Pharmaceutical Management Agency

Section H Update for Hospital Pharmaceuticals

Effective 1 January 2018

Cumulative for December 2017 and January 2018

PHARMAC
Pharmaceutical Management Agency

Contents

Summary of decisions
EFFECTIVE 1 JANUARY 2018

- Alendronate sodium (Fosamax) tab 70 mg – price decrease
- Alendronate sodium with colecalciferol (Fosamax Plus) tab 70 mg with colecalciferol 5,600 iu – price decrease
- Bendroflumethiazide [bendrofluazide] (Arrow-Bendrofluazide) tab 2.5 mg and 5 mg – price increase and addition of HSS
- Bosentan (Bosentan-Mylan) tab 62.5 mg and 125 mg, 60 tab pack size – new listing
- Bosentan (Mylan-Bosentan) tab 62.5 mg and 125 mg, 56 tab pack size – to be delisted 1 July 2018
- Calcium carbonate (Arrow-Calcium) tab 1.25 g (500 mg elemental) – price increase and addition of HSS
- Dapsone (Dapsone) tab 25 mg and 100 mg – price increase
- Dexamethasone (Ozurdex) ocular implant 700 mcg – amended restriction
- Diazepam (Arrow-Diazepam) tab 2 mg and 5 mg – price increase and addition of HSS
- Ezetimibe (Ezetimibe Sandoz) tab 10 mg – new listing and addition of HSS
- Ezetimibe (Ezemibe) tab 10 mg – to be delisted 1 March 2018
- Glyceryl trinitrate inj 1 mg per ml, 10 ml ampoule – new listing
- Ibuprofen (Fenpaed) oral liq 20 mg per ml – price increase
- Levonorgestrel (Jadelle) subdermal implant (2 x 75 mg rods) – price decrease and addition of HSS
- Melatonin tab 3 mg – addition of note
- Methylnaltrexone bromide (Relistor) inj 12 mg per 0.6 ml vial, 1 and 7 inj packs – new listing
- Nicotine (Habitrol) patch 7 mg per 24 hours, 14 mg per 24 hours and 21 mg per 24 hours; lozenge 1 mg and 2 mg; and gum (fruit and mint) 2 mg and 4 mg – price increase and addition of HSS
- Norfloxacin (Arrow-Norfloxacin) tab 400 mg – price increase
- Omeprazole cap 10 mg (Omeprazole actavis 10), cap 20 mg (Omeprazole actavis 20) and cap 40 mg (Omeprazole actavis 40) – new listing and addition of HSS
- Omeprazole (Omezol Relief) cap 10 mg, 20 mg and 40 mg – to be delisted 1 March 2018
- Paediatric oral feed (Pediasure (Vanilla)) powder 14.9 g protein, 54.3 g carbohydrate and 24.7 g fat per 100 g, can, 850 g – to be delisted 1 July 2018

Summary of decisions – effective 1 January 2018 (continued)

- Paromomycin (Humatin) cap 250 mg – amended restriction
- Potassium iodate (NeuroTabs) tab 253 mcg (150 mcg elemental iodine) – price increase
- Pravastatin (Apo-Pravastatin) tab 40 mg – new listing and addition of HSS
- Pravastatin (Chlovastin) tab 40 mg – to be delisted 1 March 2018
- Preterm formula (S-26 Gold Premgro) powder 1.9 g protein, 7.5 g carbohydrate and 3.9 g fat per 14 g, can, 400 g – to be delisted 1 July 2018
- Prochlorperazine (Nausafix) tab 5 mg – new listing and addition of HSS
- Prochlorperazine (Antinaus) tab 5 mg – to be delisted 1 March 2018
- Rocuronium bromide (DBL Rocuronium Bromide) inj 10 mg per ml, 5 ml vial – HSS suspended
- Simvastatin (Arrow-Simva) tab 10 mg, 20 mg, 40 mg and 80 mg – delist delayed
- Simvastatin (Simvastatin Mylan) tab 10 mg, 20 mg, 40 mg and 80 mg – HSS suspended
- Sodium citrate with sodium lauryl sulphoacetate (Micolette) enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml – price increase
- Tenofovir disoproxil fumarate (Viread) tab 300 mg – amended restriction
- Zoledronic acid (Zoledronic acid Mylan and Zometa) inj 4 mg per 5 ml, vial – amended restriction

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

Section H changes to Part II

Effective 1 January 2018

ALIMENTARY TRACT AND METABOLISM

16 OMEPRAZOLE (brand change)

Cap 10 mg – **1% DV Mar-18 to 2020**	1.98	90	**Omeprazole actavis 10**
Cap 20 mg – **1% DV Mar-18 to 2020**	1.96	90	**Omeprazole actavis 20**
Cap 40 mg – **1% DV Mar-18 to 2020**	3.12	90	**Omeprazole actavis 40**

Note – Omezol Relief cap 10 mg, 20 mg and 40 mg to be delisted from 1 March 2018.

