

Ontario Public Drug Programs Drug Submission Status

Generic Name: regorafenib

Brand Name: Stivarga

Strength: 40mg tablet

Manufacturer: Bayer Inc.

Indication: For the treatment of patients with ECOG status of ≤ 1 and with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-based chemotherapy, an oxaliplatin, irinotecan, an anti-VEGF therapy and, if KRAS wild type, an anti-EGFR therapy.

Rapid Review: Not Requested

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Status: |
|---------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review: (Initial Submission) | 10/04/2015 | 27/07/2015 | EO decision rendered | Funding not considered through Cancer Care Ontario's New Drug Funding Program |

Rapid Review:

Details of the Rapid Review process can be found at:

[Rapid Review Process](#)

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](#)

Updated: November 30, 2015