

Ontario Public Drug Programs Drug Submission Status

Generic Name: sapropterin dihydrochloride

Brand Name: Kuvan

Strength: 100mg tablet

Manufacturer: BioMarin Pharmaceutical Inc.

Indication: Hyperphenylalaninemia due to BH4-responsive Phenylketonuria (PKU), in combination with dietary restrictions

Rapid Review: Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	20/07/2010	20/09/2010	EO decision rendered	Funding not available through Ontario Public Drug Programs
Second Review (Resubmission #1)	10/05/2011	24/06/2011	EO decision rendered	Funding available through the Exceptional Access Program (EAP)

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: April 23, 2013