

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Rituxumab (Rituxan, Truxima, Ruxience, Riabni)</b>
BENEFIT TYPE	Medical
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 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. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
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. Rituximab will be initiated in combination with a corticosteroid taper (unless contraindicated); AND

5. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
6. **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. Rituximab 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. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
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;

- o) Documentation of a PLASMIC score between 5 and 7 (intermediate to high risk);
1. 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. Rituximab is being used in addition to plasma exchange and glucocorticoid; AND
  6. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
  7. **Dosage allowed/Quantity limit:** 375mg/m<sup>2</sup> once weekly for 4 doses (off label).

***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); AND
4. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
5. **Dosage allowed/Quantity limit:** 1g on day 1 and day 15, then 1g every 6 months (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); AND
4. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
5. **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.***

## Multiple Sclerosis (MS)

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 has a diagnosis of MS, including documentation of baseline relapse rate, lesion count, and/or disability status (e.g., EDSS); AND
4. Member has documentation of **ONE** of the following:
  - a) For primary progressive MS (PPMS): Trial and failure of Ocrevus
  - b) For relapsing forms of MS (RMS): Trial and failure of at least 2 preferred disease-modifying drugs indicated for MS; AND
5. Rituximab will not be used concurrently with another disease-modifying drug for MS; AND
6. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
7. **Dosage allowed/Quantity limit:** Consult updated clinical literature for recommendations. (Off label use)

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

For **reauthorization**:

1. Chart notes must indicate a positive clinical response such as lower relapse rate compared to baseline (i.e., for RMS) or overall stability of disease (i.e., for PPMS).

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

## Immune Thrombocytopenia (ITP)

For **initial** authorization:

1. Medication is prescribed by or in consultation with a hematologist; AND
2. Member has a documented diagnosis of ITP of at least 6 months duration; AND
3. Member's platelet count is  $<30 \times 10^9$  OR  $<50 \times 10^9$  with active symptomatic bleeding or high risk factors for bleeding; AND
4. Member has had an insufficient response to **ONE** of the following:
  - a) Corticosteroid
  - b) Immunoglobulin
  - c) Splenectomy; AND
5. Member has had an insufficient response to a thrombopoietin receptor agonist (TPO-RA) such as Promacta, Nplate, or Doptelet; AND
6. Rituximab will not be used in combination with a TPO-RA or Tavalisse; AND
7. If the request is for a non-preferred product, member has had a trial of a preferred product where applicable, or acceptable clinical reason must be provided as to why it cannot be used. See Appendix A for named preferred and non-preferred products.
8. **Dosage allowed/Quantity limit:** Consult updated clinical literature for recommendations. Example (Off-label): 4 weekly doses of 375 mg/m<sup>2</sup>

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

For **reauthorization**:

1. Chart notes must document clinically significant improvement in platelet count compared to baseline following a course of rituximab; AND
2. Patient has a relapse of symptoms and meets all initial criteria.

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

## Non-Hodgkin's Lymphoma (NHL)

These requests must be submitted through [NantHealth/Eviti](#) portal.

## Chronic Lymphocytic Leukemia (CLL)

These requests must be submitted through [NantHealth/Eviti](#) portal.

### Appendix A:

Preferred Products	Non-preferred Products
<ul style="list-style-type: none"> <li>• Ruxience</li> <li>• Truxima</li> </ul>	<ul style="list-style-type: none"> <li>• Rituxan</li> <li>• Riabni</li> </ul>

**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

<b>07/15/2015</b>	Added MCG 19th edition criteria
<b>10/04/2016</b>	Change in diagnoses to FDA approved uses, updated references with supporting guidelines and literature
<b>06/09/2020</b>	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
<b>07/28/2020</b>	Added criteria for aTTP.
<b>10/13/2020</b>	Added criteria for NMOSD. For RA, stated they must use another DMARD if they can't use MTX.
<b>02/09/2022</b>	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).
<b>07/27/2022</b>	Added new section for multiple sclerosis (off label).
<b>02/21/2023</b>	Renamed policy as Rituximab and added biosimilars. Added section for off label treatment of ITP.
<b>01/04/2024</b>	Added appendix; added criteria to trial preferred product within policy when applicable; added references.
<b>01/25/2024</b>	Approved by ODM

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2. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2022.
3. Ruxience [package insert]. New York, NY : Pfizer Inc.; 2023.
4. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; 2022.
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Effective date: 04/01/2024  
Revised date: 01/04/2024