

Ontario Public Drug Programs

Drug Submission Status

Generic Name: azilsartan medoxomil/chlorthalidone

Brand Name: Edarbyclor

Strength: 40mg/12.5mg, 80mg/12.5mg and 40mg/25mg tablet

Manufacturer: Takeda Canada Inc.

Indication: As initial therapy in patients with severe essential hypertension for whom the benefit of a prompt blood pressure reduction exceeds the risk of initiating combination therapy

Rapid Review: Not requested

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review (Initial Submission) | 28/10/2013 | 14/01/2014 | 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: March 25, 2014