Frequently Asked Questions: Funding of Tyenne® (tocilizumab) under the Ontario Drug Benefit Program

1. **What is the difference between Actemra® (tocilizumab) and Tyenne® (tocilizumab)?**

   Actemra® and Tyenne® are both tocilizumab products. Tocilizumab belongs to a class of medications called Interleukin-6 (IL-6) blockers. Tyenne® has been approved by Health Canada as a biosimilar version of Actemra. Actemra® and Tyenne® are manufactured and marketed by different companies.

2. **What is the funding status of Tyenne® (tocilizumab)?**

   As of the effective date of the May 2025 update to the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary), Tyenne® will be listed as a Limited Use (LU) benefit for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and giant cell arteritis (GCA).

3. **What are the Limited Use criteria for Tyenne® (tocilizumab)?**

   As of the effective date of the May 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.

   Tyenne® - 697, 698, 720, 721

   A. Rheumatoid Arthritis (LU Code 697)

   For the treatment of rheumatoid arthritis (RA) in patients who have severe active disease (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or, anti-CCP positive, and/or radiographic evidence of rheumatoid arthritis) and have experienced failure, intolerance, or have a contraindication to adequate trials of disease-modifying anti-rheumatic drugs (DMARDs) treatment regimens, such as one of the following combinations of treatments:

A. i) Methotrexate (20mg/week) for at least 3 months, AND

ii) leflunomide (20mg/day) for at least 3 months, in addition to

iii) an adequate trial of at least one combination of DMARDs for 3 months; OR

B. i) Methotrexate (20mg/week) for at least 3 months, AND

ii) leflunomide in combination with methotrexate for at least 3 months; OR

C. i) Methotrexate (20mg/week), sulfasalazine (2g/day) and hydroxychloroquine (400mg/day) for at least 3 months. (Hydroxychloroquine is based by weight up to 400mg per day.); AND

Tocilizumab is not being used in combination with another biologic drug used for the treatment of RA; AND

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

Maintenance/Renewal:

After 12 months of treatment, ongoing maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints compared to baseline prior to the use of tocilizumab.

For second and subsequent renewals (i.e., beyond 2 years of ongoing use of tocilizumab) the patient must demonstrate objective evidence of preservation of treatment effect.

For renewal of funding, tocilizumab must not be used in combination with another biologic for the treatment of RA and must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

Recommended Dose:

The recommended intravenous dose of tocilizumab for adult patients is 4 mg/kg followed by an increase to 8 mg/kg (up to 800mg per dose as per product monograph) based on clinical response, given once every 4 weeks.

The recommended subcutaneous dose of tocilizumab for adult patients weighing less than 100 kg is a starting dose of 162 sc mg every other week, followed by an increase to every week based on clinical response; AND

For patients weighing 100 kg or more, a dosage of 162 mg sc every week is recommended.

LU Authorization Period: 1 Year

B. Polyarticular Juvenile Idiopathic Arthritis (LU Code 698)

For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) in patients who have active disease (greater than or equal to 3 swollen joints and greater than or equal to 5 active joints) despite a trial of optimal doses of subcutaneously administered methotrexate (i.e. 15 mg/m2 per week) for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication must be documented.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

Tocilizumab is not being used in combination with another biologic drug used for the treatment of pJIA.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints compared to baseline prior to the start of tocilizumab therapy.

For second and subsequent renewals (i.e., beyond 2 years of ongoing use of tocilizumab) the patient must demonstrate objective evidence of preservation of treatment effect.

For renewal of funding, tocilizumab must not be used in combination with another biologic for the treatment of pJIA and must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

Recommended Dose:

The recommended intravenous (IV) dose of tocilizumab for patients 2 years of age and older:

- 10 mg/kg IV every 4 weeks for patients weighing less than 30 kg
- 8 mg/kg IV every 4 weeks for patients weighing 30 kg or greater (up to 800mg per dose as per product monograph)

The recommended subcutaneous (sc) dose of tocilizumab for patients 2 years of age and older:

- 162 mg sc once every 3 weeks for patients weighing less than 30kg.
- 162 mg sc once every 2 weeks for patients weighing 30 kg or greater.

