b>Restricted: For continuation only</b> (restriction → Cap 10 mg → Cap 25 mg → Cap 50 mg	added)	
112	OXYCODONE HYDROCHLORIDE (brand change)  Tab controlled-release 5 mg - 1% DV May-19 to 2021	20 20 20 20 20 20 to be delisted	Oxycodone Sandoz Oxycodone Sandoz Oxycodone Sandoz Oxycodone Sandoz Oxycodone Sandoz from 1 May 2019.
125	MIDAZOLAM (delisting) Tab 7.5 mg40.00 Note – Hypnovel tab 7.5 mg to be delisted from 1 June 2019.	100	Hypnovel
ONCO	LOGY AGENTS AND IMMUNOSUPPRESSANTS		
131	CARMUSTINE (delisting) Inj 100 mg vial532.00 Note – BiCNU inj 100 mg vial to be delisted from 1 July 2019.	1	BiCNU
134	ARSENIC TRIOXIDE (brand change) Inj 1 mg per ml, 10 ml vial4,817.00 Note – AFT inj 1 mg per ml, 10 ml vial to be delisted from 1 September 2019	10 9.	Phenasen
144	VINORELBINE († price) Inj 10 mg per ml, 1 ml vial	1 1	Navelbine Navelbine
SENS	ORY ORGANS		
201	LATANOPROST (‡ price) Eye drops 0.005%	2.5 ml	Hysite

## Changes to Section H Part II - effective 1 March 2019 (continued)

#### **VACCINES**

233 HEPATITIS B RECOMBINANT VACCINE (amended restriction criteria)

Restricted

Initiation

Any of the following:

- 1 For household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers: or
- 2 For children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
- 3 For children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
- 4 For HIV positive patients; or
- 5 For hepatitis C positive patients: or
- 6 For patients following non-consensual sexual intercourse: or
- 7 For patients following immunosuppression; or
- 8 For solid organ transplant patients; or
- 9 For post-haematopoietic stem cell transplant (HSCT) patients; or
- 10 Following needle stick injury:; or
- 11 For dialysis patients; or
- 12 For liver or kidney transplant patients.

235 INFLUENZA VACCINE (amended restriction – affected criteria only shown)

→ Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine)...9.00 1 Fluarix Tetra

Restricted

Initiation - Other conditions for patients aged 6 months to 35 months

Any of the following:

- 1 Any of the following:
  - 1.1 Diabetes; or
  - 1.2 Chronic renal disease; or
  - 1.3 Any cancer, excluding basal and squamous skin cancers if not invasive; or
  - 1.4 Autoimmune disease: or
  - 1.5 Immune suppression or immune deficiency: or
  - 1.6 HIV: or
  - 1.7 Transplant recipient; or
  - 1.8 Neuromuscular and CNS diseases/ disorders; or
  - 1.9 Haemoglobinopathies; or
  - 1.10 Is a child on long term aspirin; or
  - 1.11 Has a cochlear implant; or
  - 1.12 Errors of metabolism at risk of major metabolic decompensation; or
  - 1.13 Pre and post splenectomy: or
  - 1.14 Down syndrome: or
  - 1.15 Child who has been hospitalised for respiratory illness or has a history of significant respiratory illness; or
- 2 Child is living in the Seddon/Ward and rural Eastern Marlborough region (within the Nelson Marlborough District Health Board) and Kaikoura and Hurunui areas (within the Canterbury District Health Board); or
- 3 Child has been displaced from their homes in Edgecumbe and the surrounding region.

	Price (ex man. Excl. G \$	ST) Per	Brand or Generic Manufacturer
Changes to Section H Part II – effective 1 Mar	ch 2019 (continued	1)	
→ Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccing Restricted Initiation – Other conditions for patients 3 years and Any of the following:  1 Any of the following:  1.1 Diabetes; or  1.2 Chronic renal disease; or  1.3 Any cancer, excluding basal and squamoud Any of the following:  1.4 Autoimmune disease; or  1.5 Immune suppression or immune deficience And Individual And India	over  Is skin cancers if not in  Ty; or  ers; or  Abolic decompensation;  en hospitalised for respective unit or who are composition of the compos	or oiratory illne ulsorily deta n Marlborou as (within t	ained long-term in a ligh region (within the the Canterbury District
235 INFLUENZA VACCINE (delisted)  → Inj 45 mcg in 0.5 ml syringe (trivalent vaccine)  Note – Influvac inj 45 mcg in 0.5 ml syringe (trivalen		10 arch 2019.	Influvac
Effective 11 February 2019			
ONCOLOGY AGENTS AND IMMUNOSUPPRESSAM	NTS		
131 CARMUSTINE (new listing) Inj 100 mg vial	1,380.00	1	Emcure

Price	
(ex man. Excl. GST)	
\$	Pe

Brand or Generic Manufacturer

## Changes to Section H Part II - effective 1 February 2019

#### **ALIMENTARY TRACT AND METABOLISM**

18 IRON POLYMALTOSE (delisting delayed)

Inj 50 mg per ml, 2 ml ampoule .......15.22 5 Ferrum H

Note - Ferrum H inj 50 mg per ml, 2 ml ampoule to be delisted from 1 July 2019.

