

Gold Coast Health Plan (GCHP) Medi-Cal Clinical Guidelines Tafasitamab-cxix (Monjuvi™)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	CD19-directed cytolytic antibody indicated: - In combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). - In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL). Limitations of Use: MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.
Exclusion Criteria	- History of positive hepatitis B and/or hepatitis C serology or known seropositivity for HIV. - Received prior therapy with immunomodulatory imide (IMiDs) agents (for example, lenalidomide). - Previously treated with CD19 targeted therapy (for example, axicabtagene, tisagenlecleucel, etc.). - Received a live vaccine or required parenteral antimicrobial therapy for an active infection within 14 days prior to first dose. - Have CNS lymphoma involvement.
Required Medical Information	<u>Initial – Must meet ALL of the following:</u> - Diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma. - Patient has relapsed and/or refractory disease - Patient has at least one bidimensional measurable disease site - Received at least one but no more than three previous systemic regimens for the treatment of DLBCL. A CD20 targeted therapy (e.g. rituximab) must have been included in one therapy line. - Not eligible for autologous stem cell transplant (ASCT). - Not received an allogeneic stem cell transplant or autologous stem cell transplant within the prior three months of therapy. - Using in combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity; OR as monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity.

	<u>Renewal:</u> • Continues to meet initial approval criteria • Absence of unacceptable toxicity from the drug such as severe infusion reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc. • Positive clinical response evidenced by stabilization of disease or decrease in size of tumor or tumor spread						
Age Restriction	18 years and older. 18 to 21 years of age – check CCS eligibility						
Prescriber Restrictions	Oncologist or hematologist						
Coverage Duration	Initial – 6 months; Renewal – 12 months						
Other Criteria/Information	Criteria adapted from DHCS May 2024 <table><tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J9349</td><td>Injection, tafasitamab-cxix, 2 mg (Monjuvi) 200mg single dose vial</td><td><u>DLBCL:</u> 12 mg/kg IV infusion • Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle • Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle • Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle. <u>FL:</u> 12mg/kg IV infusion • Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle • Cycles 4 to 12: Days 1 and 15 of each 28-day cycle. </td></tr></table>	HCPCS	Description	Dosing, Units	J9349	Injection, tafasitamab-cxix, 2 mg (Monjuvi) 200mg single dose vial	<u>DLBCL:</u> 12 mg/kg IV infusion • Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle • Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle • Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle. <u>FL:</u> 12mg/kg IV infusion • Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle • Cycles 4 to 12: Days 1 and 15 of each 28-day cycle.
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	Jan. 14, 2026	N/A	Yoonhee Kim, Senior Clinical Pharmacist	N/A