

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

TENOFOVIR/EMTRICITABINE (Truvada™ - Gilead Sciences Canada, Inc.)

This recommendation is superseded by the CEDAC recommendation for this drug and indication dated December 17, 2008.

Description:

Truvada™ is a fixed dose combination of two nucleoside/nucleotide reverse transcriptase inhibitors that is approved for the treatment of HIV-1 infection in combination with other antiretroviral agents in patients 18 years of age and older.

Dosage Forms:

Tablet containing emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Truvada™ be listed as an alternative for the initial phase of treatment of adult patients with HIV infection who have experienced intolerance or adverse events with other nucleoside combinations including lamivudine in combination with zidovudine, abacavir, stavudine or didanosine and, who have not developed virologic failure or clinical progression on initial antiretroviral therapy.

Reasons for the Recommendation:

1. The Committee considered the data from one open label randomized controlled trial (RCT) of 48 weeks duration in treatment naïve patients that compared a regimen of zidovudine, lamivudine and efavirenz, against a combination of tenofovir, emtricitabine and efavirenz. The latter was associated with statistically significant improvements in virologic response (HIV-1 RNA levels <400 or <50 copies/mL). In part, this benefit may have resulted from the open-label design of the trial and the fact that more patients in the zidovudine/lamivudine arm discontinued therapy and were classified as treatment failures. There were no statistically significant differences between the two treatments in the occurrence of virologic failure or viral resistance.
2. There were fewer withdrawals due to adverse effects in the tenofovir/emtricitabine arm and this was primarily due to a lower incidence of anemia.
3. Truvada™ costs \$25.05 per day, which is more costly than other nucleoside combinations and combination products (eg. lamivudine/zidovudine costs \$19.51 per day). A

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pharmacoeconomic evaluation submitted by the manufacturer reported an incremental cost per quality adjusted life year (QALY) of approximately \$50,000 when compared to the use of zidovudine and lamivudine in treatment naïve patients. However, when the results are adjusted for patients who discontinue therapy due to reasons other than virologic failure, the incremental cost per QALY for Truvada™ compared to zidovudine/lamivudine is substantially higher

4. Given that there were no differences in true virologic failure, and given the substantially higher cost of this drug, the Committee felt that the most efficient use of this drug would be as an alternative agent for patients who were unable to tolerate the less expensive nucleoside combinations.

Of Note:

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