Ministry of Health and Long Term Care

Ontario Public Drug Programs
Drug Submission Status

Generic Name: **adalimumab**

Brand Name: **Humira**

Strength: 40mg/0.8mL vial for pediatric use, 40mg/0.8mL pre-filled syringe and 40mg/0.8mL pre-filled pen

Manufacturer: AbbVie Corporation

Indication: In combination with methotrexate, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 to 17 years of age who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs)

Rapid Review: Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	05/06/2013	16/07/2013	EO decision rendered	Funding considered through the Exception Access Program (EAP)

Rapid Review:

Details of the Rapid Review process can be found at:

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.

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- 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/en/pro/programs/drugs/ced_rec_table.aspx

Updated: February 20, 2014