Frequently Asked Questions: Funding of Omlyclo™ (omalizumab) under the Ontario Drug Benefit Program

1. **What is the difference between Xolair® (omalizumab) and Omlyclo™ (omalizumab)?**

   Xolair® and Omlyclo™ are both omalizumab products. Omalizumab works by binding to a protein in your body called immunoglobulin E (IgE), which prevents it from triggering inflammation and the release of other substances that can cause some allergic conditions. Omlyclo™ has been approved by Health Canada as a biosimilar version of Xolair®. Xolair® and Omlyclo™ are manufactured and marketed by different companies.

   Biosimilars, also referred to as subsequent entry biologics or follow-on biologics, are biologics that are highly similar to an originator biologic. Biosimilars may enter the market after the patents and data protection for the originator biologic have expired. Health Canada conducts rigorous testing to ensure that biosimilars have a highly similar structure, are equally as safe, and have the same therapeutic effect as an originator biologic. Ontario is confident in the safety and efficacy of biosimilars based on our experience over the past 7 years, as well as the experiences of many places around the world. The use of biosimilars medicines has been well-established in Europe over the past 20 years with more than 50 approved biosimilar medicines. Please refer to Health Canada's fact sheet on biosimilars for more information:

   Biosimilar biologic drugs in Canada: Fact Sheet – Canada.ca

2. **What is the funding status of Omlyclo™ (omalizumab)?**

   As of the effective date of the August 2025 update to the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary), Omlyclo™ will be listed as a Limited Use (LU) benefit for the treatment of asthma in patients 12 years and older and for the treatment of chronic idiopathic urticaria (CIU).

3. **What is the rationale for funding biosimilar omalizumab products?**

   Omlyclo™ was approved by Health Canada as a biosimilar version of the originator biologic Xolair®. Biosimilars are not identical to originator biologics. However, Health Canada conducts rigorous testing to ensure that biosimilars have a highly similar structure, are equally as safe, and have the same therapeutic effect as an originator biologic. Biosimilars also present an opportunity to achieve better value for money for

biologic drugs that will help to support the long-term sustainability of the Ontario Public Drug Programs.

4. **What are the Limited Use criteria for Omlyclo™ (omalizumab)?**

As of the effective date of the August 2025 update to the Formulary, the LU Codes and the corresponding Clinical Criteria will be as set out below.

Please refer to the e-Formulary for the most up-to-date information at:

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

Applicable LU Codes by Product:

You may also refer to the Formulary for details regarding the LU criteria.

Omlyclo™ - 726, 727, 728

Asthma (LU Code 726)

For the treatment of adults with severe uncontrolled asthma who meet the following criteria:

1. Patient is 12 years of age or older; AND

2. Diagnosed with severe asthma that is not controlled despite treatment with a high-dose inhaled corticosteroid, defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily*, in addition to a long-acting inhaled beta 2-agonist;

   **Note: Check dose comparison tables for high-dose inhaled corticosteroid equivalency comparisons for various inhaled corticosteroids.*

   Omalizumab will not be funded as a first line treatment for uncontrolled asthma and patients must try other conventional therapies for asthma that include a corticosteroid inhaler before being prescribed a biologic treatment.

   Proper inhaler technique (with a spacer if required/appropriate) and adherence to prescribed treatment should be confirmed. Patients may also be on other concomitant therapies.

AND

3. In the past 12 months, inadequately controlled asthma has resulted in at least one of the following:
    - Hospitalization for asthma
    - Two or more urgent care visits to a physician/nurse practitioner or emergency department for asthma exacerbations.
    - Use of two or more courses of high-dose oral corticosteroids (e.g. prednisone) or increase in the dose of chronic prednisone treatment to manage asthma exacerbations; AND

4. Patient has demonstrated a positive skin test or in vitro reactivity to a perennial aeroallergen (e.g. positive allergy testing by skin prick test or IgE RAST);

    Note: Removal or reduction of allergic and environmental triggers of asthma to the fullest extent possible should be attempted.

    AND

5. Has a baseline Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL inclusive prior to start of omalizumab;

    Note: Serum total IgE levels increase following administration of omalizumab due to formation of omalizumab:IgE complexes. Elevated serum total IgE levels may persist for up to 1 year following discontinuation of omalizumab. Serum total IgE levels obtained less than 1 year following discontinuation may not reflect steady state free IgE levels and should not be used to reassess the dosing regimen in asthma patients.

    AND

6. Has an actual body weight between 20 to 150 kg inclusive (Refer to Omlyclo product monograph for dosing in individuals 12 years of age and older by IgE level and weight); AND

7. Prescribed by or in consultation with a specialist in respirology or allergy/clinical immunology.

8. Omalizumab is not being used in combination with another biologic drug used for the treatment of asthma.

Renewal of omalizumab is provided for patients who have responded to treatment by improving asthma control compared to baseline before omalizumab was initiated. Depending on the baseline parameters, this may be evidenced by clinical improvements of one or more of the following;

- Decreased utilization of rescue medications [as determined by reduction in nighttime awakenings or reduction in average number of puffs/day of short-acting beta-agonists (SABA)]; OR
- Decreased frequency of asthma exacerbations (as determined by reduction in exacerbations that require hospitalization and/or urgent care visits to a hospital emergency department or physician/nurse practitioner clinic.); OR
- Reduction in asthma exacerbations that require adding or increasing doses of corticosteroids; OR
- Increase in percent predicted FEV-1 from pre-treatment baselines.

Recommended dose: Omalizumab 75 to 375 mg administered SC every 2 to 4 weeks.

