

Ontario Public Drug Programs

Drug Submission Status

Generic Name: regorafenib

Brand Name: Stivarga

Strength: 40mg FC tablet

Manufacturer: Bayer Inc.

Indication: Treatment of adult patients with metastatic and/or unresectable gastrointestinal stromal tumors who have had disease progression on or intolerance to imatinib mesylate and sunitinib malate treatment

Rapid Review: Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	30/01/2014	07/04/2014	EO decision rendered	Funding considered through the Exceptional Access Program (EAP)

Rapid Review:

Details of the Rapid Review process can be found at:

www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/rapid_review_process.aspx

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.
- 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:

www.health.gov.on.ca/en/pro/programs/drugs/ced_rec_table.aspx

Updated: September 29, 2014