20 METHYLNALTREXONE BROMIDE (new listing)

➔ Inj 12 mg per 0.6 ml vial	36.00	1	Relistor
	246.00	7	Relistor

Restricted
Initiation – Opioid induced constipation
Both:
1 The patient is receiving palliative care; and
2 Either:
2.1 Oral and rectal treatments for opioid induced constipation are ineffective; or
2.2 Oral and rectal treatments for opioid induced constipation are unable to be tolerated.

20 SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE (↑ price)
Enema 90 mg with sodium lauryl sulphoacetate

9 mg per ml, 5 ml	26.72	50	Micolette

23 CALCIUM CARBONATE (↑ price and addition of HSS)

Tab 1.25 g (500 mg elemental) – **1% DV Mar-18 to 2020**	7.52	250	**Arrow-Calcium**

24 POTASSIUM IODATE (↑ price)

Tab 253 mcg (150 mcg elemental iodine)	4.69	90	NeuroTabs

CARDIOVASCULAR SYSTEM

49 BENDROFLUMETHIAZIDE [BENDROFLUAZIDE] (↑ price and addition of HSS)

Tab 2.5 mg – **1% DV Mar-18 to 2020**	12.50	500	**Arrow-Bendrofluazide**
Tab 5 mg – **1% DV Mar-18 to 2020**	20.42	500	**Arrow-Bendrofluazide**

49 PRAVASTATIN (brand change)

Tab 40 mg – **1% DV Mar-18 to 2020**	8.06	100	**Apo-Pravastatin**

Note – Cholvastin tab 40 mg to be delisted from 1 March 2018.

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

49 SIMVASTATIN (HSS suspended and delist delayed)

Tab 10 mg – ~~1% DV Jan-18 to 2020~~	0.95	90	Arrow-Simva
			Simvastatin Mylan
Tab 20 mg – ~~1% DV Jan-18 to 2020~~	1.61	90	Arrow-Simva
	1.52		Simvastatin Mylan
Tab 40 mg – ~~1% DV Jan-18 to 2020~~	2.83	90	Arrow-Simva
	2.63		Simvastatin Mylan
Tab 80 mg – ~~1% DV Jan-18 to 2020~~	7.91	90	Arrow-Simva
	6.00		Simvastatin Mylan

Note – HSS for the Simvastatin Mylan brand of simvastatin tab 10 mg, 20 mg, 40 mg and 80 mg has been suspended until further notice. The delist of the Arrow-Simva brand has also been delayed until further notice.

50 EZETIMIBE (brand change)

➔ Tab 10 mg – **1% DV Mar-18 to 2020**	2.00	30	**Ezetimibe Sandoz**

Note – Ezemibe tab 10 mg to be delisted 1 March 2018.

51 GLYCERYL TRINITRATE (new listing)

Inj 1 mg per ml, 10 ml ampoule

53 BOSENTAN (alternate brand listing)

Tab 62.5 mg	401.79	60	Bosentan-Mylan
Tab 125 mg	401.79	60	Bosentan-Mylan

Note – this is a listing of a new pack size with an amended name. Mylan-Bosentan 56 tablet pack size to be delisted from 1 July 2018.

GENITO-URINARY SYSTEM

62 LEVONORGESTREL (↓ price and addition of HSS)

Subdermal implant (2 × 75 mg rods)

– **1% DV Mar-18 to 2020**	106.92	1	**Jadelle**

HORMONE PREPARATIONS

67 ZOLEDRONIC ACID (amended restriction)

➔ Inj 4 mg per 5 ml, vial	84.50	1	Zoledronic acid Mylan
	550.00		Zometa

Restricted
Initiation – **bone metastases**
Oncologist, haematologist or palliative care specialist
Any of the following:
1 Patient has hypercalcaemia of malignancy; or
2 Both:
  2.1 Patient has bone metastases or involvement; and
  2.2 Patient has severe bone pain resistant to standard first-line treatments; or
3 Both:
  3.1 Patient has bone metastases or involvement; and
  3.2 Patient is at risk of skeletal-related events (pathological fracture, spinal cord compression, radiation to bone or surgery to bone).