LU Authorization Period: 1 Year

C. Systemic Juvenile Idiopathic Arthritis (LU Code 720)

For the treatment of systemic juvenile idiopathic arthritis (sJIA) in patients who meet all the following:

1. Patient is at least 2 years of age; AND
2. Diagnosed with sJIA with fever (temperature greater than 38 degrees Celsius) for at least two weeks; AND
3. Patient has at least one of the following:
    - rash of systemic JIA; OR
    - serositis (e.g. pericarditis, pleuritis, or peritonitis); OR
    - lymphadenopathy (e.g. cervical, axillary, inguinal); OR
    - hepatomegaly; OR
    - splenomegaly
4. Other potential etiologies such as malignancies, serious clinical infections, other inflammatory or connective tissue diseases, have been ruled out by the prescriber; AND
5. Patient was less than 16 years of age at the onset of sJIA; AND
6. Systemic glucocorticoids cannot be used for one or more of the following reasons:
    - The patient is unresponsive and/or refractory to systemic glucocorticoids; OR
    - The patient is glucocorticoid dependent (i.e., the patient has experienced a systemic reaction such as fever, rash of sJIA, serositis, lymphadenopathy, hepatomegaly or splenomegaly while on tapering doses of systemic glucocorticoids); OR

- The patient has experienced an adverse drug reaction to a systemic glucocorticoid; OR

- The use of systemic glucocorticoids is contraindicated; AND

7. Tocilizumab is not being used in combination with another biologic drug used for the treatment of sJIA; AND

8. Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

Maintenance/Renewals:

Renewal will be considered for patients who have at least a 50% reduction in glucocorticoid dose (unless contraindicated, not tolerated, unresponsive or refractory at the time of initial request) and no evidence of active systemic disease (e.g., fever, rash of sJIA, serositis, lymphadenopathy, hepatomegaly, or splenomegaly).

For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

For renewal of funding, tocilizumab must not be used in combination with another biologic for the treatment of sJIA and must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

Recommended Dose:

The recommended intravenous (IV) dose of tocilizumab for patients 2 years of age and older:

- 12 mg/kg IV every 2 weeks for patients less than 30 kg

- 8 mg/kg IV every 2 weeks for patients weighing 30 kg or more (up to 800mg per dose as per product monograph).

The recommended subcutaneous (sc) dose of tocilizumab for patients 2 years of age and older:

- 162 mg sc once every 2 weeks for patients less than 30kg.

- 162 mg sc once every week for patients weighing 30kg or more

LU Authorization Period: 1 Year

D. Giant Cell Arteritis (LU Code 721)

For the treatment of giant cell arteritis (GCA) in symptomatic adult patients who meet the following:

1. A confirmed diagnosis of GCA by temporal artery biopsy and/or imaging tests (i.e., ultrasonography, magnetic resonance angiography, computed tomography angiography or positron emission scanning); AND

2. Tocilizumab is initiated as combination therapy with 20 mg to 60 mg of prednisone (or an equivalent glucocorticoid) with subsequent glucocorticoid tapering as symptoms stabilize; AND

3. Therapy must be prescribed by a rheumatologist or a prescriber with expertise in the diagnosis and management of GCA.; AND

4. The patient is using tocilizumab for up to 52 weeks.

Note: Patients with other sight-threatening ocular diseases must have their prescribers apply for case-by-case funding consideration through the ministry's Compassionate Review Policy.

Limited Renewal:

Renewal after an initial treatment period of 52 weeks can occur in limited circumstances when directed by a prescriber based on the patient's clinical remission status, disease activity and relevant bloodwork, imaging results, severity of disease manifestations, and risk of relapse.

Recommended Dose:

The recommended dose of tocilizumab for adult patients is 162 mg subcutaneously once every week in combination with a tapering dose of glucocorticoids.

A dose of 162 mg subcutaneously once every other week, in combination with a tapering dose of glucocorticoids, may be considered based on clinical considerations.

LU Authorization Period: 1 Year

4. What is the rationale for funding biosimilar tocilizumab products?

Tyenne® was approved by Health Canada as a biosimilar version of the originator biologic Actemra®. 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.

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

   Actemra® is currently funded under the Exceptional Access Program (EAP) for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and giant cell arteritis (GCA). At this time, patients whose tocilizumab treatment with Actemra® is already funded by the ministry via the EAP can continue to receive funding for Actemra®

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

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

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

   The ministry will not accept new EAP requests for Actemra® for patients who are treatment naïve to Actemra®, effective May 30, 2025, with the exception of a medically necessary exemption.

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

7. **Will the ministry consider EAP requests for Actemra® (tocilizumab) for patients who do not respond to Tyenne® (tocilizumab)?**

   The EAP will ONLY consider funding of Actemra® 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 tocilizumab biosimilars Tyenne® in patients who do not meet the limited use criteria on the ODB Formulary?**

   The EAP may consider requests for funding of biosimilar tocilizumab listed on the ODB Formulary for patients who do not meet the LU criteria on the ODB Formulary on a case-by-case basis.

9. **How should pharmacies submit claims for Tyenne® (tocilizumab)?**

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

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

10. **What are biosimilars?**

    Biosimilars, also referred to as subsequent entry biologics or follow-on biologics, are biologics that are highly similar to an originator biologic. Biosimilar may enter the market after the patents and data protection for the originator biologic 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

    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.