RX.PA.030.MPC RITUXIMAB PRODUCTS

The purpose of this policy is to define the prior authorization process for non-oncologic indications for Rituximab products Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase human), Ruxience (rituximab-PVVR), Truxima (rituximab-abbs) and Riabni (rituximab-arrx).
Eviti reviews prior authorization requests for all oncology related indications for Rituximab products.

Rituxan is indicated for:

- Autoimmune hemolytic anemia
- B-cell lymphoma
- Burkitt's lymphoma, In combination with chemotherapy
- Chronic lymphoid leukemia, In combination for first-line treatment
- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Chronic lymphoid leukemia, Maintenance, following rituximab-containing chemotherapy
- Graft-versus-host disease, chronic, Steroid-refractory
- Granulomatosis with polyangiitis, In combination with glucocorticoids
- Idiopathic thrombocytopenic purpura
- Mantle cell lymphoma, Maintenance, following first-line induction therapy
- Mantle cell lymphoma, Untreated, induction therapy, in combination with anthracycline-based regimens
- Microscopic polyarteritis nodosa, In combination with glucocorticoids
- Myasthenia gravis, Refractory
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy & as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, stable or responsive to prior CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell
- Pemphigus vulgaris (Moderate to Severe)
- Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia, CD20-positive, in combination with chemotherapy
- Primary Sjögren's syndrome

- Rheumatoid arthritis, In combination with methotrexate, in patients with an inadequate response to methotrexate
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate, in patients who had an inadequate response to one or more tumor-necrosis-factor antagonist therapies
- Waldenstrom macroglobulinemia

Rituxan Hycela is indicated for:

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Diffuse large B-cell lymphoma, In combination with first-line treatment
- Follicular lymphoma, In combination with first-line chemotherapy & as single-agent maintenance
- Follicular lymphoma, Relapsed or refractory
- Follicular lymphoma, Stable or responsive to prior CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy

Ruxience is indicated for:

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Granulomatosis with polyangiitis, In combination with glucocorticoids
- Microscopic polyarteritis nodosa, In combination with glucocorticoids
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination with anthracycline-based chemotherapy for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy and as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, non-progressing (including stable) after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell

Truxima is indicated for:

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Granulomatosis with polyangiitis, In combination with glucocorticoids
- Microscopic polyarteritis nodosa, In combination with glucocorticoids
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination with anthracycline-based chemotherapy for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy and as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, non-progressing (including stable) after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy

- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate, in patients who had an inadequate response to one or more tumor-necrosis-factor antagonist therapies

Riabni is indicated for:

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Granulomatosis with polyangiitis, In combination with glucocorticoids
- Microscopic polyarteritis nodosa, In combination with glucocorticoids
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination with anthracycline-based chemotherapy for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy and as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, non-progressing (including stable) after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell

Although similar in certain aspects, it is important to understand that Rituxan, Rituxan Hycela, Ruxience, Truxima and Riabni are unique products that are not interchangeable.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs, Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase human), Ruxience (rituximab-PVVR), Truxima (rituximab-abbs) and Riabni (rituximab-arrx) are subject to the prior authorization process.

PROCEDURE

A. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective drug product:

1. Rheumatoid Arthritis

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate with an inadequate response
- Must have an adequate trial (of at least 3 months) of Enbrel® with inadequate response, significant side effects/toxicities, or a have a contraindication to this therapy.
- Must be on concurrent methotrexate therapy
- Must currently not be using a TNF-blocking agent or other biologic agents in combination with Rituxan®
- Must currently not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
- Must have no evidence of severe, active infection

2. Granulomatosis with Polyangiitis (GPA)/Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

- Must be prescribed by a rheumatologist
- Must be age 2 years or older
- Must have a diagnosis of Granulomatosis with Polyangiitis/Wegener's Granulomatosis or Microscopic Polyangiitis
- For induction therapy, must be on concomitant therapy with glucocorticoids
- For maintenance therapy, must have an adequate trial (of at least 3 months) of azathioprine or methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have no evidence of severe, active infection