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

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Initiation – early breast cancer
Oncologist
All of the following:
1 Treatment to be used as adjuvant therapy for early breast cancer; and
2 Patient has been amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
3 Treatment to be administered at a minimum interval of 6-monthly for a maximum of 2 years.

INFECTIONS

76 PAROMOMYCIN (amended restriction)
➔ Cap 250 mg ..... 126.00 16 Humatin

Restricted
Clinical microbiologist, ~~or~~ infectious disease specialist **or gastroenterologist**

82 NORFLOXACIN (↑ price)
Tab 400 mg ..... 135.00 100 Arrow-Norfloxacin

86 DAPSONE (↑ price)
➔ Tab 25 mg ..... 268.50 100 Dapsone
➔ Tab 100 mg ..... 329.50 100 Dapsone

94 TENOFOVIR DISOPROXIL FUMARATE (amended restriction)
➔ Tab 300 mg ..... 531.00 30 Viread

Restricted
Initiation – Confirmed hepatitis B
Either ~~Any of the following~~:
1 All of the following:
1.1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
1.2 Patient has had previous lamivudine, adefovir or entecavir therapy; and
1.3 HBV DNA greater than 20,000 IU/mL or increased ~~less than or equal to 10-fold~~ **10 fold or higher** over nadir; and
1.4 Any of the following:
1.4.1 Lamivudine resistance - detection of M204I/V mutation; or
1.4.2 Adefovir resistance - detection of A181T/V or N236T mutation; or
1.4.3 Entecavir resistance - detection of relevant mutations including I169T, L180M T184S/A/I/L/G/C/M, ~~S202C/G/I,M204V~~ **S202C/G/I, M204V** or M250I/V mutation; or
2 Patient is either listed or has undergone liver transplantation for HBV; ~~or~~
~~3 Patient has a decompensated cirrhosis with a Mayo score > less than or equal togt; 20.~~

Initiation ~~– Pregnant or Breastfeeding,~~ **Women of child bearing age with active** ~~Active~~ hepatitis B
Limited to 12 months treatment
~~Both:~~ **All of the following:**
1 Patient is HBsAg positive~~ and pregnant~~; and
2 **Either:**
2.1 HBV DNA **>** ~~less than or equal togt;~~ 20,000 IU/mL and ALT **>** ~~less than or equal togt;~~ ULN.**; or**
2.2 HBV DNA > 20 million IU/mL and ALT normal; and
3 Any of the following:
3.1 Patient is of child bearing potential and has not yet completed a family; or
3.2 Patient is pregnant; or
3.3 Patient is breastfeeding.

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

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~~Initiation – Pregnant, prevention of vertical transmission~~
~~Limited to 6 months treatment~~
~~Both:~~
~~1 Patient is HBsAg positive and pregnant; and~~
~~2 HBV DNA less than or equal togt; 20 million IU/mL and ALT normal.~~

Initiation – Confirmed HIV
~~Both:~~ **Patient has**
~~1 C~~**c**onfirmed HIV infection.~~; and~~
~~2 Any of the following:~~
~~2.1 Symptomatic patient; or~~
~~2.2 Patient aged 12 months and under; or~~
~~2.3 Both:~~
~~2.3.1 Patient aged 1 to 5 years; and~~
~~2.3.2 Any of the following:~~
~~2.3.2.1 CD4 counts less than or equal tolt; 1000 cells/mmless than or equal to#xB3;; or~~
~~2.3.2.2 CD4 counts less than or equal tolt; 0.25 less than or equal to#xD7; total lymphocyte count; or~~
~~2.3.2.3 Viral load counts less than or equal togt; 100000 copies per ml; or~~
~~2.4 Both:~~
~~2.4.1 Patient aged 6 years and over; and~~
~~2.4.2 CD4 counts less than or equal tolt; 500 cells/mmless than or equal to#xB3;.~~

Initiation – Prevention of maternal transmission
Either:
1 Prevention of maternal foetal transmission; or
2 Treatment of the newborn for up to eight weeks.

