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), and Truxima (rituximab-abbs). 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, 2egener2ne2, and 2egener2ne) 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

Although similar in certain aspects, it is important to understand that Rituxan, Rituxan Hycela, Ruxience, and Truxima 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), and Truxima (rituximab-abbs) are subject to the prior authorization process.

PROCEDURE

III. 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 Johnson Syndrome), Rituxan may be approved along with corticosteroids or immunosuppressive agents

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.

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) □
Reauthorization	Same as initial

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

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
P&T Review	*05/21*
Annual Review	*03/21*
New Policy	*12/20*