

Pharmaceutical Management Agency

# Section H Update for Hospital Pharmaceuticals

Effective 1 December 2017



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## Summary of decisions

EFFECTIVE 1 DECEMBER 2017

- Amoxicillin (Alphamox 125) grans for oral liq 125 mg per 5 ml – new listing and addition of HSS
- Amoxicillin (Alphamox 250) grans for oral liq 250 mg per 5 ml – addition of HSS
- Amoxicillin (Amoxicillin Actavis and Ospamox) grans for oral liq 125 mg per 5 ml and 250 mg per 5 ml – to be delisted 1 February 2018
- Azithromycin tab 250 mg and 500 mg (Apo-Azithromycin) and grans for oral liq 200 mg per 5 ml (40 mg per ml) (Zithromax) – amended restriction
- Bicalutamide (Binarex) tab 50 mg – new listing and addition of HSS
- Bicalutamide (Bicalaccord) tab 50 mg – to be delisted 1 February 2018
- Brimonidine tartrate (Arrow-Brimonidine) eye drops 0.2% – price decrease and addition of HSS
- Clarithromycin (Martindale) inj 500 mg vial – reinstate HSS
- Clarithromycin (Klacid) inj 500 mg vial – to be delisted 1 May 2018
- Dexamethasone (Ozurdex) ocular implant 700 mcg – amended restriction
- Fluconazole (Mylan) cap 50 mg, 150 mg and 200 mg – new listing and addition of HSS
- Fluconazole (Ozole) cap 50 mg, 150 mg and 200 mg – to be delisted 1 February 2018
- Gadobutrol (Gadovist 1.0) inj 604.72 mg per ml (equivalent to 1 mmol per ml), 5 ml, 7.5 ml and 15 ml prefilled syringe – amended brand name
- Glyceril trinitrate (Nitronal) inj 1 mg per ml, 5 ml ampoule – to be delisted 1 February 2018
- Hepatitis B recombinant vaccine (HBvaxPRO) inj 10 mcg in 1 ml vial – HSS suspended
- Hepatitis B recombinant vaccine (Engerix-B) inj 20 mcg per 1 ml prefilled syringe – new listing
- Hepatitis B recombinant vaccine (Engerix-B) inj 20 mcg per 1 ml prefilled syringe – to be delisted 1 December 2018
- Ibuprofen (Relieve) tab 200 mg – new listing and addition of HSS
- Lamivudine (Zeffix) tab 100 mg and oral liq 5 mg per ml – restriction removed
- Levodopa with carbidopa (Sinemet) tab 100 mg with carbidopa 25 mg and tab 250 mg with carbidopa 25 mg – price decrease and addition of HSS
- Levodopa with carbidopa (Kinson) tab 100 mg with carbidopa 25 mg and (Sindopa) tab 250 mg with carbidopa 25 mg – to be delisted 1 February 2018

## Summary of decisions – effective 1 December 2017 (continued)

- Levodopa with carbidopa (Sinemet CR) tab long-acting 200 mg with carbidopa 50 mg – price decrease and addition of HSS
- Pravastatin (Apo-Pravastatin) tab 20 mg – new listing and addition of HSS
- Pravastatin (Cholvastin) tab 20 mg to be delisted 1 March 2018
- Rituximab (Mabthera) inj 10 mg per ml, 10 ml vial and 50 ml vial – amended restriction
- Sumatriptan (Apo-Sumatriptan) tab 50 mg and 100 mg, 102 tab pack – to be delisted 1 June 2018
- Voriconazole (Generic Partners) inj 200 mg vial – new listing and addition of HSS
- Voriconazole (Vfend) inj 200 mg vial – to be delisted 1 February 2018

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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## Section H changes to Part II

