PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Rituximab (Rituxan*, Truxima, Ruxience, Riabni)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Rituxan 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. Rituxan 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

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 a corticosteroid (e.g., prednisone) AND a nonsteroidal immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus); OR
   b) Member has a documented diagnosis of gMG that is seropositive for MuSK antibodies AND has a documented contraindication to corticosteroids and nonsteroidal immunosuppressants; OR
   c) Member has a documented diagnosis of gMG that is seropositive for acetylcholine receptor (AChR) antibodies AND has tried and failed a corticosteroid (e.g., prednisone) AND a nonsteroidal immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus); OR
   d) Member has a documented diagnosis of gMG that is seropositive for AChR antibodies AND has a documented contraindication to corticosteroids and nonsteroidal immunosuppressants.

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.
6. **Dosage allowed/Quantity limit:** Consult updated clinical literature for recommendations. (Off label use)

If

Chronic Lymphocytic Leukemia (CLL)

These requests must be submitted through

arthritis?search=rheumatoid%20arthritis%20treatment&topicRef=7966&source=see_link. Updated April 3, 2020. Accessed June 9, 2020.
10. Finckh A, Ciurea A, Brulhart L, et al. Which subgroup of patients with rheumatoid arthritis benefits from switching to rituximab versus alternative anti-tumour necrosis factor (TNF) agents after previous failure of an anti-TNF agent? *Annals of the Rheumatic Diseases*. 2009;69(2):387-393. doi:10.1136/ard.2008.105064
11. Solau-Gervais E, Prudhomme C, Philippe P, et al. Efficacy of rituximab in the treatment of rheumatoid arthritis. Influence of serologic status, coprescription of methotrexate and prior TNF-alpha inhibitors exposure. *Joint Bone Spine*. 2012;79(3):281-284. doi:10.1016/j.jbspin.2011.05.002
12. Harrold LR, Reed GW, Magner R, et al. Comparative effectiveness and safety of rituximab versus subsequent anti–tumor necrosis factor therapy in patients with rheumatoid arthritis with prior exposure to anti–tumor necrosis

27. Sayani FA, Abrams CS. How I treat refractory thrombotic thrombocytopenic purpura [published correction

48. Filippini G, Kruja J, Del Giovane C. Rituximab for people with multiple sclerosis. *Cochrane Database Syst Rev*. 2021;11(11):CD013874. Published 2021 Nov 8. doi:10.1002/14651858.CD013874.pub2
49. Alldredge B, Jordan A, Imitola J, Racke MK. Safety and Efficacy of Rituximab: Experience of a Single Multiple Sclerosis Center. *Clin Neuropharmacol*. 2018;41(2):56-59. doi:10.1097/WNF.0000000000000268
50. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. *Blood Adv*. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966
51. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv*. 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812

APPENDIX

Preferred Products	Non-Preferred Products
Ruxience Truxima	Rituxan

Effective date: 07/01/2023
Revised date: 02/21/2023