Blue Cross Blue Shield Blue Care Network of Michigan

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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.

Effective Date: 02/08/2024

Lunsumio™ (mosunetuzumab-axgb)

HCPCS: J9350

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. Prescribed by or in consultation with an oncologist
   d. Treatment of patients with relapsed or refractory grade 1 – 3a follicular lymphoma after at least 2 prior lines of therapy
   e. Patients must have been treated with all of the following:
      i. An alkylating agent
      ii. An anti-CD20 antibody
   f. Must have at least one measurable lesion
   g. Patients must meet all of the following
      i. ECOG performance status of 0 - 2
      ii. No known central nervous system involvement with follicular lymphoma
      iii. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
      iv. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
      v. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, unstable arrythmias, or New York Heart Association Class III or greater congestive heart failure events within 6 months
      vi. No stroke event within 2 years of therapy administration
      vii. No prior allogeneic stem cell transplant
      viii. No autoimmune disease with the exception of controlled/treated hypothyroidism, disease-related immune thrombocytopenic purpura, or hemolytic anemia
   h. Have not received prior treatment with any bispecific CD20-directed CD3 T-cell engager
   i. 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 completion of the full FDA recommended treatment course, 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:

- Lunsumio is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

- Safety and efficacy were evaluated in a phase II, open-label, multicenter, multi-cohort study of 90 patients with relapsed/refractory follicular lymphoma who had received at least two prior therapies, including an anti-CD20 monoclonal antibody and an alkylating agent. Patients were included if they had one measurable lesion, grade 1 – 3a disease, and an ECOG score of 1 or less. The study excluded patients with active infections; a history of autoimmune disease; prior allogeneic transplant; any history of CNS lymphoma; myocardial infarction, cardiac angioplasty or stenting, unstable angina, unstable arrythmias, or New York Heart Association Class III or greater congestive heart failure events within 6 months of therapy administration; or a stroke event within 2 years of therapy administration. Patients received step-up doses of 1 mg on cycle 1 day 1 and 2 mg on cycle 1 day 8, followed by 60 mg on cycle 1 day 15 and on cycle 2 day 1, then 30 mg every 3 weeks in subsequent 21 day cycles. Lunsumio was administered for 8 cycles unless patients experienced progressive disease or unacceptable toxicity. After 8 cycles, patients with a complete response discontinued therapy. Patients with a partial response or stable disease continued treatment up to 17 cycles unless they experienced progressive disease or unacceptable toxicity. The primary endpoints were objective response rate (ORR) and duration of response (DOR). An objective response was seen in 80% (72/90 [95% CI: 70 - 88]) of patients treated with Lunsumio, with a majority maintaining responses for at least 18 months (57% [95% CI: 44 - 70]). The median DOR among those who responded was almost two years (22.8 months [95% CI: 10 - not reached]). A complete response (CR) was achieved in 60% of patients (54/90 [95% CI: 49 - 70]).

- Disease should be measured/staged with PET-CT. Focal uptake in nodal and extranodal sites is considered involvement with lymphoma, including spleen, liver, bone, thyroid, and so on. A measurable node must have a longest diameter (LDi) greater than 1.5 cm. A measurable extranodal lesion should have an LDi greater than 1.0 cm. All other lesions (including nodal, extranodal, and assessable disease) should be followed as nonmeasured disease (eg, cutaneous, GI, bone, spleen, liver, kidneys, pleural or pericardial effusions, ascites).

- Lunsumio has not been studied when given following prior treatment with Lunsumio or following any other bispecific CD20-directed CD3 T-cell engager.

References:

1. Lunsumio [prescribing information}. South San Francisco, CA: Genentech, Inc.; December 2022.
2. United States Food and Drug Administration. FDA grants accelerated approval to mosunetuzumab-axgb for relapsed or refractory follicular lymphoma. 2022 Dec 22. Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mosunetuzumab-axgb-relapsed-or-refractory-follicular-lymphoma. Accessed on December 27, 2022.
3. National Comprehensive Cancer Network. B-cell lymphomas (Version 6.2023). 2023 Oct 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on December 28, 2023.

4. Budde LE, Sehn LH, Matasar M, et al. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicenter, phase 2 study. Lancet Oncol. 2022 Aug; 23 (8): 1055 - 65.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.2</td><td>Effective Date: 02/08/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/23/2023</td><td>UM medical management system update for BCNA, MAPPO, BCN, and 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></td></tr>
<tr><td>1.0</td><td>Effective Date: 02/02/2023</td><td>New policy</td></tr>
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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.*