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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 08/07/2025

Lynozofic™ (linvoseltamab-gcpt)

HCPCS: J9601

Policy:

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

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Treatment of patients with relapsed or refractory multiple myeloma after at least 4 prior lines of therapy
 - d. Patients must have been treated with all of the following:
 - i. An immunomodulatory agent
 - ii. A proteasome inhibitor
 - iii. An anti-CD38 antibody
 - e. Patients must meet all of the following
 - i. ECOG performance status of 0 - 2
 - ii. Left ventricular ejection fraction greater than or equal to 40%
 - iii. No stem cell transplant within 12 weeks of Lynzofic administration
 - f. Have not received prior treatment with any bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager therapy
 - g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
- 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: Treatment may be continued until disease progression or until unacceptable toxicity occurs

***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:

- Lynozyfic is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- Safety and efficacy were evaluated in the LINKER-MM1 trial, a phase I/II, open-label, multicenter study of 80 patients with relapsed/refractory multiple myeloma who had previously received at least 3 prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 antibody. . Subjects had not received BCMA-directed bispecific antibody therapy, prior bispecific T-cell engaging therapy, or prior BCMA CAR-T cell therapy. The study excluded patients who had known multiple myeloma brain lesions or meningeal involvement, history of a neurodegenerative condition, history of seizure within 12 months prior to study enrollment, active infection, a history of stem cell transplantation within 12 weeks, and an ECOG performance score of 2 or higher. The primary endpoint were objective response rate (ORR). The ORR was 70% with 45% achieving a complete response (CR) or better. The median time to first response was 0.95 months (range: 0.5 to 6 months). With a median follow-up of 11.3 months among responders, the estimated duration of response (DOR) rate was 89% (95% CI: 77, 95) at 9 months and 72% (95% CI: 54, 84) at 12 months.
- Due to the risk of cytokine release syndrome and neurological toxicities, the step-up doses of Lynozyfic are required to be administered in an inpatient setting.
- Lynozyfic has not been studied when given following prior treatment with Lynozyfic or following any other bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager therapy.

References:

1. Lynozyfic [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; July 2025.
2. Bumma N, Jagannath S, Lee HC, et al. Linvoseltamab for treatment of relapsed/refractory multiple myeloma. J Clin Onc. 2024 August; 42 (22): 2702 – 12.
3. National Comprehensive Cancer Network. Multiple myeloma (Version 1.2026). 2025 June 24. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on July 7, 2025.

Policy History												
#	Date	Change Description										
1.1	Effective Date: 05/13/2026	UM medical management system update for BCBS, BCN, MAPPO, and BCNA <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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1.0	Effective Date: 08/07/2025	New Policy <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>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* 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>.