Pharmaceutical Management Agency

Section H Update for Hospital Pharmaceuticals

Effective 1 February 2019

Cumulative for December 2018, January and February 2019





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Summary of decisions EFFECTIVE 1 FEBRUARY 2019

- Alendronate sodium (Fosamax) tab 70 mg price decrease, addition of HSS and restriction removed
- Alendronate sodium with colecalciferol (Fosamax Plus) tab 70 mg with colecalciferol 5,600 iu – price decrease, addition of HSS and restriction removed
- Amino acid formula (without phenylalanine) (e.g. PKU Anamix Junior Vanilla) powder 36 g protein, 32 g carbohydrate and 12.5 g fat per 100 g, 36 g sachet – new listing
- Amino acid formula (without phenylalanine) (e.g. PKU Anamix Junior Chocolate) powder 36 g protein, 32 g carbohydrate and 12.5 g fat per 100 g, 36 g sachet – new listing
- Baclofen (Medsurge) inj 2 mg per ml, 5 ml ampoule new listing and addition of HSS
- Baclofen (Lioresal Intrathecal) inj 2 mg per ml, 5 ml ampoule to be delisted
 1 April 2019
- Denosumab (Prolia) inj 60 mg prefilled syringe amended restriction
- Disulfiram (Antabuse) tab 200 mg price increase
- Epirubicin hydrochloride (Epirubicin Ebewe) in 2mg per ml, 100 ml vial
 price increase and addition of HSS
- Epirubicin hydrochloride (Epirubicin Ebewe) inj 2 mg per ml, 50 ml vial
 to be delisted 1 June 2019
- Epoetin alfa (Binocrit) inj syringe 1,000 iu in 0.5 ml, 2,000 iu in 1 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 new listing, addition of HSS, amended chemical name and restriction criteria
- Epoetin alfa (Eprex) inj syringe 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 to be delisted 1 April 2019
- Epoetin beta inj syringe, various presentations amended chemical name and restriction criteria
- Gemcitabine (Gemcitabine Ebewe) inj 10 mg per ml, 20 ml vial to be delisted
 1 June 2019
- Glecaprevir with pibrentasvir (Maviret) tab 100 mg with pibrentasvir 40 mg
 new listing
- Glatiramer acetate (Copaxone) inj 40 mg prefilled syringe new listing
- Glatiramer acetate inj 20 mg per ml, 1 ml syringe to be delisted 1 July 2019

Summary of decisions - effective 1 February 2019 (continued)

- Glyceryl trinitrate (Lycinate) tab 600 mcg to be delisted 1 March 2019
- Irinotecan hydrochloride (Irinotecan Actavis 100) inj 20 mg per ml, 5 ml vial
 price increase and addition of HSS
- Iron polymaltose (Ferrum H) inj 50 mg per ml, 2 ml ampoule delisting delayed until 1 July 2019
- Labetalol (Hybloc) tab 50 mg to be delisted 1 August 2019
- Labetalol (Hybloc) tab 100 mg to be delisted 1 December 2019
- Labetalol (Hybloc) tab 200 mg to be delisted 1 February 2020
- Latanoprost (Teva) eye drops 0.005%, 2.5 ml new listing and addition of HSS
- Latanoprost (Hysite) eye drops 0.005%, 2.5 ml price increase and to be delisted 1 April 2019
- Levobunolol hydrochloride (Betagan) eye drops 0.5%, 5 ml to be delisted
 1 June 2019
- Methylprednisolone acetate with lidocaine [lignocaine] (Depo-Medrol with Lidocaine) inj 40 mg with lidocaine [lignocaine], 1 ml vial – to be delisted 1 April 2019
- Moclobemide (Aurorix) tab 150 mg and 300 mg new listing and addition of HSS
- Moclobemide (Apo-Moclobemide) tab 150 mg and 300 mg to be delisted 1 April 2019
- Modafinil (Modavigil) tab 100 mg new listing
- Nitrofurantoin (Nifuran) tab 50 mg and 100 mg new listing and addition of HSS
- Paritaprevir, ritonavir and oimbitasvir with dasabuvir (Viekira Pak) tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56), with dasabuvir tab 250 mg (56) delisted 1 February 2019
- Paritaprevir, ritonavir and ombitasvir with dasabuvir and ribavirin (Viekira Pak RBV) tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56) with dasabuvir tab 250 mg (56) and ribavirin tab 200 mg (168) – delisted 1 February 2019
- Piperacillin with tazobactam (Tazocin EF) inj 4 g with tazobactam 0.5 g vial
 to be delisted 1 April 2019
- Procarbazine hydrochloride (Natulan) cap 50 mg price increase
- Propylene glycol (ABM) liq, 500 ml delisted 1 February 2019
- Raloxifene (Evista) tab 60 mg amended restriction
- Tocilizumab (Actemra) inj 20 mg per ml, 4 ml, 10 ml and 20 ml vials
 amended restriction

