

Ontario Public Drug Programs Drug Submission Status

Generic Name: **tolvaptan**

Brand Name: **Samsca**

Strength: 15mg, 30mg and 60mg tablet

Manufacturer: Otsuka Pharmaceutical Company, Ltd.

Indication: For the treatment of clinically important, non-hypovolemic hyponatremia

Rapid Review: Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	05/11/2012	25/03/2013	EO decision rendered	Funding not considered through Ontario Public Drug Programs
Second Review (Resubmission #1)	27/06/2013	16/07/2013	EO decision rendered	Funding not considered through Ontario Public Drug Programs

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.
- 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: January 28, 2014