Effective 1 December 2017

### CARDIOVASCULAR SYSTEM

49	PRAVASTATIN (brand change) Tab 20 mg – <b>1% DV Mar-18 to 2020</b> ..... 4.72	100	<b>Apo-Pravastatin</b>
	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 – <b>1% DV Sep-15 to 2018</b> ..... 9.00	30	<b>Apo-Azithromycin</b>
	→ Tab 500 mg – <b>1% DV Sep-15 to 2018</b> ..... 1.05	2	<b>Apo-Azithromycin</b>
	→ Grans for oral liq 200 mg per 5 ml (40 mg per ml) – <b>1% DV Oct-15 to 2018</b> ..... 12.50	15 ml	<b>Zithromax</b>

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**

23 Patient has cystic fibrosis and has chronic infection with Pseudomonas aeruginosa or Pseudomonas related gram negative organisms\*; or

34 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

*continued...*

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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## Changes to Section H Part II – effective 1 December 2017 (continued)

continued...

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 – <b>1% DV Dec-17 to 1 Sep 2020</b> .....	12.04	1	<b>Martindale</b>
	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 – <b>1% DV Feb-18 to 2020</b> .....	1.20	100 ml	<b>Alphamox 125</b>
	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 – <b>1% DV Feb-18 to 2020</b> .....	1.31	100 ml	<b>Alphamox 250</b>
	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 – <b>1% DV Feb-18 to 2020</b> .....	2.09	28	<b>Mylan</b>
	→ Cap 150 mg – <b>1% DV Feb-18 to 2020</b> .....	0.33	1	<b>Mylan</b>
	→ Cap 200 mg – <b>1% DV Feb-18 to 2020</b> .....	5.08	28	<b>Mylan</b>
	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 – <b>1% DV Feb-18 to 2019</b> .....	65.00	1	<b>Generic Partners</b>
	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
	<b>Restricted</b>			
	<b>Initiation</b>			
	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 naive 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.			

continued...

→ Restriction

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

	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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**Changes to Section H Part II – effective 1 December 2017 (continued)**  
*continued...*

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	<b>Relieve</b>
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**NERVOUS SYSTEM**

111	LEVODOPA WITH CARBIDOPA (4 price and addition of HSS) Tab 100 mg with carbidopa 25 mg – 1% DV Feb-18 to 2020 .....	17.97	100	<b>Sinemet</b>
	Tab long-acting 200 mg with carbidopa 50 mg – 1% DV Feb-18 to 2020 .....	37.15	100	<b>Sinemet CR</b>
	Tab 250 mg with carbidopa 25 mg – 1% DV Feb-18 to 2020 .....	32.67	100	<b>Sinemet</b>

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.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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## Changes to Section H Part II – effective 1 December 2017 (continued)

123	SUMATRIPTAN (delisting)			
	Tab 50 mg – <b>1% DV Jun-17 to 2019</b> .....	24.44	102	<b>Apo-Sumatriptan</b>
	Tab 100 mg – <b>1% DV Jun-17 to 2019</b> .....	46.23	102	<b>Apo-Sumatriptan</b>

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 – <b>1% DV Feb-18 to 2020</b> .....	3.80	28	<b>Binarex</b>
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 an ~~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				
<i>Limited to 12 months treatment</i>				
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 <del>anti-VEGF inhibitors</del> <b>anti-VEGF agents</b> ; 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% – <b>1% DV Feb-18 to 2020</b> .....	4.29	5 ml	<b>Arrow-Brimonidine</b>

→ Restriction

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



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**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 <b>1.0</b>
	Inj 604.72 mg per ml (equivalent to 1 mmol per ml), 7.5 ml prefilled syringe.....	180.00	5	Gadovist <b>1.0</b>
	Inj 604.72 mg per ml (equivalent to 1 mmol per ml), 15 ml prefilled syringe.....	700.00	10	Gadovist <b>1.0</b>

**VACCINES**

234	HEPATITIS B RECOMBINANT VACCINE (HSS suspended)			
	→ Inj 10 mcg in 1 ml vial			
	– <b>0% DV Jul-17 to 2020 30 Nov 2017</b> .....	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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ISSN 1179-3694 (Print) - ISSN 1179-3708 (Online)

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