Initiation – Post-exposure prophylaxis following non-occupational exposure to HIV
Both:
1 Treatment course to be initiated within 72 hours post exposure; and
2 Any of the following:
2.1 Patient has had unprotected receptive anal intercourse with a known HIV positive person; or
2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required.

Initiation – Percutaneous exposure
Patient has percutaneous exposure to blood known to be HIV positive.

MUSCULOSKELETAL SYSTEM

99	ALENDRONATE SODIUM (↓ price)			
	➔ Tab 70 mg	4.82	4	Fosamax
100	ALENDRONATE SODIUM WITH COLECALCIFEROL (↓ price)			
	➔ Tab 70 mg with colecalciferol 5,600 iu	4.82	4	Fosamax Plus
107	ROCURONIUM BROMIDE (HSS suspended)			
	Inj 10 mg per ml, 5 ml vial			
	– **1% DV Aug-16 to** ~~2019~~ **31 Dec 2017**	25.95	10	DBL Rocuronium Bromide

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

108 IBUPROFEN (↑ price)

Oral liq 20 mg per ml	2.39	200 ml	Fenpaed

NERVOUS SYSTEM

124 PROCHLORPERAZINE (brand change)

Tab 5 mg – **1% DV Mar-18 to 2020**	6.35	250	**Nausafix**

Note – Antinaus tab 5 mg to be delisted from 1 March 2018.

129 DIAZEPAM (↑ price and addition of HSS)

Tab 2 mg – **1% DV Mar-18 to 2020**	15.05	500	**Arrow-Diazepam**
Tab 5 mg – **1% DV Mar-18 to 2020**	16.18	500	**Arrow-Diazepam**

130 MELATONIN (amended note)

➔ Tab 3 mg

Note – Only for use in compounding an oral liquid formulation, for in-hospital use only.

135 NICOTINE (↑ price and addition of HSS)

Patch 7 mg per 24 hours – **1% DV Apr-18 to 2020**	16.00	28	**Habitrol**
Patch 14 mg per 24 hours – **1% DV Apr-18 to 2020**	17.59	28	**Habitrol**
Patch 21 mg per 24 hours – **1% DV Apr-18 to 2020**	20.16	28	**Habitrol**
Lozenge 1 mg – **1% DV Apr-18 to 2020**	16.61	216	**Habitrol**
Lozenge 2 mg – **1% DV Apr-18 to 2020**	18.20	216	**Habitrol**
Gum 2 mg – **1% DV Apr-18 to 2020**	33.69	384	**Habitrol (Fruit)** **Habitrol (Mint)**
Gum 4 mg – **1% DV Apr-18 to 2020**	38.95	384	**Habitrol (Fruit)** **Habitrol (Mint)**

SENSORY ORGANS

198 DEXAMETHASONE (amended restriction)

➔ Ocular implant 700 mcg	1,444.50	1	Ozurdex

Restricted
Initiation – Diabetic macular oedema
Ophthalmologist
Re-assessment required after 12 months
All of the following:
1 Patients have diabetic macular oedema with pseudophakic lens; and
2 Patient has reduced visual acuity of between 6/9 – 6/48 with functional awareness of reduction in vision; and
3 Either:
  3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
  3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and
4 Dexamethasone implants are to be administered not more frequently than once every 4 months **into each eye**, and up to a maximum of 3 implants **per eye** per year.

Continuation – Diabetic macular oedema
Ophthalmologist
Re-assessment required after 12 months
Both:
1 Patient's vision is stable or has improved (prescriber determined); and

continued...

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

continued...

2 Dexamethasone implants are to be administered not more frequently than once every 4 months **into each eye**, and up to a maximum of 3 implants **per eye** per year.

Initiation – Women of child bearing age with diabetic macular oedema
Ophthalmologist
Re-assessment required after 12 months
All of the following:
1 Patients have diabetic macular oedema; and
2 Patient has reduced visual acuity of between 6/9 – 6/48 with functional awareness of reduction in vision; and
3 Patient is of child bearing potential and has not yet completed a family; and
4 Dexamethasone implants are to be administered not more frequently than once every 4 months **into each eye**, and up to a maximum of 3 implants **per eye** per year.