#### **BLOOD AND BLOOD FORMING ORGANS**

23 EPOETIN ALFA [ERYTHROPOIETIN ALFA] (brand change, amended chemical name and restriction criteria)

→ Inj 1,000 iu in 0.5 ml syringe – 1% DV Apr-19 to 2022250.00	6	Binocrit
→ Inj 2,000 iu in 1 ml syringe – 1% DV Apr-19 to 2022100.00	6	Binocrit
→ Inj 3,000 iu in 0.3 ml syringe – 1% DV Apr-19 to 2022150.00	6	Binocrit
→ Inj 4,000 iu in 0.4 ml syringe – 1% DV Apr-19 to 202296.50	6	Binocrit
→ Inj 5,000 iu in 0.5 ml syringe – 1% DV Apr-19 to 2022125.00	6	Binocrit
→ Inj 6,000 iu in 0.6 ml syringe – 1% DV Apr-19 to 2022145.00	6	Binocrit
→ Inj 8,000 iu in 0.8 ml syringe – 1% DV Apr-19 to 2022175.00	6	Binocrit
→ Inj 10,000 iu in 1 ml syringe – 1% DV Apr-19 to 2022197.50	6	Binocrit
→ Inj 40,000 iu in 1 ml syringe – 1% DV Apr-19 to 2022250.00	1	Binocrit

Note – Eprex inj 1,000 iu in 0.5 ml, 2,000 iu in 0.5 ml, 3,000 iu in 0.3 ml, 4,000 iu in 0.4 ml, 5,000 iu in 0.5 ml, 6,000 iu in 0.6 ml, 8,000 iu in 0.8 ml, 10,000 iu in 1 ml and 40,000 iu in 1 ml syringe to be delisted from 1 April 2019.

#### Restricted

Initiation - chronic renal failure

All of the following:

- 1 Patient in chronic renal failure; and
- 2 Haemoglobin is less than or equal to 100g/L; and
- 3 Either:
  - 3.1 Both:
    - 3.1.1 Patient does not have diabetes mellitus; and
    - 3.1.2 Glomerular filtration rate is less than or equal to 30ml/min; or
  - 3.2 Both:
    - 3.2.1 Patient has diabetes mellitus; and
    - 3.2.2 Glomerular filtration rate is less than or equal to 45ml/min; and
- 4 Patient is on haemodialysis or peritoneal dialysis.

Initiation - myelodysplasia\*

Re-assessment required after 2 months

All of the following:

- 1 Patient has a confirmed diagnosis of myelodysplasia (MDS); and
- 2 Has had symptomatic anaemia with haemoglobin < 100g/L and is red cell transfusion-dependent; and
- 3 Patient has very low, low or intermediate risk MDS based on the WHO classification-based prognostic scoring system for myelodysplastic syndrome (WPSS); and
- 4 Other causes of anaemia such as B12 and folate deficiency have been excluded; and
- 5 Patient has a serum **epoetin** erythropoietin level of < 500 IU/L; and
- 6 The minimum necessary dose of epoetin erythropoietin would be used and will not exceed 80,000 iu per week.

Continuation - myelodysplasia\*

Re-assessment required after 12 months

All of the following:

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

# Changes to Section H Part II – effective 1 February 2019 (continued)

- 1 The patient's transfusion requirement continues to be reduced with **epoetin** <del>erythropoietin</del> treatment; and
- 2 Transformation to acute myeloid leukaemia has not occurred; and
- 3 The minimum necessary dose of **epoetin** erythropoietin would be used and will not exceed 80,000 iu per week.

Initiation - all other indications

Haematologist

For use in patients where blood transfusion is not a viable treatment alternative.

Note: Indications marked with \* are unapproved indications

#### 24 EPOETIN BETA [ERYTHROPOIETIN BETA] (amended chemical name and restriction criteria)

Note: Epoetin beta is considered a Discretionary Variance Pharmaceutical for epoetin alfa.

