

Ontario Public Drug Programs

Drug Submission Status

Generic Name: emtricitabine/rilpivirine/tenofovir disoproxil fumarate

Brand Name: Complera

Strength: 200mg/25mg/300mg FC tablet

Manufacturer: Gilead Sciences Inc.

Indication: For use alone as a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naïve adults

Rapid Review: Not requested

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review (Initial Submission) | 08/03/2012 | 17/04/2012 | EO decision rendered | Listed on the Ontario Drug Benefit Formulary as a General Benefit |

Rapid Review:

Details of the Rapid Review process can be found at:

www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html

Review Status:

- Screening – Ministry is screening the manufacturer’s submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.
- Submission incomplete – Manufacturer did not meet the necessary requirements to allow review to proceed.
- Submission complete & under review – Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed – A recommendation was made by the CED.
- Executive Officer (EO) decision rendered.

Funding Status:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at: www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html

Updated: September 21, 2012