

Ontario Public Drug Programs

Drug Submission Status

Generic Name: aclidinium bromide

Brand Name: Tudorza Genuair

Strength: 400mcg/actuation

Manufacturer: Almirall, S.A.

Indication: Long-term maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema

Rapid Review: Requested and Rejected

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	24/09/2013	08/10/2013	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as a General Benefit

Rapid Review:

Details of the Rapid Review process can be found at:

http://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.
- 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:

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

Updated: August 21, 2014