- → Ini 2.000 iu in 0.3 ml svringe
- → Ini 3.000 iu in 0.3 ml svringe
- → Inj 4,000 iu in 0.3 ml syringe
- → Ini 5.000 iu in 0.3 ml syringe
- → Inj 6,000 iu in 0.3 ml syringe
- → Inj 10,000 iu in 0.6 ml syringe

#### Restricted

Initiation - chronic renal failure

All of the following:

- 1 Patient in chronic renal failure: and
- 2 Haemoglobin is less than or equal to 100g/L; and
- 3 Either:
  - 3.1 Both:
    - 3.1.1 Patient does not have diabetes mellitus; and
    - 3.1.2 Glomerular filtration rate is less than or equal to 30ml/min; or
  - 3.2 Both:
    - 3.2.1 Patient has diabetes mellitus: and
    - 3.2.2 Glomerular filtration rate is less than or equal to 45ml/min; and
- 4 Patient is on haemodialysis or peritoneal dialysis.

Initiation - myelodysplasia\*

Re-assessment required after 2 months

All of the following:

- 1 Patient has a confirmed diagnosis of myelodysplasia (MDS); and
- 2 Has had symptomatic anaemia with haemoglobin < 100g/L and is red cell transfusion-dependent; and
- 3 Patient has very low, low or intermediate risk MDS based on the WHO classification-based prognostic scoring system for myelodysplastic syndrome (WPSS); and
- 4 Other causes of anaemia such as B12 and folate deficiency have been excluded; and
- 5 Patient has a serum **epoetin** ervthropoietin level of < 500 IU/L: and
- 6 The minimum necessary dose of **epoetin** erythropoietin would be used and will not exceed 80,000 iu per week.

Continuation - myelodysplasia\*

Re-assessment required after 12 months

All of the following:

- 1 The patient's transfusion requirement continues to be reduced with **epoetin** <del>erythropoictin</del> treatment; and
- 2 Transformation to acute myeloid leukaemia has not occurred; and
- 3 The minimum necessary dose of epoetin erythropoietin would be used and will not exceed 80,000 iu per week.

Initiation - all other indications

Haematologist

For use in patients where blood transfusion is not a viable treatment alternative.

Note: Indications marked with \* are unapproved indications

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

## Changes to Section H Part II - effective 1 February 2019 (continued)

CADD	IOVA	CCIII	VD G	YSTEM
UANU	11 U V A	JOUL	An o	ISIEIVI

39	LABETALOL (delisting) Tab 50 mg8.99 Note – Hybloc tab 50 mg to be delisted from 1 August 2019.	100	Hybloc
39	LABETALOL (delisting) Tab 100 mg11.36 Note – Hybloc tab 100 mg to be delisted from 1 December 2019.	100	Hybloc
39	LABETALOL (delisting) Tab 200 mg29.74 Note – Hybloc tab 200 mg to be delisted from 1 February 2020.	100	Hybloc
45	GLYCERYL TRINITRATE (delisting) Tab 600 mcg	100	Lycinate

#### **HORMONE PREPARATIONS**

64	METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] (de	elisting)	
	Inj 40 mg with lidocaine [lignocaine], 1 ml vial9.25	1	Depo-Medrol with
			Lidocaine
	Note – Depo-Medrol with Lidocaine inj 40 mg with lidocaine [lignocaine],	1 ml vial to b	e delisted from 1 April 2019.

#### INFECTIONS

/6	PIPERACILLIN WITH TAZOBACTAM (delisting)  → Inj 4 g with tazobactam 0.5 g vial	1 April 2019.	Tazocin EF	
79	NITROFURANTOIN (new listing and addition of HSS)  Tab 50 mg – <b>1% DV Apr-19 to 2021</b>	100 100	Nifuran Nifuran	
88	GLECAPREVIR WITH PIBRENTASVIR (new listing)  Note: the supply of treatment is via PHARMAC's approved direct distration found on PHARMAC's website https://www.pharmac.govt.nz/hepatiti Tab 100 mg with pibrentasvir 40 mg24,750.00		,	an be
88	PARITAPREVIR, RITONAVIR AND OIMBITASVIR WITH DASABUVIR (deliste	d)		

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/.

Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg

DIDED A CILL IN MITH TAZOD A CTAM (delicting)

1

Note – Viekira Pak Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56), with dasabuvir tab 250 mg (56) delisted 1 February 2019.

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

## Changes to Section H Part II – effective 1 February 2019 (continued)

89 PARITAPREVIR. RITONAVIR AND OMBITASVIR WITH DASABUVIR AND RIBAVIRIN (delisted)

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/.

Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg

(56) and ribavirin tab 200 mg (168) delisted 1 February 2019.

#### MUSCULOSKELETAL SYSTEM

94 ALENDRONATE SODIUM (1 price, addition of HSS and restriction removed)
Tab 70 mq - 1% DV Apr-19 to 2022.......2.44 4 Fosamax

Initiation - Osteoporosis

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineraldensity (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults-(i.e. T-Score less than or equal to -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 less than or equal to -3.0 (see Note); or
- 5 A 10-year risk of hip fracture greater than or equal to 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 ralexifene.