LU Authorization Period: 1 Year

Chronic Idiopathic Urticaria (CIU) – Initial Criteria (LU Code 727)

For the treatment of moderate to severe chronic idiopathic urticaria (CIU) in patients who meet all the following criteria:

1. Patient is 12 years of age or older; AND
2. Diagnosed with moderate to severe CIU [Weekly urticaria activity score (UAS7) of 16 or greater]; AND
3. Remains symptomatic despite management with optimal doses of standard oral therapies for CIU (e.g. histamine H1 receptor antagonists [e.g. cetirizine, desloratadine, loratadine, fexofenadine]); AND
4. Omalizumab is not being used in combination with another biologic drug used for the treatment of CIU; AND
5. Prescribed by a specialist (e.g. allergist, immunologist, dermatologist, etc.).

Recommended dose: 300 mg SC every 4 weeks

Note the following guidance:

Severe urticaria - UAS7 of 28 to 42
Moderate urticaria - UAS7 of 16 to 27
Mild urticaria – UAS7 of 7 to 15
Well-controlled urticaria – UAS7 of 1 to 6
Urticaria-free – UAS7 of 0 (zero)

Patients who achieve symptom control for at least 12 weeks while on therapy should have a trial of stopping treatment.

LU authorization period: 6 months

Chronic idiopathic urticaria (CIU) – Renewal Criteria (LU Code 728)

All patients new to the Ontario Drug Benefit (ODB) Program should meet the RFU Code for initiation.

Renewal of funding of omalizumab will be provided for the treatment of chronic idiopathic urticaria (CIU) in patients who meet the following criteria:

1. Patient is 12 years of age or older; AND

2. Omalizumab is prescribed by a specialist (e.g. allergist, immunologist, dermatologist, etc.); AND

3. Omalizumab is not being used in combination with another biologic drug used for the treatment of CIU; AND

4. Patient's response to omalizumab previously funded under the ODB program meets at least ONE of the following criteria:

   i. Has achieved symptom control on omalizumab and tried stopping therapy but experienced symptom relapse of their urticaria while off treatment.

   ii. Has experienced a partial improvement in response with omalizumab treatment by demonstrating a reduction of the weekly urticaria activity score (UAS7) by 9.5 points or more but patient has not been able to achieve complete symptom control for more than 12 consecutive weeks.

   iii. Has responded to omalizumab in the past but has been rediagnosed with moderate to severe CIU with UAS7 of 16 or higher.

Notes:

1. Patients who achieve complete symptom control for at least 12 weeks while on therapy should have a trial of stopping treatment to establish whether the condition has gone into spontaneous remission.

2. Patients must demonstrate a minimum response to omalizumab for CIU by reducing the UAS7 score by at least 9.5 points from baseline before initiation of omalizumab for CIU.

Note the following guidance:

Urticaria-free – UAS7 of 0 (zero)
Well-controlled urticaria – UAS7 of 1 to 6
Mild urticaria – UAS7 of 7 to 15
Moderate urticaria - UAS7 of 16 to 27
Severe urticaria - UAS7 of 28 to 42

Recommended dose: 300 mg every 4 weeks

LU Authorization period: 1 year

5. Will patients whose treatment with Xolair® (omalizumab) is already funded by the ministry be required to switch to a biosimilar omalizumab product?

Xolair® is currently funded under the Exceptional Access Program (EAP) for the treatment of asthma in patients 12 and older and chronic idiopathic urticaria (CIU). At this time, patients whose omalizumab treatment with Xolair® is already funded by the ministry via the EAP can continue to receive funding for Xolair®.

Omalizumab is subject to the ministry's biosimilar policy and the transition period for Xolair® will be announced and communicated at a later time.

During the transition period, recipients who are on Xolair® will be required to transition to an ODB funded biosimilar version of omalizumab in order to maintain publicly funded coverage for omalizumab.

6. **Will the ministry consider new requests for Xolair® (omalizumab) reimbursement under the Exceptional Access Program (EAP)?**

   The ministry will not accept new EAP requests for Xolair® for patients who are treatment naïve to Xolair®, effective August 29, 2025, with the exception of a medically necessary exemption.

   In limited circumstances, the Exceptional Access Program (EAP) will consider funding Xolair® if the patient has a medically necessary exemption that requires them to use Xolair® instead of a biosimilar version.

7. **Will the ministry consider EAP requests for Xolair® (omalizumab) for patients who do not respond to Omlyclo™ (omalizumab)?**

   The EAP will ONLY consider funding of Xolair® for patients who meet a medical exemption. The medical exemption generally requires the patient to have tried at least two biosimilar versions (if applicable) and experienced adverse effects, intolerances, and/or lack of efficacy documented by their prescriber on the Health Canada side effect form for each biosimilar used. The request for a medical exemption with the completed Health Canada side effect forms may be submitted to the EAP for case-by-case review.

8. **Will the ministry consider EAP requests for the omalizumab biosimilar Omlyclo™ in patients for asthma and CIU who do not meet the limited use criteria on the ODB Formulary?**

   The EAP may consider requests for funding of biosimilar omalizumab listed on the ODB Formulary for patients who do not meet the LU criteria on the ODB Formulary on a case-by-case basis. It should be noted that EAP does not consider funding of all indications of omalizumab which have received Health Canada notice of compliance as the established requirements for consideration of provincial funding have not been completed by the manufacturers at this time.

9. **How should pharmacies submit claims for Omlyclo™ (omalizumab)?**

   Pharmacies should submit claims using the drug identification number (DIN) of the respective omalizumab product and the appropriate LU/Reason for Use (RFU) code.

   Omlyclo™ is an omalizumab product approved by Health Canada as a biosimilar version of Xolair®. However, these products are not “interchangeable” – i.e., pharmacists will require a prescription from the prescriber specific to the brand of omalizumab that they are dispensing with the relevant LU/RFU code provided by the prescriber.

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.