

1 February 2007

To All Pharmaceutical Suppliers, Hospital Pharmacists, Medical Groups and Interested Parties

**Proposal to list tenofovir disoproxil fumarate (Viread) and emtricitabine (Emtriva) and amend the listing of liposomal amphotericin (AmBisome) in the Pharmaceutical Schedule**

PHARMAC and Gilead Sciences (NZ) have entered into a provisional agreement for the listing of tenofovir disoproxil fumarate (Viread) and emtricitabine (Emtriva) in Sections B and Part II of Section H of the Pharmaceutical Schedule from 1 April 2007. We are now seeking feedback on this proposal. Details of the proposal are as follows:

***Tenofovir disoproxil fumarate (Viread) and emtricitabine (Emtriva)***

- tenofovir disoproxil fumarate and emtricitabine would be listed in Sections B and H of the Pharmaceutical Schedule from 1 April 2007 at the following prices and subsidies (ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form	Strength	Pack Size	Price/ subsidy
tenofovir disoproxil fumarate	Viread	Tablet	300 mg	30	\$531.00
emtricitabine	Emtriva	Capsule	200 mg	30	\$307.20

- The listing of tenofovir disoproxil fumarate and emtricitabine in Section B would be subject to the following restrictions:

Special Authority for Subsidy - Form SA0779

Initial application - (Confirmed HIV/AIDS) only from a named specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Confirmed 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 < 1,000 cells/mm<sup>3</sup>; or
      - 2.3.2.2 CD4 counts < 0.25 × total lymphocyte count; or
      - 2.3.2.3 Viral load counts > 100,000 copies per ml; or
  - 2.4 Both:
    - 2.4.1 Patient aged 6 years and over; and
    - 2.4.2 CD4 counts < 350 cells/mm<sup>3</sup>.

Note

Subsidies for a combination of up to three anti-retroviral medications, including a maximum of two protease inhibitors. Combinations including ritonavir plus indinavir or saquinavir or atazanavir will be counted as one protease inhibitor for the purpose of accessing funding to anti-retrovirals.

Initial application - (Percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where person with percutaneous exposure to blood known to be HIV positive.

**Note**

Subsidies for a combination of up to three anti-retroviral medications, including a maximum of two protease inhibitors. Combinations including ritonavir plus indinavir or saquinavir or atazanavir will be counted as one protease inhibitor for the purpose of accessing funding to anti-retrovirals.

Initial application - (Prevention of maternal transmission) only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria:

Either:

- 1 Prevention of maternal foetal transmission; or
- 2 Treatment of the newborn for up to eight weeks.

**Note**

Subsidies for a combination of up to three anti-retroviral medications, including a maximum of two protease inhibitors. Combinations including ritonavir plus indinavir or saquinavir or atazanavir will be counted as one protease inhibitor for the purpose of accessing funding to anti-retrovirals.

Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of a Pharmaceutical for an indication for which it is not approved or contraindicated.

Renewal - (Confirmed HIV/AIDS) only from a named specialist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

***Liposomal Amphotericin (AmBisome)***


- Liposomal amphotericin (AmBisome) would continue to be listed in Section H of the Pharmaceutical Schedule at current price (ex-manufacturer, excluding GST) as follows:

Pharmaceutical	Brand	Form	Strength	Pack Size	Price
liposomal amphotericin	AmBisome	Injection	50 mg	10	\$3,450.00

- A discount on invoice for liposomal amphotericin (AmBisome) would apply from 1 April 2007 to 31 March 2010.

It is anticipated that the proposed changes, if approved by PHARMAC's Board, or Chief Executive under delegated authority, would take effect from 1 April 2007. If you wish to make comments for the PHARMAC Board to consider when making its decision on whether to accept this proposal, please forward them to PHARMAC by **5:00 pm, 16 February 2007**. All comments submitted by this date will be considered.

Yours sincerely



Jackie Evans  
Therapeutic Group Manager