Initiation - glucocorticosteroid therapy

Re-assessment required after 12 months

#### Both:

- 1 The patient is receiving systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
  - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the meannormal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
  - 2.2 The patient has a history of one significant esteoporotic fracture demonstrated radiologically; or
  - 2.3 The patient has had a Special Authority approval for zoledronic acid (glucocorticosteroid therapy) or raloxifene.

Continuation - glucocorticosteroid therapy

Re-assessment required after 12 months

The patient is continuing systemic glucocorticosteriod therapy (greater than or equal to 5 mg per day prednisone equivalents).

#### Notes:

- 1—BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry-(DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- 2 Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.

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

# Changes to Section H Part II – effective 1 February 2019 (continued)

3 Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHOhas quantified this as forces equivalent to a fall from a standing height or less.

- 4 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.
- 95 ALENDRONATE SODIUM WITH COLECALCIFEROL (‡ price, addition of HSS and restriction removed) Tab 70 mg with colecalciferol 5.600 iu

70 mg with colectioner 5,000 it

Initiation - Osteoporosis

Any of the following:

- 1—History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineraldensity (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults-(i.e. T-Score less than or equal to -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 less than or equal to -3.0 (see Note); or
- 5 A 10-year risk of hip fracture greater than or equal to 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:

Initiation - alucocorticosteroid therapy

Re-assessment required after 12 months

Both:

- 1 The patient is receiving systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day-prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
  - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the meannormal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
  - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
  - 2.3 The patient has had a Special Authority approval for zoledronic acid (glucocorticosteroid therapy) or raloxifene.

Continuation - glucocorticosteroid therapy

Re-assessment required after 12 months

The patient is continuing systemic glucocorticosteriod therapy (greater than or equal to 5 mg per day prednisone equivalents).

Notes:

- 1—BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- 2 Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score greater than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.

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

# Changes to Section H Part II – effective 1 February 2019 (continued) continued...

- 3 Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHOhas quantified this as forces equivalent to a fall from a standing height or less.
- 4 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.
- 97 ZOLEDRONIC ACID (amended restriction)

Initiation – Osteoporosis

Any specialist

Therapy limited to 3 doses

Both:

- 1 Any of the following:
  - 1.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
  - 1.2 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
  - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
  - 1.4 Documented T-Score greater than or equal to -3.0 (see Note); or
  - 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
  - 1.6 Patient has had a Special Authority approval for alendronate (Underlying cause Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Initiation – glucocorticosteroid therapy

Any specialist

Re-assessment required after 12 months

All of the following:

- 1 The patient is receiving systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
  - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
  - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
  - 2.3 The patient has had a Special Authority approval for alendronate (Underlying cause glucocorticosteroid therapy) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

## Changes to Section H Part II - effective 1 February 2019 (continued)

99 DENOSUMAB (amended restriction)

All of the following:

- 1 The patient has severe, established osteoporosis; and
- 2 Either:
  - 2.1 The patient is female and postmenopausal; or
  - 2.2 The patient is male or non-binary; and
- 3 Any of the following:
  - 3.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
  - 3.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, ordensitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons; or
  - 3.3 History of two significant osteoporotic fractures demonstrated radiologically; or
  - 3.4 Documented T-Score less than or equal to -3.0 (see Note); or
  - 3.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
  - 3.6 Patient has had a Special Authority approval for alendronate (Underlying cause Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 4 Zoledronic acid is contraindicated because the patient's creatinine clearance is less than 35 mL/min; and
- 5 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); and
- 6 The patient must not receive concomitant treatment with any other funded antiresorptive agent for this condition or teriparatide.

#### Notes:

- 1 BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- 2 Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with denosumab.
- 3 Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- 4 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.
- 5 Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: risedronate sodium tab 35 mg once weekly; alendronate sodium tab 70 mg or tab 70 mg with cholecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily. 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.

Price	
(ex man. Excl. GST)	
\$	Per

Brand or Generic Manufacturer

## Changes to Section H Part II – effective 1 February 2019 (continued)

100 RALOXIFENE (amended restriction)

#### Initiation

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Notes); 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 greater than or equal to -3.0 (see Notes); or
- 5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Notes); or
- 6 Patient has had a prior-Special Authority approval for zoledronic acid (Underlying cause Osteoporosis) or has had a Special Authority approval for alendronate (Underlying cause – Osteoporosis) prior to 1 February 2019.

#### Notes:

- 1 BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- 2 Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- 3 Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- 4 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.

#### 103 BACLOFEN (brand change)

Inj 2 mg per ml, 5 ml ampoule – **1% DV Apr-19 to 2021**.......372.98 5 **Medsurge** Note – Lioresal Intrathecal inj 2 mg per ml, 5 ml ampoule to be delisted from 1 April 2019.

