

28 April 2005

To: All Pharmaceutical Suppliers, Medical Groups and Interested Parties

CONSULTATION ON WIDENING ACCESS TO LOPINAVIR WITH RITONAVIR (KALETRA)

PHARMAC proposes to widen access to lopinavir with ritonavir (Kaletra) from 1 July 2005, which means that lopinavir with ritonavir would no longer be restricted for salvage treatment only. Lopinavir with ritonavir would remain listed on the Pharmaceutical Schedule subject to the Special Authority – Hospital Pharmacy criteria and restrictions which apply to the prescribing and dispensing of the therapeutic subgroup of pharmaceuticals comprising Antiretrovirals. The current Special Authority for access to Antiretrovirals is as follows:

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

Both:

- 1 Confirmed HIV/AIDS; and
- 2 Any of the following:
 - 2.1 Symptomatic patient; or
 - 2.2 Both:
 - 2.2.1 Asymptomatic patient; and
 - 2.2.2 Patient aged 12 months and under; or
 - 2.3 Both:
 - 2.3.1 Asymptomatic patient; and
 - 2.3.2 Patient has viral load counts > 10,000 copies per ml or equivalent value on the Chiron test; or
 - 2.4 All of the following:
 - 2.4.1 Asymptomatic patient; and
 - 2.4.2 Patient aged 1 to 5 years; and
 - 2.4.3 CD4 counts < 1,000 cells/mm³; or
 - 2.5 All of the following:
 - 2.5.1 Asymptomatic patient; and
 - 2.5.2 Patient aged 1 to 5 years; and
 - 2.5.3 CD4 counts < 0.25 × total white cell count; or
 - 2.6 All of the following:
 - 2.6.1 Asymptomatic patient; and
 - 2.6.2 Patient aged 6 years and over; and
 - 2.6.3 CD4 counts < 500 cells/mm³.

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 will be counted as one protease inhibitor for the purpose of accessing funding to anti-retrovirals.

Initial application - (Percutaneous exposure) only from a named general physician. Approvals valid for 6 weeks for applications meeting the following criteria:

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 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 general physician. Approvals valid for 1 year for applications meeting the following criteria:

Both:

3 Treatment with zidovudine; and

4 Either:

4.1 Prevention of maternal foetal transmission; or

4.2 Treatment of the newborn for up to six weeks.

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

The treatment remains appropriate and the patient is benefiting from treatment.

This proposal will be considered by the PHARMAC Board or by the Chief Executive under Delegated Authority in May 2005. If you have comments to make on this proposal and would like those comments to be considered by the PHARMAC Board or the Chief Executive then please send them to Deepti Chotai at PHARMAC **by 5 p.m. on 13 May 2005**. The Board will consider all comments submitted by this date.

Yours sincerely

A handwritten signature in black ink, appearing to read 'D. Chotai', with a small dot at the end.

Deepti Chotai
Therapeutic Group Manager