Continuation – Women of child bearing age with diabetic macular oedema
Ophthalmologist
Re-assessment required after 12 months
All of the following:
1 Patient's vision is stable or has improved (prescriber determined); and
2 Patient is of child bearing potential and has not yet completed a family; and
3 Dexamethasone implants are to be administered not more frequently than once every 4 months **into each eye**, and up to a maximum of 3 implants **per eye** per year.

SPECIAL FOODS

225	PRETERM FORMULA (delist)			
	➔ Powder 1.9 g protein, 7.5 g carbohydrate and 3.9 g fat per 14 g, can	15.25	400 g	S-26 Gold Premgro
	Note – S-26 Gold Premgro to be delisted from 1 July 2018.			
226	PAEDIATRIC ORAL FEED (delist)			
	➔ Powder 14.9 g protein, 54.3 g carbohydrate and 24.7 g fat per 100 g, can	28.00	850 g	Pediasure (Vanilla)
	Note – Pediasure (Vanilla) powder, 850 g can, to be delisted from 1 July 2018.			

Changes to Section H Part II – effective 1 December 2017

CARDIOVASCULAR SYSTEM

49 PRAVASTATIN (brand change)
Tab 20 mg – **1% DV Mar-18 to 2020** ..... 4.72 100 **Apo-Pravastatin**
Note – Cholvastin tab 20 mg to be delisted from 1 March 2018.

51 GLYCERYL TRINITRATE (delisting)
Inj 1 mg per ml, 5 ml ampoule ..... 22.70 10 Nitronal
Note – Nitronal inj 1 mg per ml, 5 ml ampoule to be delisted from 1 February 2018.

INFECTIONS

78 AZITHROMYCIN (amended restriction)
➔ Tab 250 mg – **1% DV Sep-15 to 2018** ..... 9.00 30 **Apo-Azithromycin**
➔ Tab 500 mg – **1% DV Sep-15 to 2018** ..... 1.05 2 **Apo-Azithromycin**
➔ Grans for oral liq 200 mg per 5 ml (40 mg per ml)
– **1% DV Oct-15 to 2018** ..... 12.50 15 ml **Zithromax**

Restricted
Initiation – bronchiolitis obliterans syndrome, cystic fibrosis and atypical Mycobacterium infections
Any of the following:
1 Patient has received a lung transplant**, stem cell transplant, or bone marrow transplant** and requires treatment ~~or prophylaxis~~ for bronchiolitis obliterans syndrome*; or
2 **Patient has received a lung transplant and requires prophylaxis for bronchiolitis obliterans syndrome*; or**
~~2~~**3** Patient has cystic fibrosis and has chronic infection with Pseudomonas aeruginosa or Pseudomonas related gram negative organisms*; or
~~3~~**4** Patient has an atypical Mycobacterium infection.
Note: Indications marked with * are Unapproved Indications

Initiation – non-cystic fibrosis bronchiectasis*
Respiratory specialist or paediatrician
Re-assessment required after 12 months
All of the following:
1 For prophylaxis of exacerbations of non-cystic fibrosis bronchiectasis*; and
2 Patient is aged 18 and under; and
3 Either:
3.1 Patient has had 3 or more exacerbations of their bronchiectasis, within a 12 month period; or
3.2 Patient has had 3 acute admissions to hospital for treatment of infective respiratory exacerbations within a 12 month period.
Note: Indications marked with * are Unapproved Indications. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis will be subsidised in the community.

Continuation – non-cystic fibrosis bronchiectasis*
Respiratory specialist or paediatrician
Re-assessment required after 12 months
All of the following:
1 The patient has completed 12 months of azithromycin treatment for non-cystic fibrosis bronchiectasis; and
2 Following initial 12 months of treatment, the patient has not received any further azithromycin treatment for non-cystic fibrosis bronchiectasis for a further 12 months, unless considered clinically inappropriate to stop treatment; and

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

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3 The patient will not receive more than a total of 24 months' azithromycin cumulative treatment (see note).
Note: Indications marked with * are Unapproved Indications. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis will be subsidised in the community.

Initiation – other indications
Re-assessment required after 5 days
For any other condition.

Continuation – other indications
Re-assessment required after 5 days
For any other condition.