Price	
(ex man. Excl. GST)	
\$	Per

Brand or Generic Manufacturer

## Changes to Section H Part II – effective 1 February 2019 (continued)

## **NERVOUS SYSTEM**

114	MOCLOBEMIDE (brand change)  Tab 150 mg – <b>1% DV Apr-19 to 2021</b>	Aurorix Aurorix
124	GLATIRAMER ACETATE (new listing)  → Inj 40 mg prefilled syringe2,275.00 12	Copaxone
124	GLATIRAMER ACETATE (delisting)  → Inj 20 mg per ml, 1 ml syringe  Note – Glatiramer acetate inj 20 mg per ml, 1 ml syringe to be delisted from 1 July 2019.	
127	MODAFINIL (new listing)  → Tab 100 mg	Modavigil
128	DISULFIRAM († price) Tab 200 mg	Antabuse
ONCO	LOGY AGENTS AND IMMUNOSUPPRESSANTS	
131	EPIRUBICIN HYDROCHLORIDE († price and addition of HSS) Inj 2 mg per ml, 100 ml vial – <b>1% DV Apr-19 to 2021</b> 85.00	Epirubicin Ebewe
131	EPIRUBICIN HYDROCHLORIDE (delisting) Inj 2 mg per ml, 50 ml vial	Epirubicin Ebewe
133	GEMCITABINE (delisting) Inj 10 mg per ml, 20 ml vial8.36 1 Note – Gemcitabine Ebewe inj 10 mg per ml, 20 ml vial to be delisted 1 June 2019.	Gemcitabine Ebewe
135	IRINOTECAN HYDROCHLORIDE († price and addition of HSS) Inj 20 mg per ml, 5 ml vial – <b>1% DV Apr-19 to 2021</b> 71.44	Irinotecan Actavis 100
136	PROCARBAZINE HYDROCHLORIDE († price) Cap 50 mg980.00 50	Natulan

Price		Brand or
(ex man. Excl. 0	GST)	Generic
\$	Per	Manufacturer

## Changes to Section H Part II – effective 1 February 2019 (continued)

181	TOCILIZUMAB (amended restrictions – affected criteria shown only)		
	→ Inj 20 mg per ml, 4 ml vial220.00	1	Actemra
	→ Inj 20 mg per ml, 10 ml vial550.00	1	Actemra
	→ Inj 20 mg per ml, 20 ml vial1,100.00	1	Actemra

#### Restricted

Initiation - cytokine release syndrome

Paediatric haematologist, paediatric oncologist

Treatment limited to 3 doses.

#### Either:

- 1 All of the following:
  - 1.1 The patient is enrolled in the Children's Oncology Group AALL1331 trial; and
  - 1.2 The patient has developed grade 3 or 4 cytokine release syndrome (CRS) associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia: and
  - 1.3 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses; or
- 2 All of the following:
  - 2.1 The patient is enrolled in the Malaghan Institute of Medical Research Phase I ENABLE trial; and
  - 2.2 The patient has developed CRS or CAR T-Cell Related Encephalopathy Syndrome (CRES) associated with the administration of CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma: and
  - 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS and CRES for CAR T-cell therapy (Neelapu et al. Nat Rey Clin Oncol 2018:15:47-62) at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

#### SENSORY ORGANS

201	LATANOPROST (brand change) Eye drops 0.005% – <b>1% DV Apr-19 to 2021</b> 1.57	2.5 ml	Teva
201	LATANOPROST († price) Eye drops 0.005%1.84 Note – Hysite eye drops 0.005% to be delisted from 1 April 2019.	2.5 ml	Hysite
201	LEVOBUNOLOL HYDROCHLORIDE (delisting) Eye drops 0.5%	5 ml	Betagan
EXTE	MPORANEOUSLY COMPOUNDED PREPARATIONS		
212	PROPYLENE GLYCOL (delisted) Liq	500 ml	ABM
SPEC	AL FOODS		

