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 Riabni (rituximab-arrx), 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.

	Products
Preferred	• Riabni (rituximab-arrx) • Ruxience (rituximab-PVVR) • Truxima (rituximab-abbs)
Non-preferred	• Rituxan (rituximab) • Rituxan Hycela (rituximab and hyaluronidase human)

- **Requests for non-preferred products must have a documented trial and failure/ intolerance or contraindication to ALL preferred 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
- 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
- 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
- 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

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

PROCEDURE

A. INITIAL 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, unless contraindicated
- Must have an adequate trial (of at least 3 months each) of Etanercept (Enbrel), Adalimumab (Humira) and Tofacitinib (Xeljanz) with inadequate response, significant side effects/toxicities, or a have a contraindication to these therapies.
    - Must be on concurrent methotrexate or leflunomide therapy, unless contraindicated.
- Must currently not be using a TNF-blocking agent or other biologic agents in combination with rituximab products.
    - 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
- Must currently not have PML or have a history of PML
- 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. 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 3 months with 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), rituximab may be approved along with corticosteroids or immunosuppressive agents

Off-Label Uses:

4. 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

5. Multiple Sclerosis
- Member has a documented diagnosis of highly active refractory or aggressive relapsing remitting Multiple Sclerosis
- Member has a documented trial and failure, intolerance to, or contraindication to TWO of the following:
    - At least one Interferon product [interferon beta-1a (Avonex®, Rebif®) or interferon beta1b (Betaseron®, Extavia®)]
    - Glatiramer (Copaxone®)
    - Dimethyl Fumarate (Tecfidera®)
- Must be prescribed by or in consultation with a neurologist

- Rituximab will not be used concurrently with another disease modifying agent such as Ocrevus, Rebif, Gilenya, Tysabri, etc.

6. Immune Thrombocytopenic Purpura (ITP)

- Must have a documented diagnosis of chronic, refractory immune thrombocytopenia
- Must have a documented platelet count (within 30 days) of < 30,000 cells/ µL or member has a documented active bleed
- Must be prescribed by or in consultation with a hematologist
- Must have a documented trial (for at least 30 days) and failure, intolerance to, or a contraindication to a systemic corticosteroid
- Must have a documented trial (at least 2 doses) and failure, intolerance to, or contraindication to IVIG therapy
- Must have a documented trial and failure, intolerance to, or contraindication to TWO of the products: Nplate, Promacta, or Doptelet
- Must not be prescribed concurrently with a thrombopoietin receptor agonist such as Nplate, Promacta, Doptelet
- Dosing must not exceed 375 mg/m^2 once weekly

7. Neuromylitiis Optica Spectrum Disorder (NMOSD)

- Must be $\geq$ 18 years of age
- Must have a documented diagnosis of neuromyelitis optica spectrum disorder
- Must have documentation of serologic testing for anti-aquaporin-4 immunoglobulin (AQP4-IgG)/NMO-IgG antibodies
- Member has a documented experience of at least one relapse within the previous 12 months
- Member exhibits one of the following core clinical characteristics of NMOSD:
    - Optic neuritis
    - Acute myelitis
    - Area postrema syndrome
    - Acute brainstem syndrome
    - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- Must have a documented trial and failure of Soliris (eculizumab) for at least 3 months unless intolerant or contraindicated
- Must not be prescribed concurrently with other biologics or monoclonal antibodies indicated for NMOSD such as Soliris, Ultomiris, Actemra, Uplizna, etc.
- Must be prescribed by or in consultation with a neurologist
- Induction dose must not exceed 1 g once every 2 weeks (x2 doses) or 375 mg/m^2 once weekly for 4 weeks

8. Myasthenia Gravis

- Must have a documented diagnosis of refractory myasthenia gravis
- Must have Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 6 at baseline

- Must have documentation of anti-acetylcholine receptor (AChR) antibody positive or muscle-specific tyrosine kinase (MuSKAb) antibody positive
- Must have a documented trial and failure for at least 3 months, intolerance to, or contraindication to at least THREE agents such as azathioprine, cyclosporine, methotrexate, mycophenolate, pyridostigmine, neostigmine, corticosteroids, Tacrolimus
- Must have a documented trial and failure of Soliris (eculizumab) for at least 3 months unless intolerant or contraindicated
- Must be prescribed by or in consultation with a neurologist
- Initial dose must not exceed 375 mg/m^2 once a week

9. Autoimmune Hemolytic Anemia (AIHA)

- Must have a documented diagnosis of primary autoimmune hemolytic anemia (includes primary cold agglutinin disease or warm type diagnosis; secondary and drug induced AIHA are excluded indications)
- Documentation of trial and failure, intolerance to, or contraindication to a systemic glucocorticoid
- Must be prescribed by or in consultation with a hematologist

B. Oncology –

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

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

D. Rituximab products will be considered investigational or experimental for any other use and will not be covered.

E. <u>Reauthorization Criteria:</u>

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

<u>MPC Renewal:</u>

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.
- Must be prescribed by a rheumatologist

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.

- Must be prescribed by a rheumatologist

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.
- Must be prescribed by a transplant specialist

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.
- Must be prescribed by a dermatologist

5. Multiple Sclerosis

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- Must be prescribed by or in consultation with a neurologist
- Rituximab will not be used concurrently with another disease modifying agent such as Ocrevus, Rebif, Gilenya, Tysabri, etc.

6. Immune Thrombocytopenic Purpura (ITP)

- Must provide documented initial response to rituximab therapy
- Documentation of continued thrombocytopenia < 20,000 or <30,000 and clinically significant bleeding
- Dosing must not exceed 375 mg/m^2 once weekly
- Must be prescribed by or in consultation with a hematologist

7. Neuromyelitis Optica

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- Must be prescribed by or in consultation with a neurologist

8. Myasthenia Gravis

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- Must be prescribed by or in consultation with a neurologist
- Maintenance dose and frequency must not exceed 375 mg/m^2 every month

9. Autoimmune Hemolytic Anemia (AIHA)

- Chart documentation from the provider that the member's condition has stabilized or improved based upon the prescriber's assessment while on therapy and clinical rationale for re-treatment

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- Must be prescribed by or in consultation with a hematologist

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
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- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

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) • MS: 3 months • ITP: 1 month • NMOSD: 3 months • MG: 3 months • AIHA: 1 month
Reauthorization	• Same as initial • WG and MPA: 6 months • MS: 6 months • ITP: 3 months • NMOSD: 6 months • MG: 6 months • AIHA: 1 month

CPT Codes:

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

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Addition of initial and reauthorization criteria for Autoimmune Hemolytic Anemia	*01/2024*
Selected Revision *Removal of off-label treatment indications without criteria (Graft vs host disease, primary Sjogren's syndrome)*	*10/2023*
Selected Revision *Addition of preferred vs non-preferred products* *Additional criteria for off-label indications: Multiple Sclerosis, Immune Thrombocytopenic Purpura, Neuromyelitis Optica Spectrum Disorder, Myasthenia Gravis*	*08/2023*
Annual Review	*02/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal*	*10/2022*
Annual Review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
New Policy	*11/2020*