Medical Policy and Prior Authorization Notice

Rituxamab (Rituxan®)

Publication- 12/1/2025
Effective Date-1/1/2026

PURPOSE:

The goal of this policy is to establish standards for unapproved use (off label use) of Rituximab at Parkland Community Health Plan (PCHP) for the best possible member care, safety, and resource management. Throughout the policy, Rituximab refers to Rituximab and biosimilars as appropriate.

SCOPE:

This policy applies to all members of STAR and CHIP receiving Rituximab prescription as a Clinician Administered Drug (CAD) for indications not explicitly approved by the FDA (off-label use).

DEFINITIONS:

Unapproved indication/ off-label use- A health care provider prescribes a medication for an unapproved use when deemed medically appropriate for the member. The drug can be:

- Used for a disease or medical condition that is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.
- Given in a different way, such as when a medication is approved as a capsule, but it is given instead in an oral solution.
- Given in a different dose, such as when a medication is approved at a dose of one tablet every day, but a patient is told by their healthcare provider to take two tablets every day.

Biosimilars:

HCPCS	Generic/biosimilar	Brand Name
J9312	Injection Rituximab, 10mg	(Rituxan®)
Q5115	Injection Rituximab-abbs, biosimilar 10mg	(Truxima®)
Q5119	Injection Rituximab-pvvr, biosimilar 10mg	(Ruxience ®)
Q5123	Injection Rituximab-arrx, biosimilar 10mg	(Riabni®)

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POLICY:

- A) **Multiple Sclerosis (MS) (G35):**

  - Rituximab may be considered a second-line option in patients with refractory or remitting multiple sclerosis who failed first-line therapy.
  - MS could be relapsing-remitting, primary progressive disease, and secondary progressive disease

  - Rituximab is medically necessary for MS when **ALL** of the following criteria are met: **For initial therapy**, ALL of the following:
    - **One** of the following:
      - Diagnosis of primary progressive multiple sclerosis (PPMS) or
      - Diagnosis of relapsing forms of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses)

    - Patient is **NOT** receiving Rituxmab in combination of **any** of the following:
      - Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)
      - B cell targeted therapy (e.g., ocrelizumab, belimumab, ofatumumab)
      - Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)

    - Initial authorization will be for no more than 12 months

  - For **continuation of therapy**, **ALL** of the following:
    - Patient is **not** receiving Rituximab in combination with any of the following:
      - Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)
      - B cell targeted therapy (e.g., ocrelizumab, belimumab, ofatumumab)
      - Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)

  - **Reauthorization critieria**
    - Stabilization or improvement in neurologic function
    - Reduction in relapse frequency
    - No new contraindications or intolerances
    - No infusion-related anaphylaxis, serious infections, or prolonged hypogammaglobulinemia unless managed appropriately
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  Approval Timeframe- no more than 12 months

B) **Nephrotic Syndrome (ICD-10: N04.9/ N05.8):**

- Off-label use of Rituximab may be considered medically necessary for the treatment of nephrotic syndrome when **ALL** of the following criteria are met:

  - Diagnosis of nephrotic syndrome associated with **ONE** of the following histological subtypes:

- Idiopathic membranous nephropathy (IMN) or
- Focal segmental glomerulosclerosis (FSGS) or
- Minimal change disease (MCD) or
- Membranoproliferative glomerulonephritis (MPGN) or
- Lupus nephritis or
- IgA nephropathy

- Prescribed by or in consultation with a nephrologist

- Failure of oral corticosteroids, unless contraindicated or clinically significant adverse effects are documented

- Failure of **ONE** of the following immunosuppressant agents, unless clinically significant adverse effects are experienced or contraindicated:
  - Cyclophosphamide
  - Chlorambucil
  - Tacrolimus
  - Cyclosporine
  - Mycophenolate mofetil
- No concurrent use with other biologic Disease-modifying antirheumatic drugs (DMARDs) or Janus kinase (JAK) inhibitors.

- Dosing must meet **ONE** of the following:
  - Dose does not exceed 375mg/m2 IV infusion once weekly up to 4 doses
  - Dose is supported by practice guidelines or peer reviewed literature for the relevant off-label use (health care provider must submit supporting evidence).
- Initial authorization will be for no more than 6 months

- **Reauthorization criteria**
  - Improvement or stability in organ function eg kidney function
  - Reduction in proteinuria or maintained remission
  - Stable or improved serum Albumin
  - No new contraindications or intolerances
  - No infusion-related anaphylaxis, serious infections, or prolonged hypogammaglobulinemia unless managed appropriately

Approval Timeframe-6 months

C) **Systemic Lupus Erythematosus (SLE) (M.32.9):**

- Off-label use of Rituximab may be considered medically necessary for the treatment of SLE when **ALL** of the following criteria are met:

  - Age ≥ 6 years
  - Confirmed diagnosis of SLE classification criteria
  - Documented disease severity with **ONE** or more of the following:
    - Class III, IV, or V lupus nephritis (biopsy or clinical diagnosis)
    - Refractory autoimmune cytopenia's (e.g., thrombocytopenia, hemolytic anemia)
    - Neuropsychiatric lupus
    - Other severe organ-threatening disease manifestations

- Failure, intolerance or contraindication to at least **TWO** of the following conventional immunosuppressive agents:
  - Mycophenolate mofetil
  - Azathioprine
  - Cyclophosphamide
  - Methotrexate
  - Belimumab
  - High dose corticosteroids (≥ 20mg/day prednisone or equivalent)
- Treatment plan and dosing regimen consistence with:
  - 375mg/m2 weekly x 4 doses
  - Retreatment no more frequently than every 6 months, unless clinical evidence supports more frequent use
- Monitoring and Safety Plan include:
  - Baseline and periodic **CBC, renal function, urinalysis,** and **B-cell count** (if available)
  - Screening for **HBV/HCV, HIV, and tuberculosis** prior to initiation
  - Premedication to prevent infusion reactions
  - Plan for assessing treatment response

- **Reauthorization criteria**:

  - Reduction in relapse frequency
  - Improvement or stability in organ function in proteinuria and renal function
  - Documented clinical improvement or stabilization (e.g., proteinuria reduction, platelet counts, decreased corticosteroid use)
  - No new contraindications or intolerances
  - No infusion-related anaphylaxis, serious infections, or prolonged hypogammaglobulinemia unless managed appropriately
  - Repeat cycles requested no more frequently than every 6 months unless strongly justified

  Approved Timeframe- 6 months

NOTE:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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REFERENCES:

Clinical Policy: Rituximab (Rituxan), Rituximab-pvvr (Ruxience), Rituximab-abbs (Truxima), Rituximab-Hyaluronidase (Rituxan Hycela): CP.PHAR.260. file:///C:/Users/P114395/Downloads/CP.PHAR.260%20(1).pdf

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