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Summary of decisions
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• 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
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• Fluconazole (Mylan) cap 50 mg, 150 mg and 200 mg – new listing and addition of HSS
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• 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
Section H changes to 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.

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

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

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<tr>
<td>→ Inj 500 mg vial – 1% DV Dec-17 to 1 Sep 2020</td>
<td>12.04 1 Martindale</td>
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<td>Note – Klacid inj 500 mg vial to be delisted from 1 May 2018.</td>
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<th>AMOXICILLIN (brand change)</th>
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<td>Grans for oral liq 125 mg per 5 ml – 1% DV Feb-18 to 2020</td>
<td>1.20 100 ml Alphamox 125</td>
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<td>Note – Amoxicillin Actavis and Ospamox grans for oral liq 125 mg per 5 ml to be delisted from 1 February 2018.</td>
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<td>Grans for oral liq 250 mg per 5 ml – 1% DV Feb-18 to 2020</td>
<td>1.31 100 ml Alphamox 250</td>
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<td>Note – Amoxicillin Actavis and Ospamox grans for oral liq 250 mg per 5 ml to be delisted from 1 February 2018.</td>
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<th>FLUCONAZOLE (brand change)</th>
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<tr>
<td>→ Cap 50 mg – 1% DV Feb-18 to 2020</td>
<td>2.09 28 Mylan</td>
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<tr>
<td>→ Cap 150 mg – 1% DV Feb-18 to 2020</td>
<td>0.33 1 Mylan</td>
</tr>
<tr>
<td>→ Cap 200 mg – 1% DV Feb-18 to 2020</td>
<td>5.08 28 Mylan</td>
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<tr>
<td>Note – Ozole cap 50 mg, 150 mg and 200 mg to be delisted from 1 February 2018</td>
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<tr>
<td>→ Inj 200 mg vial – 1% DV Feb-18 to 2019</td>
<td>65.00 1 Generic Partners</td>
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<tr>
<td>Note – Vfend inj 200 mg vial to be delisted from 1 February 2018</td>
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<th>93</th>
<th>LAMIVUDINE (restriction removed)</th>
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<tr>
<td>Tab 100 mg</td>
<td>6.00 28 Zeffix</td>
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<tr>
<td>Oral liq 5 mg per ml</td>
<td>270.00 240 ml Zeffix</td>
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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 antitumour necrosis factor treatment; or
6. Anti Hbc positive patient who is receiving rituximab in combination with immunosuppressive chemotherapies for a malignancy.

continued...
Changes to Section H Part II – effective 1 December 2017 (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:
2. 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 (4 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)
   \( \rightarrow \) Inj 10 mg per ml, 10 ml vial ...................................... 1,075.50 2 Mabthera
   \( \rightarrow \) 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)
   \( \rightarrow \) 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 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 (4 price and addition of HSS)
   Eye drops 0.2% – 1% DV Feb-18 to 2020 .............................. 4.29 5 ml Arrow-Brimonidine

\( \rightarrow \) Restriction

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