CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Rituxan (rituximab)
BILLING CODE	J9312
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT—see "Dosage Allowed" sections
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Rituxan (rituximab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 confirmed diagnosis of severe GPA or MPA, **or** non-severe disease (non-organ threatening, non-life-threatening) refractory to glucocorticoids in combination with methotrexate; AND
4. Rituxan will be initiated in combination with glucocorticoids; AND
5. Member has at least ONE of the following:
   a) Member's disease remains active or has progressed despite at least a 3 month trial of glucocorticoids in combination with cyclophosphamide;
   b) Further treatment with cyclophosphamide would exceed the maximum cumulative dose;
   c) Cyclophosphamide is contraindicated or not tolerated by the member.
6. **Dosage allowed:** Please refer to the Dosing and Administration section of the package insert.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member tolerates infusions; AND
2. Chart notes demonstrate clinical improvement of disease signs and symptoms.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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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); AND
5. Member has tried and failed or has contraindication to high dose corticosteroid (equivalent to 1.5mg/kg/day prednisone) and an adjuvant immunosuppressive agent such as azathioprine or mycophenolate mofetil.
6. **Dosage allowed:** Initial: Two 1000mg doses separated by 2 weeks; Maintenance: 500mg infusion at month 12 and every 6 months thereafter or based on clinical evaluation -- no sooner than 16 weeks following the previous infusion; Relapse: 1000mg infusion.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member tolerates infusions; AND
2. Chart notes demonstrate clinical improvement of signs and symptoms (e.g. healed lesions, fewer new lesions, etc.)

If member meets all the reauthorization requirements above, 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.
6. **Dosage allowed:** Two 1000mg doses separated by 2 weeks; subsequent courses repeated no sooner than every 16 weeks (every 24 weeks is typical).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member tolerates infusions; AND
2. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, etc.)

If member meets all the reauthorization requirements above, 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:** 375mg/m^2 once weekly for 4 doses (off label).[26]

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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:** 1g on day 1 and day 15, then 1g every 6 months[32] (off label)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member tolerates infusions; AND
2. Chart notes must document disease stabilization, symptom improvement, and/or reduced frequency of relapses.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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.

CareSource considers Rituxan (rituximab) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
8/20/2013	Change in diagnosis
7/15/2014	Added diagnosis TTP and additional criteria to CD20+ CLL

7/15/2015	Added MCG 19th edition criteria
10/4/2016	Change in diagnoses to FDA approved uses, updated references with supporting guidelines and literature
6/9/2020	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
7/28/2020	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.

References:

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