

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Drug Submission Status

Generic Name: BEVACIZUMAB

Brand Name: Aybintio

Strength: 25 mg/mL (100mg/4 mL) and 25 mg/mL (400mg/16mL) single use vial

Manufacturer: Samsung Bioepis Co., Ltd.

Indications:

Metastatic Colorectal Cancer (mCRC)

AYBINTIO in combination with fluoropyrimidine-based chemotherapy is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum.

Locally Advanced, Metastatic or Recurrent Non-Small Cell Lung Cancer (NSCLC)

AYBINTIO, in combination with carboplatin/paclitaxel chemotherapy regimen, is indicated for treatment of patients with unresectable advanced, metastatic or recurrent non-squamous nonsmall cell lung cancer.

Platinum-Sensitive Recurrent Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer

AYBINTIO, in combination with carboplatin and gemcitabine is indicated for the treatment of patients with first recurrence platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer. These patients should not have received prior VEGF-targeted therapy including AYBINTIO.

Platinum-Resistant Recurrent Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer

AYBINTIO in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens. These patients should not have received prior VEGF-targeted therapy including AYBINTIO.

Malignant Glioma (WHO Grade IV) - Glioblastoma

AYBINTIO, in combination with lomustine, is indicated for the treatment of patients with glioblastoma after relapse or disease progression, following prior therapy.

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	03/02/2022	25/02/2022	Submission complete and 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: February 25, 2022