



CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

FOSAMPRENAVIR (Telzir™ –GlaxoSmithKline)

Description: Fosamprenavir is a pro-drug of amprenavir, a HIV-1 protease inhibitor (PI), which is indicated for the treatment of patients with HIV-1 infection in combination with low dose ritonavir plus other antiretroviral agents.

Recommendation: The Canadian Expert Drug Advisory Committee recommends that fosamprenavir be listed in a similar manner as drug plans list other protease inhibitors as part of HIV treatment regimens.

Reasons for the Recommendation:

1. In a randomized controlled trial involving treatment-naïve adult patients with HIV-1 infection, fosamprenavir-ritonavir, administered once daily, had a similar effect on viral load and CD4+ cell counts as nelfinavir, administered twice daily. Both treatments were used in combination with other antiretroviral agents.
2. Clinical trial data to date provides no evidence to support equivalence of fosamprenavir-ritonavir when compared to lopinavir-ritonavir in the treatment of PI experienced adult patients with HIV-1 infection.
3. Fosamprenavir has a similar adverse effect profile as other PIs. Adverse events most frequently leading to fosamprenavir discontinuation were gastrointestinal events (especially diarrhea), dehydration, and elevations of transaminases and triglycerides. Lipodystrophy is also a common adverse effect of PIs. Fat redistribution occurred more often in patients treated with fosamprenavir-ritonavir than with lopinavir-ritonavir.
4. Fosamprenavir is comparable in price to other available protease inhibitors.

Of Note:

1. Once daily dosing and reduction of a large daily pill burden are potential advantages of fosamprenavir.
2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

Common Drug Review