Ontario

Ministry of Health

Drugs and Devices Division

Drug Submission Status

Generic Name: CABOTEGRAVIR AND CABOTEGRAVIR and RILPIVIRINE

Brand Name: Vocabria AND Cabenuva

Strength: 30 mg tablet, AND 200 mg/mL / 300 mg/mL (400 mg/2mL and 600 mg/2mL) Kit, IM, ER injectable suspension, 200 mg/mL / 300 mg/mL (600 mg/3mL and 900 mg/3mL) Kit, IM, ER injectable suspension

Manufacturer: Viiv Healthcare ULC.

Indication:

VOCABRIA (cabotegravir tablets) is indicated, in combination with EDURANT (rilpivirine tablets), as a complete regimen for short-term treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL) as:

- an oral lead-in to assess tolerability of cabotegravir prior to initiating CABENUVA
- oral bridging therapy for missed CABENUVA injections

CABENUVA (cabotegravir and rilpivirine extended release injectable suspensions) is indicated:

- as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in patients who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL).

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	26/03/2020	25/11/2020	Submission complete & under review	N/A

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

* The Committee to Evaluate Drugs (CED) is the Ministry's independent expert advisory committee on drug-related issues. The committee is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

** The Ontario Steering Committee for Cancer Drugs (OSCCD) was created to enhance and support the administration of Ontario's cancer drug programs. The committee advises the Ministry of Health and Long-Term Care's Ontario Public Drug Programs and Cancer Care Ontario's Provincial Drug Reimbursement Programs.

Updated: November 25, 2020