

Ministry of Health

# Drugs and Devices Division

## Drug Submission Status

Generic Name: adalimumab

Brand Name: HYRIMOZ

Strength: 40mg/0.8mL and 20mg/0.4mL SC sterile solution

Manufacturer: Sandoz Canada Inc.

Expansion of the indications:

### Pediatric Crohn's Disease

- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 13 to 17 years of age weighing  $\geq$  40 kg with severely active Crohn's disease and/or who have had an inadequate response or were intolerant to conventional therapy (a corticosteroid and/or aminosalicylate and/or an immunosuppressant) and/or a tumour necrosis factor alpha antagonist.

### Hidradenitis Suppurativa

- Treatment of active moderate to severe hidradenitis suppurativa in adult and adolescent patients (12 to 17 years of age weighing  $\geq$  30 kg) who have not responded to conventional therapy (including systemic antibiotics).

### Pediatric Uveitis

- Treatment of chronic non-infectious anterior uveitis in pediatric patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	29/07/2021	10/01/2021	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as Limited Use Benefit

## 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:

[The CED recommendation and the EO decision](#)

\* [The Committee to Evaluate Drugs \(CED\)](#) is the Ministry's independent expert advisory committee on drug-related issues. The committee is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

\*\* [The Ontario Steering Committee for Cancer Drugs \(OSCCD\)](#) was created to enhance and support the administration of Ontario's cancer drug programs. The committee advises the Ministry of Health and Long-Term Care's Ontario Public Drug Programs and Cancer Care Ontario's Provincial Drug Reimbursement Programs.