218 AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (new listing)

→ Powder 36 g protein, 32 g carbohydrate and 12.5 g fat per 100 g. 36 g sachet

→ Powder 36 g protein, 32 g carbohydrate and 12.5 g fat per 100 g, 36 g sachet

e.a. PKU Anamix Junior Vanilla

e.g. PKU Anamix Junior Chocolate

Price (ex man. Excl. 0	GST)	Brand or Generic
\$	Per	Manufacturer

## Changes to Section H Part II - effective 1 January 2019

#### **ALIMENTARY TRACT AND METABOLISM**

17	POTASSIUM IODATE (addition of HSS) Tab 253 mcg (150 mcg elemental iodine) - 1% DV Mar-19 to 2020	90	NeuroTabs
18	IRON POLYMALTOSE (new listing) Inj 50 mg per ml, 2 ml ampoule	5	Ferrosig
21	COLECALCIFEROL (new listing) Oral liq 188 mcg per ml (7,500 iu per ml)9.00	4.8 ml	Puria
BLOO	D AND BLOOD FORMING ORGANS		
24	FOLIC ACID († price) Oral liq 50 mcg per ml	25 ml	Biomed
33	CALCIUM GLUCONATE (new listing) Inj 10%, 10 ml ampoule		e.g. Max Health
33	CALCIUM GLUCONATE (delisting) Inj 10%, 10 ml ampoule	10	Hospira
CARD	IOVASCULAR SYSTEM		
42	FUROSEMIDE [FRUSEMIDE] (addition of HSS) Tab 500 mg – 1% DV Mar-19 to 202125.00	50	Urex Forte
42	AMILORIDE HYDROCHLORIDE (new listing) Tab 5 mg		

#### Tab 5 mg

METOLAZONE (restriction removed)

#### Initiation

43

Any of the following:

Tab 5 mg

- 1—Patient has refractory heart failure and is intolerant or has not responded to loop diuretics and/or loop-thiazidecombination therapy; or
- Patient has severe refractory nephrotic oedema unresponsive to high dose loop diuretics and concentrated albumin infusions; or
- 3 Paediatric patient has oedema secondary to nephrotic syndrome that has not responded to loop diuretics.

#### **DERMATOLOGICALS**

54	HYDROCORTISONE BUTYRATE († price and addition of HSS)		
	Oint 0.1% – 1% DV Mar-19 to 2021	100 g	Locoid
	Milky emul 0.1% – 1% DV Mar-19 to 2021	100 ml	Locoid Crelo

Oint 1% with natamycin 1% and neomycin sulphate 0.5%	mafucort mafucort ocoid
Crm 1% with natamycin 1% and neomycin sulphate 0.5%	mafucort
Scalp lotn 0.1% – 1% DV Mar-19 to 20217.30 100 ml Local INFECTIONS  72 AMIKACIN (amended pack size and price)	ocoid
72 AMIKACIN (amended pack size and price)	
→ Inj 5 mg per ml, 5 ml syringe	omed
, 3	-Amoxiclav -Amoxiclav
84 METRONIDAZOLE († price) Inj 5 mg per ml, 100 ml bag	axter
NERVOUS SYSTEM	
APOMORPHINE HYDROCHLORIDE (delisted) Inj 10 mg per ml, 1 ml ampoule Note – Apomorphine hydrochloride inj 10 mg per ml, 1 ml ampoule delisted 1 January 2019.	
107 DESFLURANE (HSS extended) Soln for inhalation 100%, 240 ml bottle - 1% DV Sep-16 to 2020 <del>2019</del>	uprane
107 ISOFLURANE (HSS extended) Soln for inhalation 100%, 250 ml bottle - 1% DV Sep-16 to 2020 <del>2019</del>	errane
108 SEVOFLURANE (HSS extended) Soln for inhalation 100%, 250 ml bottle - 1% DV Sep-16 to 2020 2019	axter
119 DOMPERIDONE (brand change) Tab 10 mg – <b>1% DV Mar-19 to 2021</b>	narmacy Health
119 HYOSCINE HYDROBROMIDE († price)  → Patch 1.5 mg	copoderm TTS
3	ozaril ozaril o pack). Existing

Price		Bra
(ex man. Excl. G	ST)	Ge
\$	Per	Ma

Brand or Generic Manufacturer

## Changes to Section H Part II - effective 1 January 2019 (continued)

#### 129 VARENICLINE (brand change)

Note – Champix tab 0.5 mg x 11 and 1 mg x 14 and tab 1 mg (28 tab and 56 tab pack) to be delisted from 1 March 2019.

#### **ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS**

#### 135 IRINOTECAN HYDROCHLORIDE (delisted)

#### 160 AFLIBERCEPT (amended restriction criteria – affected criteria shown only)

Initiation - Wet Age Related Macular Degeneration

Ophthalmologist

Re-assessment required after 3 months

Either:

- 1 All of the following:
  - 1.1 Any of the following:
    - 1.1.1 Wet age-related macular degeneration (wet AMD); or
    - 1.1.2 Polypoidal choroidal vasculopathy; or
    - 1.1.3 Choroidal neovascular membrane from causes other than wet AMD: and
  - 1.2 Either:
    - 1.2.1 The patient has developed severe endophthalmitis or severe posterior uveitis following treatment with bevacizumab: or
    - 1.2.2 There is worsening of vision or failure of retina to dry despite three intraocular injections of bevacizumab four weeks apart; and
  - 1.3 There is no structural damage to the central fovea of the treated eye; and
  - 1.4 Patient has not previously been treated with ranibizumab for longer than 3 months; or
- 2 Any of the following Either:
  - 2.1 Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months; or
  - 2.2 Patient has previously\* (\*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment: or
  - 2.3 Patient has current approval to use ranibizumab for treatment of wAMD; or
  - 2.4 Patient is currently receiving treatment with aflibercept and has documented previous poor response to bevacizumab.