79 CLARITHROMYCIN (reinstate HSS)
➔ Inj 500 mg vial – **1% DV Dec-17 to 1 Sep 2020** ..... 12.04 1 **Martindale**
Note – Klacid inj 500 mg vial to be delisted from 1 May 2018.

80 AMOXICILLIN (brand change)
Grans for oral liq 125 mg per 5 ml – **1% DV Feb-18 to 2020** ..... 1.20 100 ml **Alphamox 125**
Note – Amoxicillin Actavis and Ospamox grans for oral liq 125 mg per 5 ml to be delisted from 1 February 2018.

80 AMOXICILLIN (addition of HSS)
Grans for oral liq 250 mg per 5 ml – **1% DV Feb-18 to 2020** ..... 1.31 100 ml **Alphamox 250**
Note – Amoxicillin Actavis and Ospamox grans for oral liq 250 mg per 5 ml to be delisted from 1 February 2018.

84 FLUCONAZOLE (brand change)
➔ Cap 50 mg – **1% DV Feb-18 to 2020** ..... 2.09 28 **Mylan**
➔ Cap 150 mg – **1% DV Feb-18 to 2020** ..... 0.33 1 **Mylan**
➔ Cap 200 mg – **1% DV Feb-18 to 2020** ..... 5.08 28 **Mylan**
Note – Ozole cap 50 mg, 150 mg and 200 mg to be delisted from 1 February 2018

85 VORICONAZOLE (brand change)
➔ Inj 200 mg vial – **1% DV Feb-18 to 2019** ..... 65.00 1 **Generic Partners**
Note – Vfend inj 200 mg vial to be delisted from 1 February 2018

93 LAMIVUDINE (restriction removed)
Tab 100 mg ..... 6.00 28 Zeffix
Oral liq 5 mg per ml ..... 270.00 240 ml Zeffix

~~Restricted~~
~~Initiation~~
~~Gastroenterologist, infectious disease specialist, paediatrician or general physician~~
~~Limited to 12 months treatment~~
~~Any of the following:~~
~~1 Hepatitis B virus (HBV) DNA positive cirrhosis prior to liver transplantation; or~~
~~2 Hepatitis B surface antigen (HBsAg) positive and have had a liver, kidney, heart, lung or bone marrow transplant; or~~
~~3 HBV naïve patient who has received a liver transplant from a hepatitis B core antibody (anti-HBc) positive donor; or~~
~~4 HbsAg positive patient who is receiving chemotherapy for a malignancy, or high dose steroids (at least 20 mg/day for at least 7 days), or who has received such treatment within the previous two months; or~~
~~5 HBsAg positive patient who is receiving anti tumour necrosis factor treatment; or~~
~~6 Anti-HBc positive patient who is receiving rituximab in combination with immunosuppressive chemotherapies for a malignancy.~~

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

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~~Continuation – patients who have maintained continuous treatment and response to lamivudine~~
~~Gastroenterologist, infectious disease specialist, paediatrician or general physician~~
~~Re-assessment required after 2 years~~
~~All of the following:~~
~~1 Have maintained continuous treatment with lamivudine; and~~
~~2 Most recent test result shows continuing biochemical response (normal ALT); and~~
~~3 HBV DNA < 100,000 copies per ml by quantitative PCR at a reference laboratory.~~

~~Continuation – when given in combination with adefovir dipivoxil for patients with cirrhosis and resistance to lamivudine~~
~~Gastroenterologist, infectious disease specialist, paediatrician or general physician~~
~~Re-assessment required after 2 years~~
~~All of the following:~~
~~1 Lamivudine to be used in combination with adefovir dipivoxil; and~~
~~2 Patient is cirrhotic; and~~
~~Documented resistance to lamivudine defined as:~~
~~3 All of the following:~~
~~3.1 Patient has raised serum ALT (> 1 × ULN); and~~
~~3.2 Patient has HBV DNA greater than 100,000 copies per mL, or viral load greater than or equal to 10-fold over nadir; and~~
~~3.3 Detection of M204I or M204V mutation.~~

~~Continuation – when given in combination with adefovir dipivoxil for patients with resistance to adefovir dipivoxil~~
~~Gastroenterologist, infectious disease specialist, paediatrician or general physician~~
~~Re-assessment required after 2 years~~
~~Both:~~
~~1 Lamivudine to be used in combination with adefovir dipivoxil; and~~
~~Documented resistance to lamivudine defined as:~~
~~2 All of the following:~~
~~2.1 Patient has raised serum ALT (> 1 × ULN); and~~
~~2.2 Patient has HBV DNA greater than 100,000 copies per mL, or viral load greater than or equal to 10-fold over nadir; and~~
~~2.3 Detection of N236T or A181T/V mutation.~~

