CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

TENOFOVIR
(Viread® - Gilead Sciences Canada, Inc)

Description:
Tenofovir is a nucleotide analogue that is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in patients 18 years of age and older.

Dosage Forms:
300 mg tablet

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that tenofovir be listed as an alternative treatment for adult patients who have experienced adverse events or virologic failure with nucleoside reverse transcriptase inhibitors.

Reasons for the Recommendation:

1. The Committee considered the data from two randomized controlled trials (RCTs) that used tenofovir as part of a non-nucleoside reverse transcriptase inhibitor (NNRTI) based regimen in previously untreated adult patients. In a double-blind RCT comparing tenofovir with stavudine, each added to lamividine and efavirenz, there was no difference in efficacy between tenofovir and stavudine. In an open-label RCT comparing a regimen of zidovudine, lamivudine and efavirenz, against a combination of tenofovir, emtricitabine and efavirenz, the latter was associated with a superior virologic response (HIV-1 RNA levels <400 or <50 copies/mL), although it is not clear if this was due to the inclusion of tenofovir and/or emtricitabine in this regimen. In both RCTs, tenofovir was associated with fewer withdrawals due to adverse events.

2. In patients with virologic failure (>400 copies/mL), two RCTs demonstrated that adding tenofovir to an existing regimen suppressed viral load more than placebo. There is insufficient evidence that tenofovir is more effective than appropriate comparators in treatment experienced patients.

3. A potential therapeutic advantage for tenofovir is convenience of administration when it compliments a once-daily antiretroviral regimen.

4. Tenofovir costs $16.25 per day, which is considerably more costly than other currently available nucleoside analog reverse transcriptase inhibitors (NRTIs). The Committee felt that tenofovir was not cost-effective at this price in treatment naïve

patients and therefore should be reserved for patients who have experienced adverse events or virologic failure with other NRTIs.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.