GCHP Medi-Cal Clinical Guidelines
Rituximab Hyaluronidase (Rituxan Hycela™)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	• Non-Hodgkin's lymphoma (NHL) • Chronic lymphocytic leukemia (CLL) Rituxan Hycela is not indicated for non-malignant conditions
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	**For all indications** Confirmation that Rituxan Hycela™ will be initiated only after patient has received at least one full dose of rituximab by intravenous infusion **Non-Hodgkin Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL):** • Oncology clinic notes with treatment plan showing medically necessity. • Alternative treatments (i.e., Rituxan™) that have been tried or considered, have failed, or reasons they are contraindicated. • Oncology clinic notes with complete and signed treatment plan / order for Rituxan Hycela™ **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 & failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.
Age Restriction	18 years of age (For ages 18 – 21, check for CCS eligibility)
Prescriber Restrictions	• Oncologists or Hematologist-Oncologist • Off-Label Indications: The diagnosis and treatment must be within the scope of the treating physician's board-certified specialty.
Coverage Duration	Initial: Six months Renewal: 12 months
Other Criteria / Information	Criteria adapted from DHCS OCT 2024

HCPCS	Description	Dosing, Units
J9311	Injection, rituximab 10mg and hyaluronidase (Rituxan Hycela™)	**CLL** – 1,600 mg/26,800 Units subcutaneously on Day one of Cycles 2-6 (every 28 days) for a total of five cycles following a full intravenous dose at Day one, Cycle one (i.e., six cycles in total). **NHL** • Relapsed or refractory low-grade or follicular, CD20+, B-cell – 1,400 mg/23,400 Units subcutaneously once weekly for three or seven weeks, following a full dose of a rituximab. • Previously untreated follicular, in combination with first line chemotherapy and in patients achieving a complete or partial response to rituximab in combination with chemotherapy – 1,400 mg/23,400 Units subcutaneously once weekly for three or seven weeks, following a full dose of a rituximab. • Non-progressing, Follicular Lymphoma after first line CVP chemotherapy -- 1,400 mg/23,400 Units subcutaneously once weekly for three weeks every six months to maximum of 16 doses as a single agent following completion of 6-8 cycles of cyclophosphamide, vincristine, and prednisone chemotherapy. • Retreatment for Relapsed or Refractory, Follicular Lymphoma - 1,400 mg/23,400 Units subcutaneously once weekly for three or seven weeks, following a full dose of a rituximab at week one. • Previously untreated diffuse large B-cell lymphoma – 1,400 mg/23,400 Units subcutaneously on Day one of Cycles 2-8 of CHOP chemotherapy for up to seven cycles following a full dose of a rituximab product by intravenous infusion at Day one, Cycle one of CHOP chemotherapy (i.e., up to 6–8 cycles in total).

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
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