Note: Criteria 2.3 and 2.4 will be removed from 1 January 2019.

Initiation - Diabetic Macular Oedema

Ophthalmologist

Re-assessment required after 4 months

Either:

- 1 All of the following:
  - 4.1 Patient has centre involving diabetic macular oedema (DMO); and
  - 4-2 Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly; and
  - 1.3 Patient has reduced visual acuity between 6/9 6/36 with functional awareness of reduction in vision; and
  - $\pm 4$  Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and

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

# Changes to Section H Part II – effective 1 January 2019 (continued) continued...

1.5 There is no centre-involving sub-retinal fibrosis or foveal atrophy; or

2 Patient is currently receiving treatment with aflibercept and has documented previous poor response to bevacizumab.

Note: Criterion 2 will be removed from 1 January 2019.

#### **SENSORY ORGANS**

197	CHLORAMPHENICOL († price) Eye drops 0.5%1.95	10 ml	Chlorafast
VARI	ous		
205	DESFERRIOXAMINE MESILATE (brand change) Inj 500 mg vial – 1% DV Mar-19 to 2021	10	DBL Desferrioxamine Mesylate for Injection BP
	Note – Desferal ini 500 mg vial to be delisted from 1 March 2019.		-

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

## Changes to Section H Part II - effective 1 December 2018

#### ALIMENTARY TRACT AND METABOLISM

10 METFORMIN HYDROCHLORIDE (Brand change)

Tab immediate-release 850 mg – **1% DV Feb-19 to 2021**.......7.04 500 **Apotex** 

Note - Metformin Mylan tab immediate-release 850 mg to be delisted 1 February 2019.

10 PANCREATIC ENZYME (Pharmacode change)

Cap pancreatin 150 mg (amylase 8,000 Ph Eur U,

lipase 10,000 Ph Eur U, total protease 600 Ph

Eur U) – 1% DV Sep-18 to 2021......34.93 100 Creon 10000

Note – this is a new Pharmacode listing 2535300; 954322 to be delisted from 1 May 2019.

17 CALCIUM CARBONATE (delisting)

Tab eff 1.75 g (1 g elemental)......2.07 10 Calsource

Note - Calsource tab eff 1.75 g (1 g elemental) to be delisted from 1 July 2019.

18 MAGNESIUM OXIDE WITH MAGNESIUM ASPARTATE, MAGNESIUM AMINO ACID CHELATE AND MAGNESIUM CITRATE (new listing)

Cap 500 mg with magnesium aspartate 100 mg, magnesium

amino acid chelate 100 mg and magnesium citrate 100 mg

(360 mg elemental magnesium)

Note – magnesium oxide with with magnesium aspartate, magnesium amino acid chelate and magnesium citrate cap 500 mg with magnesium aspartate 100 mg, magnesium amino acid chelate 100 mg and magnesium citrate 100 mg (360 mg elemental magnesium) to be delisted from 1 March 2019.

18 MAGNESIUM AMINO ACID CHELATE (new listing)

Cap 750 mg (150 mg elemental)

Note - magnesium amino acid chelate cap 750 mg (150 mg elemental) to be delisted from 1 March 2019.

#### **HORMONE PREPARATIONS**

62 TESTOSTERONE († price)
---------------------------

65 CLOMIFENE CITRATE (delisting)

Note – Serophene tab 50 mg to be delisted from 1 March 2019.

#### INFECTIONS

72 AMIKACIN (	1	price)
---------------	---	--------

79 LINEZOLID (brand change)

→ Inj 2 mg per ml, 300 ml bottle – 1% DV Feb-19 to 2021 .......... 18.50 1 Linezolid Kabi

Note – Zyvox inj 2 mg per ml, 300 ml bag, 10 inj pack to be delisted 1 February 2019.

Price		Brand or
(ex man. Excl. GS	ST)	Generic
\$	Per	Manufacturer

## Changes to Section H Part II – effective 1 December 2018 (continued)

MUSCUL	USKEI	FΤΔΙ	<b>SYSTEM</b>

94	ALENDRONATE SODIUM (delisting)			
	→ Tab 40 mg	133.00	30	Fosamax
	Note – Fosamax tab 40 mg to be delisted from 1 May 2019.			

