

Ontario Public Drug Programs Drug Submission Status

Generic Name: empagliflozin & metformin HCl

Brand Name: Synjardy

Strength: 5 mg & 500 mg, 5 mg & 850 mg, 5 mg & 1000 mg, 12.5 mg & 500 mg, 12.5 mg & 850 mg and 12.5 mg & 1000 mg FC tablet

Manufacturer: Boehringer Ingelheim Canada Ltd.

Indication: As an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus inadequately controlled on:

- metformin;
- sulfonylurea in combination with metformin;
- pioglitazone in combination with metformin;
- insulin in combination with metformin;

Or in patients already being treated and achieving glycemic control with:

- metformin and empagliflozin as separate tablets;
- sulfonylurea in combination with metformin and empagliflozin as separate tablets;
- pioglitazone in combination with metformin and empagliflozin as separate tablets;
- insulin in combination with metformin and empagliflozin as separate tablets

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	20/09/2016	16/01/2017	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as General Benefit with Therapeutic Notes

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: October 24, 2018