Ontario

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Drug Submission Status

Generic Name: ADALIMUMAB

Brand Name: Yuflyma

Strength: 100 mg/mL SC solution, prefilled syringe and pre-filled pen (auto-injector)

Manufacturer: Celltrion Healthcare Co. Ltd.,

Indications:

Yuflyma (adalimumab injection in pre-filled syringe or pre-filled pen) is indicated for:

Rheumatoid Arthritis

- Reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Yuflyma can be used alone or in combination with methotrexate (MTX) or other disease-modifying anti-rheumatic drugs (DMARDs).

Polyarticular Juvenile Idiopathic Arthritis

- In combination with methotrexate, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients, 2 years of age and older who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Yuflyma can be used as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is not appropriate. Adalimumab injection has not been studied in pediatric patients with polyarticular juvenile idiopathic arthritis aged less than 2 years.

Psoriatic Arthritis

- Reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis patients. Yuflyma can be used in combination with methotrexate (MTX) in patients who do not respond adequately to methotrexate alone.

Ankylosing Spondylitis

- Reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Adult Crohn’s Disease

- Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. Yuflyma is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

Adult Ulcerative Colitis

- Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy including corticosteroids and/or azathioprine or 6-mercaptopurine (6-MP) or who are intolerant to such therapies. The efficacy of adalimumab injection in patients who have lost response to or were intolerant to TNF blockers has not been established.

Hidradenitis Suppurativa

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

Plaque Psoriasis

- Treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, Yuflyma should be used after phototherapy has been shown to be ineffective or inappropriate.

Adult Uveitis

- Treatment of non-infectious uveitis (intermediate, posterior and panuveitis) in adult patients with inadequate response to corticosteroids or as corticosteroid sparing treatment in corticosteroid-dependent patients.

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)	04/10/2021	03/02/2022	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.

Updated: May 31, 2022