#### **NERVOUS SYSTEM**

110	PARACETAMOL (brand change) Suppos 500 mg – <b>1% V Feb-19 to 2021</b> 12.40 Note – Paracare suppos 500 mg to be delisted from 1 February 2019.	50	Gacet
115	DIAZEPAM († price) Rectal tubes 5 mg	5	Stesolid
116	LAMOTRIGINE (Pharmacode change) Tab dispersible 25 mg		Logem Logem Logem 1g, 2553384 and tab
120	CLOZAPINE (Pharmacode change) Tab 25 mg		Clozaril 1019.
121	ZIPRASIDONE (HSS reinstated) Cap 20 mg – <b>1% DV Dec-18 to 2021</b> 14.50	60	Zusdone
128	DISULFIRAM († price) Tab 200 mg55.00	100	Antabuse

#### **ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS**

144 ABIRATERONE ACETATE (amended restriction criteria)

→ Tab 250 mg .......4,276.19 120 Zytiga

Restricted

Initiation

Medical oncologist, radiation oncologist or urologist

Re-assessment required after 5 6 months

All of the following:

- 1 Patient has prostate cancer; and
- 2 Patient has metastases; and
- 3 Patient's disease is castration resistant; and
- 4 Either:
  - 4.1 All of the following:
    - 4.1.1 Patient is symptomatic; and
    - 4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
    - 4.1.3 Patient has ECOG performance score of 0-1; and
    - 4.1.4 Patient has not had prior treatment with taxane chemotherapy; or
  - 4.2 All of the following:

Price	
(ex man. Excl. GST)	
\$	Per

Brand or Generic Manufacturer

# Changes to Section H Part II – effective 1 December 2018 (continued) continued...

- 4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and
- 4.2.2 Patient has ECOG performance score of 0-2; and
- 4.2.3 Patient has not had prior treatment with abiraterone.

#### Continuation

Medical oncologist, radiation oncologist or urologist

Re-assessment required after 5 6 months

All of the following:

- 1 Significant decrease in serum PSA from baseline: and
- 2 No evidence of clinical disease progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The treatment remains appropriate and the patient is benefiting from treatment.

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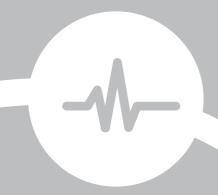
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Lycinate	12	Puria
M		R
Magnesium amino acid chelate	24	Raloxifene
Magnesium oxide		Recombinant factor VIII
Magnesium oxide with magnesium aspartate,	. •	S
magnesium amino acid chelate and		Scopoderm TTS
magnesium citrate	24	Serophene
m-Amoxiclay	21	Sevoflurane
Maviret	12	Sodium fusidate [fusidic acid]
	24	Stesolid
Metformin hydrochloride	24	
Methylprednisolone acetate with lidocaine	10	Suprane
[Lignocaine]	12	Tallat access also
Metolazone	20	Taliglucerase alfa
Metronidazole		Tazocin EF
Midazolam		Testosterone
Moclobemide	18	Tocilizumab
Modafinil	18	U
Modavigil		Urex Forte
Moroctocog alfa [Recombinant factor VIII]	. 5	V
N		Valganciclovir
Natulan	18	Valganciclovir Mylan
Navelbine	. 7	Varenicline
NeuroTabs	20	Varenicline Pfizer
Nifuran	12	Viekira Pak
Nitrofurantoin	12	Viekira Pak-RBV
Nivestim	. 6	Vinorelbine
0		X
Octocog alfa [Recombinant factor VIII]		Xyntha
(Advate)	. 5	z
Octocog alfa [Recombinant factor VIII]		Ziprasidone
(Kogenate FS)	. 6	Zoledronic acid
Oxycodone hydrochloride		Zoledronic acid Mylan
Oxycodone Sandoz		Zusdone
P		Zytiga
Pancreatic enzyme	24	

Paracetamol	25
Paritaprevir, ritonavir and oimbitasvir	
with dasabuvir	12
Paritaprevir, ritonavir and ombitasvir	
with dasabuvir and ribavirin	13
Phenasen	
Pimafucort	21
Piperacillin with tazobactam	12
PKU Anamix Junior Chocolate	19
PKU Anamix Junior Vanilla	19
Potassium iodate	20
Procarbazine hydrochloride	18
Prolia	16
Propylene glycol	19
Puria	20
R	
Raloxifene	17
Recombinant factor VIII	5, 6
Scopoderm TTS	21
Serophene	24
Sevoflurane	21
Sodium fusidate [fusidic acid]	
Stesolid	25
Suprane	21
aliglucerase alfa	
azocin EF	12
estosterone	24
ocilizumab	19
J	
Jrex Forte	20
/alganciclovir	
/alganciclovir Mylan	
/arenicline	22
/arenicline Pfizer	22
/iekira Pak	12
/iekira Pak-RBV	13
/inorelbine	. 7
(	
Syntha	. 5
liprasidone	25
Oledronic acid	, 15
Oledronic acid Mylan	
'usdone	25
/ytiga	25

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