

6 April 2005

To: All Pharmaceutical Suppliers, Medical Groups and Interested Parties

CONSULTATION ON AMENDING THE SPECIAL AUTHORITY FOR ACCESS TO ANTIRETROVIRAL THERAPY

PHARMAC proposes amending the Special Authority criteria for access to antiretroviral therapy from 1 July 2005. The amended Special Authority would allow subsidies for a combination of up to three anti-retroviral medications, but including a maximum of two protease inhibitors, for prevention of foetal transmission and for the treatment of the new born for up to eight weeks.

The Special Authority would be as follows (changes in bold and strikethrough):

~~Special Authority for Subsidy – Form: SA0575~~

~~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 x 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.

Special Authority for Subsidy - Form: SA-001

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 Patient aged 12 months and under; or

2.3 Both:

2.3.1 Patient aged 1 to 5 years; and

2.3.2 Either:

2.3.2.1 CD4 counts < 1,000 cells/mm³; or

2.3.2.2 CD4 counts < 0.25 × total white cell count; or

2.4 Both:

2.4.1 Patient aged 6 years and over; and

2.4.2 CD4 counts < 350 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 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 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:

Either:

3 Prevention of maternal foetal transmission; or

4 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 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 general physician. Approvals valid without further renewal unless notified where 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 20 April 2005**. The Board will consider all comments submitted by this date.

Yours sincerely



Deepti Chotai
Therapeutic Group Manager