CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Rituximab (Rituxan, Ruxience, Truxima)
BILLING CODE	See below
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Rituximab is a monoclonal antibody that targets the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab mediates B-cell lysis. B cells are believed to play a role in the pathogenesis of rheumatoid arthritis (RA) and associated chronic synovitis. In this setting, B cells may be acting at multiple sites in the autoimmune/inflammatory process.

Rituximab was initially approved by the FDA in 1997 as Rituxan. The FDA subsequently approved Truxima (2018) and Ruxience (2019) as biosimilars to Rituxan.

Rituximab will be considered for coverage when the following criteria are met:

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

For **initial** authorization:
1. Member is 2 years old or older; AND
2. Medication must be prescribed by or in consultation with a nephrologist or rheumatologist; AND
3. Member has a diagnosis of one of the following:
   a) Severe GPA or MPA,
   b) Non-severe GPA or MPA (non-organ threatening, non-life-threatening) refractory to glucocorticoid in combination with methotrexate or mycophenolate mofetil (MMF); AND
4. Rituximab will be initiated in combination with glucocorticoids; AND
5. For a non-preferred product, intolerance to all preferred products is required (see Appendix).
6. **Dosage allowed/Quantity limit:** Please refer to the Dosing and Administration section of the package insert.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes demonstrate clinical improvement of disease signs and symptoms.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Pemphigus Vulgaris (PV)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Must be prescribed by or in consultation with a dermatologist; AND
3. Member has a documented diagnosis of moderate to severe PV; AND
4. Rituxan will be initiated in combination with a corticosteroid taper (unless contraindicated).

5. **Dosage allowed/Quantity limit:** Initial: Two 1000mg doses separated by 2 weeks; Maintenance: 500mg infusion at month 12 and every 6 months thereafter or based on clinical evaluation. Relapse: 1000mg infusion. Subsequent infusions may be administered no sooner than 16 weeks following the previous infusion.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate clinical improvement of signs and symptoms (e.g. healed lesions, fewer new lesions, etc.)

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication is being prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately- to severely- active RA; AND
4. Rituxan is being used in combination with methotrexate, or another non-biologic DMARD if unable to tolerate methotrexate; AND
5. Member must have inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonists (e.g. adalimumab, etanercept, infliximab) for at least 3 months each. Note: TNF antagonists require prior authorization; AND
6. For a non-preferred product, intolerance to all preferred products is required (see Appendix).
7. **Dosage allowed/Quantity limit:** Two 1000mg doses separated by 2 weeks; subsequent courses repeated no sooner than every 16 weeks (every 24 weeks is typical).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, etc.)

If all the above requirements are met, the medication will be approved for an additional 12 months.

Acquired Thrombotic Thrombocytopenic Purpura (aTTP)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a presumptive or confirmed diagnosis of aTTP including ALL of the following:
   a) Lab results showing thrombocytopenia (platelet count less than 150,000);
   b) Microangiopathic hemolytic anemia (MAHA) confirmed by presence of schistocytes on blood smear;
   c) Documentation of a PLASMIC score between 5 and 7 (intermediate to high risk);[25]
   d) Testing shows an ADAMTS13 activity level less than 10%, OR test has been ordered and results are pending.
4. Member's platelet count has not responded after at least 4 days of plasma exchange and glucocorticoid; AND
5. Rituxan is being used in addition to plasma exchange and glucocorticoid.
6. **Dosage allowed/Quantity limit:** 375mg/m^2 once weekly for 4 doses (off label).[26]

If all the above requirements are met, the medication will be approved for 30 days.

For **reauthorization**:
1. Member is experiencing a relapse of symptoms (thrombocytopenia and MAHA); AND
2. ADAMTS13 activity is less than 20% (lab report required).

If all the above requirements are met, the medication will be approved for an additional 30 days.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of NMOSD and is seropositive for aquaporin-4 (AQP4) IgG antibodies (documentation required).
4. **Dosage allowed/Quantity limit:** 1g on day 1 and day 15, then 1g every 6 months[32] (off label)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document disease stabilization, symptom improvement, and/or reduced frequency of relapses.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Generalized Myasthenia Gravis (gMG)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member meets one of the following:
   a) Member has a documented diagnosis of gMG that is seropositive for MuSK antibodies AND has tried and failed corticosteroid treatment with or without a non-steroid immunosuppressant
   b) Member has a documented diagnosis of refractory gMG that is seropositive for AChR antibodies AND has tried and failed ALL of the following: pyridostigmine, corticosteroid, and at least 2 non-steroid immunosuppressives (e.g., azathioprine, mycophenolate mofetil, tacrolimus)
4. **Dosage allowed/Quantity limit:** Consult updated clinical literature for recommendations. A variety of regimens have shown efficacy. (Off label use)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document clinically meaningful improvement in symptom severity and functioning compared to previous treatment.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Non–Hodgkin's Lymphoma (NHL)

These requests must be submitted through NantHealth/Eviti portal.
NOTE: For a non-preferred product, intolerance to all preferred products is required (see Appendix).

Chronic Lymphocytic Leukemia (CLL)

These requests must be submitted through NantHealth/Eviti portal.
NOTE: For a non-preferred product, intolerance to all preferred products is required (see Appendix).

CareSource considers Rituximab not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/20/2013	Change in diagnosis
07/15/2014	Added diagnosis TTP and additional criteria to CD20+ CLL
07/15/2015	Added MCG 19th edition criteria
10/04/2016	Change in diagnoses to FDA approved uses, updated references with supporting guidelines and literature
06/09/2020	Transferred policy to new template, indicated Eviti carve-outs. Revised criteria for vasculitis diagnoses (GPA, MPA); previously listed as ANCA vasculitis – updated age, specified trial for non-severe, simplified the cyclophosphamide trial language. Revised criteria for Rheumatoid Arthritis – changed from trial of 2 TNF to 1 TNF. Added new diagnosis Pemphigus Vulgaris and its criteria
07/28/2020	Added criteria for aTTP.
10/13/2020	Added criteria for NMOSD. For RA, stated they must use another DMARD if they can't use MTX.
02/09/2022	Transferred to new template. RA: Added new reference. GPA/MPA: Added references and made updates per new guidelines. Added MMF to #3. Removed requirement for trial/failure of cyclophosphamide. PV: Added new references. Removed required trial/failure of steroid and adjuvant immunosuppressant. Added new section for myasthenia gravis (off label).
04/15/2022	Added biosimilars to policy.

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APPENDIX

Preferred Products	Non-Preferred Products
• Ruxience - Q5119 • Truxima - Q5115	• Rituxan - J9312

Effective date: 10/01/2022
Revised date: 02/09/2022