Ministry of Health
Drugs and Devices Division

Truxima (rituximab) Frequently Asked Questions

1. What is the funding status of Truxima (rituximab)?

Effective **March 31, 2020**, Truxima (rituximab) will be listed on the ODB Formulary/Comparative Drug Index (Formulary) as a Limited Use (LU) benefit for eligible ODB recipients for the treatment of Rheumatoid Arthritis (RA).

Effective **March 16, 2020**, Truxima became funded for specific oncology indications through the Ministry's New Drug Funding Program (NDFP) overseen by Ontario Health (Cancer Care Ontario). The funding criteria for Truxima for oncology indications can be found on Cancer Care Ontario's website at

https://www.cancercareontario.ca/en

2. What are the Limited Use Criteria for Truxima for RA?

As of the March 2020 formulary effective date, the Reason for Use (RFU) Code and its associated reimbursement criteria for Truxima for RAwill be as set out below. Please refer to the e-Formulary for the most up-to-date information.

A. Rheumatoid Arthritis – Initiation (RFU Code 575)

For the treatment of adults with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints, and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria:

1. Patient has experienced failure to respond, documented intolerance, or contraindication to optimal use of one of the following disease modifying, anti-rheumatic (DMARD) regimens:

    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

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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.)

2. Patient has experienced failure to respond, documented intolerance, or contraindication to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, golimumab, certolizumab pegol).

3. Patient is not using rituximab in a maintenance setting.

4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab.

5. Rituximab is not used in combination with another biologic to treat the patient's RA.

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

One course of treatment is 1000 mg followed two weeks later by the second 1000 mg dose

LU Authorization Period: 3 months

B. Rheumatoid Arthritis – Re-treatment (RFU Code 576)

For the re-treatment of patients with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints, and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria;

1. Patient has met the initiation criteria for rituximab in accordance with RFU 575;

2. Patient has experienced loss of effect after having responded to the prior treatment course of rituximab (Response is defined as a 20% reduction in the swollen joint count compared to the joint count prior to the first, pre-treatment course evaluated at 3 to 4 months following the administered course AND improvement in 2 swollen joints); AND

3. Patient is not using rituximab in a maintenance setting; AND

4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab; AND

5. Rituximab is not used in combination with another biologic to treat the patient's RA.

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

One course of re-treatment is 1000 mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

3. What is difference between Truxima and Rituxan?

Truxima is a rituximab biologic product that has been approved by Health Canada as a biosimilar to Rituxan, the originator product. Truxima and Rituxan are manufactured and marketed by different companies. Truxima has Health Canada approval for use in the treatment of Rheumatoid Arthritis (RA), Non-Hodgkin's Lymphoma (NHL), and Chronic Lymphocytic Leukemia (CLL).

Please refer to the product monograph for more information on Truxima. The Health Canada website provides further details on biosimilars.

4. Are patients with an existing Exceptional Access Program (EAP) approval for Rituxan required to switch to Truxima?

No. Patients who have an existing EAP approval for Rituxan can continue to receive Rituxan.

Truxima for the treatment of patients with severe RA will be made available on the Ontario Drug benefit formulary as Limited Use benefit.

Prescriptions for Truxima for the treatment of RA meeting the LU criteria do not require an EAP application. After reviewing the criteria for funding, prescribers can write the appropriate RFU code on the prescription to be provided to the dispensing pharmacy.

5. Will the ministry consider new requests for Rituxan (rituximab) reimbursement under the EAP, for the treatment of RA?

Similar to other publicly funded biosimilars, the ministry will not accept new requests for Rituxan for the treatment of RA in patients who are treatment-naïve to Rituxan, effective **March 31, 2020**.

The EAP will continue to consider requests for Rituxan for other indications.

6. Will the ministry consider requests for Rituxan reimbursement under the EAP for patients who do not respond to, or are intolerant to Truxima?

The ministry will not consider requests for Rituxan for treatment-naïve patients who do not respond to Truxima, or are intolerant to Truxima under any program. The prescriber may wish to consider other therapeutic options.

7. Is Truxima currently funded for indications other than RA?

Effective March 16, 2020, Truxima became funded for specific oncology indications through the Ministry's New Drug Funding Program (NDFP) overseen by Ontario Health (Cancer Care Ontario). The funding criteria for Truxima for oncology indications can be found on Cancer Care Ontario's website at:

https://www.cancercareontario.ca/en

8. How should pharmacies submit claims for Truxima? Are Truxima and Rituxan Interchangeable?

Pharmacies should be submitting claims using the drug identification number (DIN) of the product and the appropriate reason for use code.

Truxima is a rituximab product approved by Health Canada as a biosimilar to Rituxan. However, the two products are not "interchangeable" – i.e., pharmacists will require a new prescription from the prescriber specific to the brand of rituximab that they are dispensing.

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