

Ontario Public Drug Programs

Drug Submission Status

Generic Name: belimumab

Brand Name: Benlysta

Strength: 120mg/vial and 400mg/vial lyophilized powder for IV infusion

Manufacturer: GlaxoSmithKline Inc.

Indication: In addition to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE)

Rapid Review: Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	30/11/2011	19/12/2011	EO decision rendered	Funding not considered through Ontario Public Drug Programs
Reconsideration (Resubmission #1)	02/11/2012	16/11/2012	EO decision rendered	Funding not considered through Ontario Public Drug Programs

Rapid Review:

Details of the Rapid Review process can be found at:

www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html

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/english/providers/program/drugs/ced_rec_table.html

Updated: May 27, 2013