• Zoledronic acid (Aclasta) inj 5 mg per 100 ml, vial – amended restriction	

Summary of decisions – effective 1 February 2019 (continued)

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

Section H changes to Part II

Effective 1 February 2019

ALIMENTARY TRACT AND METAROLISM

18 IRON POLYMALTOSE (delisting delayed)

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)

Binocrit	6	→ Inj 1,000 iu in 0.5 ml syringe – 1% DV Apr-19 to 2022 250.00	
Binocrit	6	→ Inj 2,000 iu in 1 ml syringe – 1% DV Apr-19 to 2022	
Binocrit	6	→ Inj 3,000 iu in 0.3 ml syringe – 1% DV Apr-19 to 2022 150.00	
Binocrit	6	→ Inj 4,000 iu in 0.4 ml syringe – 1% DV Apr-19 to 202296.50	
Binocrit	6	→ Inj 5,000 iu in 0.5 ml syringe – 1% DV Apr-19 to 2022 125.00	٠
Binocrit	6	→ Inj 6,000 iu in 0.6 ml syringe – 1% DV Apr-19 to 2022 145.00	٠
Binocrit	6	→ Inj 8,000 iu in 0.8 ml syringe – 1% DV Apr-19 to 2022 175.00	٠
Binocrit	6	→ Inj 10,000 iu in 1 ml syringe – 1% DV Apr-19 to 2022 197.50	٠
Binocrit	1	→ Inj 40,000 iu in 1 ml syringe – 1% DV Apr-19 to 2022250.00	٠

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:

continued...

6

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** erythropoietin 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
- → Inj 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** erythropoictin 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 (ex man. Excl. GST)		Brand or Generic	_
` \$	Per	Manufacturer	

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

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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 mcg8.00 Note – Lycinate tab 600 mcg to be delisted from 1 March 2019.	100	Lycinate

HORMONE PREPARATIONS

64	METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] (delisting)	
	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 be delisted from 1 April 201	19.

INFECTIONS

76	PIPERACILLIN WITH TAZOBACTAM (delisting) → Inj 4 g with tazobactam 0.5 g vial	15.50	1	Tazocin EF	
	Note – Tazocin EF inj 4 g with tazobactam 0.5 g vial to be	e delisted from 1 A	pril 2019.		
79	NITROFURANTOIN (new listing and addition of HSS)				
	Tab 50 mg - 1% DV Apr-19 to 2021	22.20	100	Nifuran	
	Tab 100 mg – 1% DV Apr-19 to 2021	37.50	100	Nifuran	
88	GLECAPREVIR WITH PIBRENTASVIR (new listing) Note: the supply of treatment is via PHARMAC's ap found on PHARMAC's website https://www.pharma	•		,	an be
	Tab 100 mg with pibrentasvir 40 mg	24,750.00	84	Maviret	
88	PARITAPREVIR, RITONAVIR AND OIMBITASVIR WITH DA	ASABUVIR (delisted	i)		

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

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 raloxifene.

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 esteoperotic 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.

continued...

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.

ALENDRONATE SODIUM WITH COLECALCIFEROL (‡ price, addition of HSS and restriction removed)

Tab 70 mg with colecalciferol 5,600 iu

Initiation - Osteoporosis

Any of the following:

95

- 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.

continued...

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
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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

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

100 RALOXIFENE (amended restriction)

→ Tab 60 mg.......53.76 28 Evista

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

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

NERVOUS SYSTEM

114	MOCLOBEMIDE (brand change) Tab 150 mg – 1% DV Apr-19 to 2021	Aurorix Aurorix
124	GLATIRAMER ACETATE (new listing) → Inj 40 mg prefilled syringe	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 – 1% DV Apr-19 to 202185.00	Epirubicin Ebewe
131	EPIRUBICIN HYDROCHLORIDE (delisting) Inj 2 mg per ml, 50 ml vial32.50 1 Note – Epirubicin Ebewe inj 2 mg per ml, 50 ml vial to be delisted 1 June 2019.	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 – 1% DV Apr-19 to 2021 71.44	Irinotecan Actavis 100
136	PROCARBAZINE HYDROCHLORIDE († price) Cap 50 mg980.00 50	Natulan

