GCHP Medi-Cal Clinical Guidelines
Rituximab (Rituxan™), Rituximab-abbs (Truxima™), Rituximab-pvvr (Ruxience™), Rituximab-arrx (Riabni™)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	**Rituximab (Rituxan™), Rituximab-abbs (Truxima™), Rituximab-pvvr (Ruxience™), Rituximab-arrx (Riabni™)** • Rheumatoid arthritis (RA) • Granulomatosis with polyangiitis (Wegener's granulomatosis) (GPA) • Microscopic polyangiitis (MPA) **Rituximab (Rituxan™) only** • Pemphigus vulgaris Additional accepted off-label uses (reviewed case-by-case), including, but not limited to: Antibody-mediated rejection in cardiac transplantation, auto-immune hemolytic anemia (refractory), Burkitt lymphoma, graft-versus-host disease (chronic, steroid-refractory), advanced Hodgkin lymphoma, immune thrombocytopenia (refractory), lupus nephritis (refractory), myasthenia gravis (refractory), posttransplant lymphoproliferative disorder, thrombotic thrombocytopenic purpura (acquired), Waldenström macroglobulinemia, multiple sclerosis.
Exclusion Criteria	• Positive for HBsAg or anti-HBc, without concurrent HBV therapy • CD20-negative B-cell non-Hodgkin lymphoma • Concurrent use of live vaccine • Active infection • Untreated or active tuberculosis

Required Medical Information	**GPA & MPA:** • Active severe, relapsed, or refractory disease present (e.g., progressive glomerulonephritis, alveolar hemorrhage, vasculitic neuropathy), AND • Administered in combination with glucocorticoids. **RA:** • Rheumatologist's clinic notes confirming the diagnosis of moderately- to severely active rheumatoid arthritis and treatment plan. • Administered in combination with methotrexate, unless unable to tolerate or contraindicated to methotrexate. • Subsequent course of rituximab approval must demonstrate favorable response to prior administration of rituximab. **Pemphigus vulgaris (Rituxan™ only):** • Dermatologist's clinic notes confirming the diagnosis AND • Administered with corticosteroids. **Off-label indications:** 1) The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic and professional specialists. 2) In addition, one of the following is required: a. Documentation of trial and failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.
Age Restriction	For GPA/MPA: 2 years of age or older (For ages 2-21, check for CCS eligibility) For all other indications: 18 years of age (For ages 18 – 21, check for CCS eligibility)
Prescriber Restrictions	• GPA, MPA – Nephrologist, Rheumatologist, Pulmonologist, Cardiologist, Vascular Surgeon, Immunologist, or ENT • RA – Rheumatologist • Pemphigus Vulgaris – Dermatologist, Rheumatologist, or Ophthalmologist (if ocular involvement) • Off-Label Indications: The diagnosis and treatment must be within the scope of the treating physician's board-certified specialty.
Coverage Duration	GPA/MPA, induction of remission: Six months GPA/MPA, maintenance of remission: 12 months (renewable) RA: Initial three months; renewals six months Pemphigus Vulgaris: Initial (induction) - One time; Maintenance: 12 months (two doses, six months apart)

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<tr>
<td>Other Criteria / Information</td>
<td>Criteria adapted from DHCS OCT 2024 & MCG
Claims with the following ICD-10-CM diagnosis codes will not require Prior Authorization for reimbursement

NHL: C82.00 – C83.39
CLL: C91.10 – C91.12

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J9312</td><td>Injection, rituximab 10mg (Rituxan™)</td><td rowspan="4">GPA/MPA
Induction – 375mg/m2 once weekly for four doses or 1gm IV once every two weeks for two doses
Maintenance – 500mg IV once every two weeks for two doses then 500mg or 1gm IV once every four to six months
Pemphigus Vulgaris (Rituxan™ only)
Induction - Two doses of 1gm IV separated by two weeks
Maintenance – 500mg IV at month 12, and every six months thereafter
Relapse – 1gm upon relapse (no sooner than 16 weeks from previous infusion)
RA
Induction – Two doses of 1gm IV separated by two weeks
Maintenance – 1gm IV every 16-24 weeks</td></tr>
<tr><td>Q5115</td><td>Injection, rituximab-abbs, biosimilar 10mg (Truxima™)</td></tr>
<tr><td>Q5123</td><td>Injection, rituximab-arrx, biosimilar 10mg (Riabni™)</td></tr>
<tr><td>Q5119</td><td>Injection, rituximab-pvvr, biosimilar 10mg (Ruxience™)</td></tr>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	11/5/2024	11/5/2024	Pearl Okonkwo, Temp-Clinical Programs Pharmacist Yoonhee Kim, Interim Director of Pharmacy Services	N/A
Approved	N/A	11/14/2025	Pharmacy & Therapeutics (P&T) Committee	5/1/2025