

Ontario Public Drug Programs Drug Submission Status

Generic Name: elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate

Brand Name: Stribild

Strength: 150mg/150mg/ 200mg/300mg tablet

Manufacturer: Gilead Sciences Inc.

Indication: As a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naïve adult patients aged 18 years and older

Rapid Review: Not Requested

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Status: |
|---------------------------------------|---------------------------|----------------------------------|----------------------|--|
| First Review: (Initial Submission) | 03/04/2013 | 09/05/2013 | EO decision rendered | Listed on the Ontario Drug Benefit Formulary as a General Benefit with Therapeutic Notes |

Rapid Review:

Details of the Rapid Review process can be found at:

[Rapid Review Process](#)

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.
- Ontario Steering Committee for Cancer Drugs (OSCCD) review completed-A recommendation was made by the OSCCD.
- 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:

[The CED recommendation and the EO decision](#)

Updated: November 30, 2015