3. Renal and/or Pancreatic Transplant Desensitization in Combination with IVIG

- Must be prescribed by a transplant specialist
- Must be age 18 years or older
- Must currently not have PML or have a history of PML
- Must be awaiting kidney and/or pancreas transplant requiring desensitization as defined by:
    - For deceased donor transplants, must have one of the following:
        - Panel reactive antibody (PRA) level >30%
        - PRA <30% with a previous kidney and/or pancreas transplant

- For living donor transplants, must have the following:
  - Positive crossmatch
  - Positive donor-specific antibody using Luminex® assay

4. Oncology

******All prior authorization requests for an oncology indication needs to be forwarded to Eviti for review******

5. Pemphigus Vulgaris (PV)

- Must have a diagnosis of biopsy-proven moderate to severe pemphigus vulgaris
- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must currently not have PML or have a history of PML
- Must have an adequate trial of at least one of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
  - Immunosuppressants (such as azathioprine or methotrexate)
  - Corticosteroids
- In rapidly progressive, extensive, or debilitating cases (i.e., Stevens JohnsonSyndrome), Rituxan may be approved along with corticosteroids or immunosuppressive agents

6. Neuromyelitis optica spectrum disorder (NMOSD)

- Must be prescribed by or in consultation with a neurologist or ophthalmologist
- Must have a diagnosis of neuromyelitis optica spectrum disorder
- Must have documentation of anti-aquaporin-4 (AQP4) antibody status
- For members who are AQP4 antibody *positive*, must have documented previous trial and failure, contraindication, or intolerance to Soliris (eculizumab)

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Rituxan and biosimilars will be considered investigational or experimental for any other use and coverage may be provided if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, DrugDex, Lexi-Drug, etc…) or at least two published peer-reviewed randomized controlled trials for the treatment of the diagnosis(es) for which it is prescribed. Abstracts (including meeting abstracts) are excluded from review consideration. These requests will be reviewed on a case by case basis to determine medical necessity.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for the continuation of treatment. Authorization is extended as specified below:

1. Rheumatoid Arthritis:

- For an additional course of treatment, based upon review of documentation from the prescriber indicating that the member's condition has improved as a result of therapy. Authorization is not granted until 16 weeks has passed since the previous treatment.

2. Granulomatosis with Polyangiitis/Wegener's Granulomatosis and Microscopic Polyangiitis:

- For an additional 6 months, based upon review of documentation from the prescriber indicating that the member is continuing to benefit from treatment.

3. Renal and/or Pancreatic Desensitization Candidates:

- For an additional course of treatment (with the above regimen) if the member has not yet received a renal and/or pancreatic transplant. Authorization is not granted until 6 months have passed since the initial treatment.

4. Pemphigus Vulgaris (PV)

- For an additional course of treatment, based upon review of documentation from the prescriber indicating that the member's condition has improved as a result of therapy. Authorization is not granted until 12 months has passed since the initial treatment and 6 months for every subsequent treatment after the second treatment course.

5. Neuromyelitis optica spectrum disorder (NMOSD)

- For an additional 12 months, based upon review of documentation from the prescriber indicating that the member is continuing to benefit from treatment.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• RA and PV: 1 course of treatment (two 1000mg doses given on day 1 and 15) • WG and MPA: 1 month • Transplant Desensitization: 1 course of treatment (one 1000mg dose given on day 15) • NMOSD: 3 months

Reauthorization	• RA and PV: 1 course of treatment (two 1000mg doses given on day 1 and 15) • WG and MPA: 6 months • Transplant Desensitization: 1 course of treatment (one 1000mg dose given on day 15) • NMOSD: 1 year

CPT Codes:

J- Code	Description
J9312	Injection, rituximab, 10mg
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10mg
J9311	Injection, rituximab, 10mg and hyaluronidase
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10mg

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Update to off-label restrictions	*04/2022*
Added NMOSD Criteria and Riabni	*02/2022*
Annual Review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*05/2021*
Annual Review	*03/2021*
New Policy	*12/2020*