Price	Brand or
(ex man. Excl. 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 vial	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 Rev 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% – 1% DV Apr-19 to 20211.57	2.5 ml	Teva
201	LATANOPROST († price) Eye drops 0.005%	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	IAL 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.g. 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-thiazide combination 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

	(ex	Price x man. Excl. G \$	SST) Per	Brand or Generic Manufacturer
Char	nges to Section H Part II – effective 1 January 20	19 (continu	ed)	
55	HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN († p Crm 1% with natamycin 1% and neomycin sulphate 0.5% Oint 1% with natamycin 1% and neomycin sulphate 0.5%	3.35	15 g 15 g	Pimafucort Pimafucort
56	HYDROCORTISONE BUTYRATE († price and addition of HSS) Scalp lotn 0.1% – 1% DV Mar-19 to 2021		100 ml	Locoid
INFE	CTIONS			
72	AMIKACIN (amended pack size and price) → Inj 5 mg per ml, 5 ml syringe	181.50 18.	.15 10 1	Biomed
76	AMOXICILLIN WITH CLAVULANIC ACID († price) Inj 500 mg with clavulanic acid 100 mg vial Inj 1,000 mg with clavulanic acid 200 mg vial		10 10	m-Amoxiclav m-Amoxiclav
84	METRONIDAZOLE († price) Inj 5 mg per ml, 100 ml bag	55.00	10	Baxter
NER	VOUS SYSTEM			
106	APOMORPHINE HYDROCHLORIDE (delisted) Inj 10 mg per ml, 1 ml ampoule Note – Apomorphine hydrochloride inj 10 mg per ml, 1 ml am	npoule deliste	d 1 January 2	2019.
107	DESFLURANE (HSS extended) Soln for inhalation 100%, 240 ml bottle - 1% DV Sep-16 to 2020 2019	1,350.00	6	Suprane
107	ISOFLURANE (HSS extended) Soln for inhalation 100%, 250 ml bottle - 1% DV Sep-16 to 2020 2019	1,020.00	6	Aerrane
108	SEVOFLURANE (HSS extended) Soln for inhalation 100%, 250 ml bottle - 1% DV Sep-16 to 2020 2019	840.00	6	Baxter
119	DOMPERIDONE (brand change) Tab 10 mg – 1% DV Mar-19 to 2021 Note – Prokinex tab 10 mg to be delisted from 1 March 2019		100	Pharmacy Health
119	HYOSCINE HYDROBROMIDE († price) → Patch 1.5 mg	14.11	2	Scopoderm TTS
120	CLOZAPINE (Pharmacode change) Tab 100 mg	14.73 29.45	50 100	Clozaril Clozaril
	Note – New Pharmacode listings, tab 100 mg 2534878 (50 t Pharmacodes to be delisted 1 July 2019.	ab pack) and	2534886 (10	00 tab pack). Existing

Price	
(ex man. Excl. GS	T)
\$	Per

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

129 VARENICLINE (brand change)

Note – Champix tab $0.5~{\rm mg}$ x $11~{\rm and}$ 1 ${\rm mg}$ x $14~{\rm and}$ tab 1 ${\rm mg}$ (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
 - +.4 Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and

continued...

Price		Brand or	
(ex man. Excl. G	ST)	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%	10 ml	Chlorafast
VAR	ious		
205	DESFERRIOXAMINE MESILATE (brand change) Inj 500 mg vial – 1% DV Mar-19 to 2021 84.53	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) \$ Pe 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

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	TESTOS	STERONE (f price)

65 CLOMIFENE CITRATE (delisting)

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

INFECTIONS

72 .	amikacin ((†	price)
------	------------	----	--------

→ Inj 5 mg per ml, 5 ml syringe.......181.50 10 Biomed

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. GST)		Generic	
\$	Per	Manufacturer	

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

MUSCULOSKELETAL SYSTEM

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 – 1% V Feb-19 to 202112.40 Note – Paracare suppos 500 mg to be delisted from 1 February 2019.	50	Gacet
115	DIAZEPAM († price) Rectal tubes 5 mg40.87	5	Stesolid
116	LAMOTRIGINE (Pharmacode change) Tab dispersible 25 mg		Logem Logem Logem ng, 2553384 and tab
120	CLOZAPINE (Pharmacode change) Tab 25 mg		Clozaril 2019.
121	ZIPRASIDONE (HSS reinstated) Cap 20 mg – 1% DV Dec-18 to 2021 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:

continued...

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

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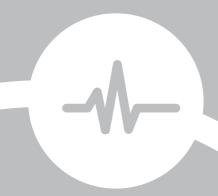
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