

Pharmacy Policy

Monjuvi

Policy Number: 9.721

Revision Number: 1.0

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
<p>Well Sense Health Plan</p> <input type="checkbox"/> New Hampshire Medicaid	<p>Boston Medical Center HealthNet Plan</p> <input checked="" type="checkbox"/> MassHealth - MCO <input checked="" type="checkbox"/> MassHealth - ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Monjuvi (Tafasitamab-cxix 200 mg)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. Member must have a diagnosis of refractory or relapsed diffuse large B-cell lymphoma (DLBCL); AND 2. Member must be 18 years of age or older; AND

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	<p>3. Therapy will be initiated in combination with lenalidomide for a maximum of 12 cycles; AND</p> <p>4. Member must have two prior lines of therapy (i.e. chemo-immunotherapy, if previously received anti-CD19 therapy re-biopsy must indicate CD-19 positive disease; AND</p> <p>5. Member is not a candidate for intensive therapy such as high dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT).</p>
Age Restriction	18 years of age
Prescriber Restriction	Prescribed by or in consultation of an oncologist.
Coverage Duration	12 Months
Quantity Limit	None
Other criteria	<p>1. Member has met initial criteria; AND</p> <p>2. Member does not show evidence of progressive disease while on therapy; AND</p> <p>3. Combination therapy with lenalidomide may not exceed a maximum of 12 cycles.</p>

Applicable Coding:

Code	Medication
J9349	Injection, tafasitamab-cxix, 2mg for MONJUVI

Clinical Background Information and References

1. Monjuvi (tafasitamab) [prescribing information]. Boston, MA: Morphosys US Inc; August 2020.
2. Salles G, Duell J, González Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *Lancet Oncol.* 2020;21(7):978-988. doi:10.1016/S1470-2045(20)30225-4 [PubMed 32511983]
3. UpToDate. Tafasitamab: Drug information. Topic 129156 Version 34.0. Accessed March 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Department	P&T Committee

Policy Revisions History

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Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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