Ontario

Ministry of Health

Drugs and Devices Division

Generic Name: letermovir

Brand Name: Prevymis

Strength: 240 mg and 480 mg tablets, and Solution for injection, 20 mg/mL, 240 mg/vial and 480 mg/vial, intravenous

Manufacturer: Merck Canada Inc.

Indication: For the prophylaxis of cytomegalovirus (CMV) infection in adult patients who have received an allogeneic hematopoietic stem cell transplant (HSCT) according to clinical criteria.

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	26/01/2018	04/07/2018	EO decision rendered	Funding considered through the Exceptional Access Program (EAP)

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: January 22, 2020