

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Drug Submission Status

Generic Name: trastuzumab

Brand Name: KANJINTI

Strength: 150 mg intravenous, powder for solution, single dose vial

Manufacturer: Amgen Canada Inc.

Indication:

Early Breast Cancer (EBC)

KANJINTI (trastuzumab) is indicated for the treatment of patients with early stage breast cancer with ECOG 0 - 1 status, whose tumours overexpress HER2,

- following surgery and after chemotherapy
- following adjuvant chemotherapy consisting of doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel
- in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.

Metastatic Breast Cancer (MBC)

KANJINTI is indicated for the treatment of patients with MBC whose tumours overexpress HER2.

The benefits of treatment with KANJINTI in patients who do not overexpress HER2 (HER2 expression 0 as defined by a validated immunohistochemical [IHC] assay) or who exhibit lower level overexpression (HER2 overexpression 1+ as defined by a validated IHC assay, and the subgroup of patients with HER2 overexpression 2+ as defined by a validated IHC assay that corresponds to 1+ scoring by the investigative clinical trial assay), are unclear.

KANJINTI can be used in combination with pertuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Metastatic Gastric Cancer (MGC)

KANJINTI in combination with capecitabine or intravenous 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease.

KANJINTI should only be administered to patients with MGC whose tumours have HER2 overexpression as defined by IHC2+ confirmed by FISH+, or IHC 3+ as determined by an accurate and validated assay.

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	17/02/2020	06/12/2021	EO decision rendered	Funding considered through Cancer Care Ontario's New Drug Funding Program

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: March 24, 2022