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P&T Date: 08/07/2025

Monjuvi® (tafasitamab-cxix)

HCPCS: J9349

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:

- a. FDA approved indication
- b. FDA approved age
- c. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)
 - i. Must have had a prior treatment line of therapy with a CD20-targeting therapy
 - ii. Must be used in combination with lenalidomide for up to 12 cycles and as monotherapy thereafter
 - iii. Must not be eligible for autologous stem cell transplant (ASCT)
 - iv. Should not be used if treatment failure has occurred with lenalidomide
- d. Relapsed or refractory follicular lymphoma (FL)
 - i. Must have had a prior treatment line of therapy with a CD20-targeting therapy
 - ii. Must be used in combination with lenalidomide for up to 12 cycles, in combination with rituximab for up to 5 cycles, and as monotherapy thereafter
- e. Should not be used if treatment failure has occurred with Monjuvi or another CD19-directed antibody therapy
- f. Must have an ECOG performance score of 0 - 2

B. Quantity Limitations, Authorization Period and Renewal Criteria

- a. Quantity Limits: Align with FDA recommended dosing
- b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
- c. Renewal Criteria: Continuation of therapy until disease progression or unacceptable toxicity

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Monjuvi is indicated for use 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) and in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).
- Safety and efficacy were evaluated in the L-MIND trial, a single arm, open-label, phase 2 study of 71 patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Patients had 1 to 3 prior systemic therapies and were not candidates for high dose chemotherapy (HDC) followed by autologous stem cell transplantation. Patients were included if they had had prior treatment with a CD20-targeted therapy and had an ECOG performance score of 0 to 2. Patients were excluded if they had received prior therapy with a CD19-directed therapy or angiogenesis inhibitor. Subjects received Monjuvi 12 mg/kg intravenously in combination with lenalidomide for a maximum of 12 cycles followed by Monjuvi monotherapy until disease progression or unacceptable toxicity. The primary endpoint was best overall response rate, defined as the proportion of complete and partial responders, and duration of response. Best overall response was met in 39 (55%) patients with 37% having a complete response and 18% a partial response. The duration of response was 21.7 months.
- Safety and efficacy were evaluated in the inMIND trial, a randomized, double-blind, placebo-controlled phase III trial of 548 patients with relapsed or refractory FL grade 1, 2, or 3a. Patients were included if they had had prior treatment with a CD20-targeted therapy and had an ECOG performance score of 0 to 2. Subjects received Monjuvi 12 mg/kg intravenously in combination with lenalidomide for a maximum of 12 cycles and rituximab for a maximum of 5 cycles followed by Monjuvi monotherapy until disease progression or unacceptable toxicity. The primary endpoint was progression free survival (PFS). The mean PFS was 22.4 months with Monjuvi compared to 13.9 months with placebo which was statistically significant (p-value < 0.0001).

References:

1. Monjuvi [prescribing information]. Boston, MA: MorphoSys US, Inc.; June 2025.
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 multicenter, prospective, single-arm, phase 2 study. *Lancet Oncol*. 2020 Jul; 21 (7): 978 - 88.
3. SEER Cancer Stat Facts: Diffuse Large B-Cell Lymphoma. National Cancer Institute. Bethesda, MD. Available at: <https://seer.cancer.gov/statfacts/html/dlbcl.html>. Accessed on August 3, 2020.
4. National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2025). 2025 Feb 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on June 26, 2025.
5. Clinicaltrials.gov. A phase 3 study to assess efficacy and safety of tafasitamab plus lenalidomide and rituximab compared to placebo plus lenalidomide and rituximab in patients with relapsed/refractory (R/R) follicular lymphoma or marginal zone lymphoma (NCT04680052). Available at: <https://clinicaltrials.gov/study/NCT04680052?term=NCT04680052&rank=1#study-overview>. Accessed on June 26, 2025.

Policy History												
#	Date	Change Description										
1.8	Effective Date: 08/07/2025	Updated to include the new FDA approved indication of follicular lymphoma and removed the prescriber requirement										
1.7	Effective Date: 02/13/2025	Annual review of criteria was performed, no changes were made										
1.6	Effective Date: 02/08/2024	Annual review of criteria was performed, no changes were made										
1.5	Effective Date: 02/02/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days										
1.4	Effective Date: 10/06/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time										
1.3	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made.										
1.2	Effective Date 01/18/2021	UM medical management system update for BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCNA	Yes											
1.1	Effective Date 11/20/2020	UM medical management system update for BCN, BCNA, and MAPPO <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	No											
BCN	Yes											
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BCNA	Yes											
1.0	Effective Date: 10/08/2020	New policy										

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.