



FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

TENOFOVIR DISOPROXIL FUMARATE 300 mg tablet [Viread® – Gilead Sciences Canada Ltd]

Description:

Tenofovir disoproxil fumarate is a nucleotide analog indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in patients 18 years and older who have experienced virologic failure on other regimens. This drug has received a conditional marketing authorization from Health Canada under the Notice of Compliance with Conditions policy to reflect the promising nature of the clinical evidence for this indication and the need for confirmatory studies to verify the clinical benefit.

Recommendation:

The Canadian Expert Drug Advisory Committee recommends that tenofovir disoproxil fumarate not be listed.

Reasons for the Recommendation:

1. In patients with virologic failure (>400 copies/mL), the two randomized controlled trials demonstrated that adding tenofovir to an existing regimen suppressed viral load more than placebo. There was no statistically significant improvement in a non-weighted mean change from baseline in CD4+ cell counts at 24 weeks.
2. No randomized controlled trials are available to compare tenofovir with an active comparator in treatment experienced patients.
3. At \$16.25 per day, tenofovir is more costly than nucleoside analog reverse transcriptase inhibitors (NRTIs). The daily costs of NRTIs are: abacavir – \$12.50; stavudine – \$8.50; zidovudine – \$10.20; didanosine – \$9.94; lamivudine – \$8.80; and zalcitabine – \$6.45.
4. Because there is no evidence demonstrating that tenofovir has a therapeutic advantage over appropriate comparators in treatment experienced patients and because it is more costly than NRTIs, tenofovir is not recommended for listing.

Of Note:

1. The randomized controlled trials of tenofovir in antiretroviral treatment-experienced patients do not reflect the current clinical practice of changing the drug regimen (a class change rather than adding another drug to a failing regimen) for adults experiencing virologic failure.
2. There is some evidence that adding tenofovir in treatment experienced patients increases rates of hypophosphatemia, a laboratory abnormality associated with renal toxicity. This finding has also been observed in observational studies.
3. Tenofovir might be considered for coverage on an individual basis for patients who are intolerant or have proven resistant to other NRTIs. Genotypic analyses may help limit use to mutations that do not confer cross-resistance to tenofovir.

Common Drug Review