Frequently Asked Questions: Funding of Riximyo (rituximab) and Ruxience (rituximab) under the Ontario Drug Benefit Program

1. What is the funding status of Riximyo (rituximab) and Ruxience (rituximab)?

Effective July 31, 2020,

Riximyo (rituximab) is 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).

Ruxience (rituximab) is listed on the ODB Formulary as a LU benefit for eligible ODB recipients for the treatment of RA, and for the management of patients with Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA).

Riximyo and Ruxience are funded for specific oncology indications through the Ministry's New Drug Funding Program (NDFP) administered by Ontario Health (Cancer Care Ontario). The funding criteria for Riximyo and Ruxience for oncology indications will be communicated by Ontario Health.

2. What are the Limited Use Criteria for Riximyo and Ruxience for RA?

As of the July 2020 formulary effective date, the Reason for Use (RFU) Codes and their associated reimbursement criteria for Riximyo and Ruxience for RA are as set out below. Please refer to the e-Formulary for the most up-to-date information.

A. Rheumatoid Arthritis – Initiation (Riximyo - RFU Code 581; Ruxience - RFU Code 583)

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

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. <u>Rheumatoid Arthritis – Re-treatment (Riximyo - RFU Code 582; Ruxience - RFU Code 584)</u>

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 581 or 583

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 are the Limited Use Criteria for Ruxience for GPA/MPA?

As of the July 2020 formulary effective date, the Reason for Use (RFU) Codes and their associated reimbursement criteria for Ruxience for MPA/GPA are as set out below. Please refer to the e-Formulary for the most up-to-date information.

C. Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA) (Ruxience - RFU Code 585)

Rituximab is used in combination with glucocorticoids for the induction of remission in patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA), for Patients who meet all of the following criteria:

1. The Patient must have severe active disease that is life or organ-threatening as supported by laboratory and/or imaging reports, AND

2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA, AND

3. Cyclophosphamide cannot be used by the Patient for ONE of the of the following reasons:

   a. The Patient has failed a minimum of six IV pulses of cyclophosphamide; OR

   b. The Patient has failed three months of oral cyclophosphamide therapy; OR

   c. The Patient has a severe intolerance or an allergy to cyclophosphamide; OR

   d. Cyclophosphamide is contraindicated; OR

e. The Patient has received a cumulative lifetime dose of at least 25 g of cyclophosphamide; OR

f. The Patient wishes to preserve ovarian/testicular function for fertility.

4. The request if from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The Patient should not have received a course or rituximab in the prior 6 months. The recommended dosing regimen for the initial treatment would be a once weekly infusion dosed at 375 mg/m^2 x 4 weeks.

Case-by-case considerations for patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 month (1 treatment course)

D. <u>Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA) who have achieved disease remission (Ruxience - RFU Code 586)</u>

Rituximab (Ruxience) treatment will be used for Patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA) who have achieved disease remission. Patient must meet all of the following criteria:

1. The Patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports.

2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA. A copy of the laboratory report must be provided.

3. Stabilization of the condition with induction doses of cyclophosphamide (injectable or oral doses are acceptable) and a glucocorticoid as combination over 4 to 6 months until disease remission prior to initiation of rituximab.

4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The Patient should not have received a dose of rituximab in the prior 6 months. Doses of rituximab administered at intervals more frequently than every 6 months are not funded. The recommended dosing regimen: A fixed dose regimen of Rituximab of 500mg IV every 6 months.

Case-by-case considerations for Patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 year

4. What is difference between Riximyo/Ruxience and Rituxan?

Riximyo and Ruxience are rituximab biologic products that have been approved by Health Canada as a biosimilar to Rituxan, the originator product. Riximyo, Ruxience and Rituxan are manufactured and marketed by different companies.

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

5. Are patients with an existing Exceptional Access Program (EAP) approval for Rituxan required to switch to Riximyo or Ruxience?

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

Riximyo and Ruxience for the treatment of patients with severe RA, and Ruxience for GPA/MPA will be made available on the Ontario Drug Benefit formulary as Limited Use benefits.

Prescriptions for Riximyo for RA and prescriptions for Ruxience for RA and GPA/MPA 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.

6. Will the ministry consider new requests for Rituxan (rituximab) reimbursement under the EAP, for the treatment of GPA/MPA?

Similar to other original biologics with publicly funded biosimilars, the ministry will not accept new requests for Rituxan for the treatment of GPA/MPA in patients who are treatment-naïve to Rituxan, effective July 31, 2020.

7. Will the ministry consider requests for Rituxan reimbursement under the EAP for patients who do not respond to, or are intolerant to Riximyo and Ruxience?

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

8. Is Riximyo and Ruxience currently funded for indications other than RA? Is Ruxience funded for indications other than RA and GPA/MPA?

Effective August 4, 2020, Riximyo and Ruxience became funded for specific oncology indications through the Ministry's New Drug Funding Program (NDFP) administered by Ontario Health (Cancer Care Ontario). The funding criteria for Riximyo and Ruxience for oncology indications can be found on Cancer Care Ontario's website at:

https://www.cancercareontario.ca/en

9. How should pharmacies submit claims for Riximyo and Ruxience? Are Riximyo, Ruxience and Rituxan Interchangeable?

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

Riximyo and Ruxience are rituximab products approved by Health Canada as a biosimilar to Rituxan. However, the three products are not "interchangeable" – i.e., pharmacists will require a 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.