MUSCULOSKELETAL SYSTEM

108	IBUPROFEN (new listing)				
	Tab 200 mg – **1% DV Feb-18 to 2020**	11.71	1,000		**Relieve**

NERVOUS SYSTEM

111	LEVODOPA WITH CARBIDOPA (↓ price and addition of HSS)				
	Tab 100 mg with carbidopa 25 mg				
	– **1% DV Feb-18 to 2020**	17.97	100		**Sinemet**
	Tab long-acting 200 mg with carbidopa 50 mg				
	– **1% DV Feb-18 to 2020**	37.15	100		**Sinemet CR**
	Tab 250 mg with carbidopa 25 mg				
	– **1% DV Feb-18 to 2020**	32.67	100		**Sinemet**

Note – Kinson tab 100 mg with carbidopa 25 mg and Sindopa tab 250 mg with carbidopa 25 mg to be delisted from 1 February 2018.

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

123 SUMATRIPTAN (delisting)

Tab 50 mg – **1% DV Jun-17 to 2019**	24.44	102	**Apo-Sumatriptan**
Tab 100 mg – **1% DV Jun-17 to 2019**	46.23	102	**Apo-Sumatriptan**

Note – this is the delisting of 102 tab pack only from 1 June 2018. The 100 tab pack remains listed.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

149 BICALUTAMIDE (brand change)

Tab 50 mg – **1% DV Feb-18 to 2020**	3.80	28	**Binarex**

Note – Bicalaccord tab 50 mg to be delisted from 1 February 2018.

173 RITUXIMAB (restriction amended – affected criteria only shown)

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

Continuation - Chronic lymphocytic leukaemia
Re-assessment required after 12 months.
All of the following:
1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
2 The patient has had a**n** ~~rituximab treatment-free~~ interval of 36 months or more **since commencement of initial rituximab treatment**; and
3 The patient does not have chromosome 17p deletion CLL; and
4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
5 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine for a maximum of 6 treatment cycles

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

SENSORY ORGANS

198 DEXAMETHASONE (amended restriction – affected criteria only shown)

➔ Ocular implant 700 mcg	1,444.50	1	Ozurdex

Restricted
Initiation – Diabetic macular oedema
Ophthalmologist
Limited to 12 months treatment
All of the following:
1 Patients have diabetic macular oedema with pseudophakic lens; and
2 Patient has reduced visual acuity of between 6/9 – 6/48 with functional awareness of reduction in vision; and
3 Any of the following:
  3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
  3.2 Patient is unsuitable or contraindicated to treatment with ~~anti-VEGF inhibitors~~ **anti-VEGF agents**; and
4 Dexamethasone implants are to be administered not more frequently than once every 4 months, and up to a maximum of 3 implants per year.

202 BRIMONIDINE TARTRATE (↓ price and addition of HSS)

Eye drops 0.2% – **1% DV Feb-18 to 2020**	4.29	5 ml	**Arrow-Brimonidine**

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

VARIOUS

208 GADOBUTROL (amended brand name)

Inj 604.72 mg per ml (equivalent to 1 mmol per ml), 5 ml prefilled syringe	120.00	5	Gadovist **1.0**
Inj 604.72 mg per ml (equivalent to 1 mmol per ml), 7.5 ml prefilled syringe	180.00	5	Gadovist **1.0**
Inj 604.72 mg per ml (equivalent to 1 mmol per ml), 15 ml prefilled syringe	700.00	10	Gadovist **1.0**

VACCINES

234 HEPATITIS B RECOMBINANT VACCINE (HSS suspended)

➔ Inj 10 mcg in 1 ml vial			
– **0% DV Jul-17 to ~~2020~~ 30 Nov 2017**	0.00	1	HBvaxPRO

234 HEPATITIS B RECOMBINANT VACCINE (new listing)

➔ Inj 20 mcg per 1 ml prefilled syringe	0.00	1	Engerix-B

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.
Note – Engerix-B inj 20 mcg per 1 ml prefilled syringe to be delisted from 1 December 2018.

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