Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

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: 10/03/2024

Columvi™ (glofitamab-gxbm)

HCPCS: J9286

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 diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS) or LBCL arising from follicular lymphoma after at least 2 prior lines of therapy
   d. Patients must have been treated with all of the following:
      i. An anti-CD20 antibody containing regimen
      ii. An anthracycline containing regimen
   e. Patients must meet all of the following
      i. ECOG performance status of 0 - 2
      ii. No prior allogenic stem cell transplant
      iii. No known active CNS involvement of lymphoma
   f. Have not received prior treatment with Columvi or any other bispecific CD20-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: Continue for a maximum of 12 cycles or until disease progression or unacceptable toxicity, whichever occurs first

***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:

- Columvi is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

- Safety and efficacy were evaluated in the NP30179 study, a phase I/II, open-label, multicenter, single-arm trial that included 132 patients with relapsed or refractory DLBCL after two or more lines of systemic therapy, which included an anti-CD20 monoclonal antibody regimen and an anthracycline containing regimen. Subjects also must have CD20 positive disease, measurable disease, and an ECOG score of 0 – 2. Patients were also excluded from the trial if creatinine clearance was greater than 50 mL/min; alanine aminotransferase was less than 3 times the upper limit of normal; they had known active CNS involvement of lymphoma; there was an infection that was uncontrolled or required IV or long-term oral antimicrobial therapy; or they could not have HIV infection or hepatitis B or C virus infection if the viral load was detectable. Those with myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months of study entry were not enrolled in the trial. The primary outcome was complete response rate (CR). The median time to a complete response was 42 days (95% CI: 42, 44) and the majority (78%) of complete responses were ongoing at 12 months. The 12 month progression-free survival was 37% (95% CI: 28, 46).

- 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).

- Due to the risk of cytokine release syndrome (CRS), Columvi should be administered in an inpatient setting during cycle 1, day 8. Patients who experienced any grade CRS following the cycle 1 day 8 dose should be hospitalized during and for 24 hours after completion of cycle 1 day 15 dosage of 10 mg. For subsequent doses, patients who experienced grade 2 or greater CRS with their previous infusion should be hospitalized during and for 24 hours after the completion of the next Columvi infusion.

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

References:

1. Columvi [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2023.
2. National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2024). 2024 April 30. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on August 1, 2024.
3. Dickinson MJ, Carlo-Stella C, Morschhauser F, at al. Glofitamab for relapsed or refractory diffuse large b-cell lymphoma. NEJMed. 2022 Dec 15; 387: 2220 – 31.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.3</td><td>Effective Date: 10/03/2024</td><td>Updated to remove requirements that the disease is CD20 positive, the disease is measurable, creatinine clearance greater than 50 mL/min, hepatic transaminases less than 2 times the upper limit of normal, no infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy, no HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable, no myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months, and that the disease must not have been refractory to a prior Gazyva monotherapy regimen</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/08/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.1</td><td>Effective Date: 03/01/2024</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: 08/10/2023</td><td>New Policy</td></tr>
</table>

** 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.*