Notice from the Executive Officer:

Funding of ustekinumab under the Ontario Drug Benefit Program

April 30, 2024

Jamteki™ (ustekinumab injection) and Wezlana™ (ustekinumab injection) are approved by Health Canada as biosimilar versions of Stelara® (ustekinumab injection) and Wezlana™ I.V. (ustekinumab for injection) is approved by Health Canada as a biosimilar version of Stelara® I.V. (ustekinumab for injection). The funding of these products is being aligned with the funding of other biosimilars under the Ontario Drug Benefit (ODB) Program's new start policy, which requires recipients initiating treatment on a biologic drug to start on a biosimilar. Biosimilars have similar efficacy and safety as originator biologics and present an opportunity to achieve better value for money for biologic drugs that will help to support the long-term sustainability and accessibility of Ontario's public drug programs.

As of the effective date of the April 2024 update to the ODB Formulary/Comparative Drug Index (Formulary), changes to the funding of ustekinumab under the ODB Program will be as follows:

Jamteki™ (ustekinumab injection) will be listed on the Formulary as a Limited Use (LU) benefit for the treatment of the following indications in accordance with the criteria set out on the Formulary:

- Plaque Psoriasis
- Psoriatic Arthritis

Wezlana™ (ustekinumab injection) and Wezlana™ I.V. (ustekinumab for injection) will be listed on the Formulary as LU benefits for the treatment of the following indications in accordance with the criteria set out on the Formulary:

- Plaque Psoriasis (Wezlana™)
- Psoriatic Arthritis (Wezlana™)
- Ulcerative Colitis (Wezlana™ and Wezlana™ I.V.)
- Crohn's Disease (Wezlana™ and Wezlana™ I.V.)

Prescribers should be informed and stay current with official indications for drug products in accordance with Health Canada's approved product monograph.

Details of the LU criteria will also be posted in the April 2024 Formulary update, which can be found on the ministry's website at:

Formulary / Comparative Drug Index (CDI) Edition 43 | Ontario Drug Benefit (ODB)
Formulary / Comparative Drug Index (CDI) and Monthly Formulary Updates | ontario.ca

Effective with the April 2024 Formulary update, Stelara® (ustekinumab injection) will be funded in accordance with the following LU criteria:

- LU Code: 419

  For the treatment of severe* plaque psoriasis in patients 18 years of age or older who have experienced failure, intolerance, or have a contraindication to adequate trials of several standard therapies**, but only for patients established on Stelara (ustekinumab) therapy prior to April 30, 2024.

  *Definition of severe plaque psoriasis:

  Body Surface Area (BSA) involvement of at least 10%, or involvement of the face, hands, feet or genital regions, AND

  Psoriasis Area and Severity Index (PASI) score of at least 10 (not required if there is involvement of the face, hands, feet or genital regions), AND

  Dermatology Life Quality Index (DLQI) score of at least 10

  **Definition of failure, intolerance or contraindication to adequate trials of standard therapies:
  - 6 month trial of at least 3 topical agents including vitamin D analogues and steroids; AND
  - 12 week trial of phototherapy (unless not accessible); AND
  - 6 month trial of at least 2 systemic, oral agents used alone or in combination:
    - Methotrexate 15-30mg per week
    - Acitretin (could have been used with phototherapy)
    - Cyclosporine

Maintenance/Renewal:

After 3 months of therapy, patients who respond to therapy should have:
- At least a 50% reduction in PASI, AND
- at least a 50% reduction in BSA involvement, AND
- at least a 5 point reduction in DLQI score

Approvals will only allow for standard dosing for Stelara® 45 mg to be administered at weeks 0, 4 and every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight of over 100 kg. In patients weighing over 100 kg, both the 45 mg and 90 mg doses were shown to be efficacious. However, 90 mg was efficacious in a higher percentage of these patients. If the patient has not responded after 12 weeks of treatment, the physician should consider switching to an alternative biologic agent.

LU authorization: 1 year

Details of the changes to the funding of Stelara® (ustekinumab injection) will also be posted in the April 2024 Formulary update, which can be found on the ministry's website at:

Formulary / Comparative Drug Index (CDI) Edition 43 | Ontario Drug Benefit (ODB)
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To further inform healthcare providers and patients, we have also included a Frequently Asked Questions (FAQs) document for reference purposes.

Additional information:

For pharmacies:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other health care providers and the public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.