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: 10/03/2024

Tecvayli™ (teclistamab-cqyv)

HCPCS: J9380

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 multiple myeloma after at least 4 prior lines of therapy
   e. Patients must have been treated with all of the following:
      i. An immunomodulatory agent
      ii. A proteasome inhibitor
      iii. An anti-CD38 antibody
   f. Patients must meet all of the following
      i. ECOG performance status of 0 - 2
      ii. No known central nervous system involvement with myeloma
      iii. No allogenic stem cell transplant within the past 6 months
      iv. No autologous stem cell transplant within the past 12 weeks
   g. Have not received prior treatment with any bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager therapy
   h. 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:

- Tecvayli is a bispecific 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 MajesTEC-1 study, a single-arm, multi-cohort, open-label, phase I/II trial of 110 patients with relapsed or refractory multiple myeloma who had previously received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Subjects had not received prior BCMA-targeted therapy. About 78% of patients had received at least 4 prior lines of therapy, with a median number of 5. The study excluded patients who had stroke, seizure, allogeneic stem cell transplantation (SCT) within the past 6 months, an ECOG performance score of 2 or higher, known active CNS involvement or clinical signs of meningeal involvement of multiple myeloma, or active or documented history of autoimmune disease. The primary endpoint was overall response rate (ORR). The median time to first response was 1.2 months (range: 0.2 to 5.5 months). With a median follow-up of 7.4 months among responders, the estimated duration of response (DOR) rate was 90.6% (95% CI: 80.3%, 95.7%) at 6 months and 66.5% (95% CI: 38.8%, 83.9%) at 9 months. The ORR was 61.8% (95% CI: 52.1%, 70.9%).

- 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 and neurological toxicities, the step-up doses of Tecvayli are required to be administered in an inpatient setting.

- Tecvayli has not been studied when given following prior treatment with Tecvayli or following any other bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager therapy.

References:

1. Tecvayli [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; May 2024.
2. Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. NEJM. 2022 Aug 11; 387 (6): 495 - 505.
3. Usmani SZ, Garfall AL, van de Donk NWCJ, et al. Teclistamab, a b-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC-1): a multicentre, open-label, single-arm, phase 1 study. Lancet. 2021 Aug 21; 398 (10301): 665 - 74.
4. National Comprehensive Cancer Network. Multiple myeloma (Version 4.2024). 2024 April 26. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on August 12, 2024.

<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 the requirements of active disease, liver function, kidney function, no uncontrolled infection, no detectable hepatitis B or C viral load, cardiac function, no stroke event within 6 months of therapy administration, no pulmonary disease requiring oxygen dependence, no seizures within 6 months of therapy administration, and no active autoimmune disease. Also added the requirements that the patient has not had an allogenic stem cell transplant within the past 6 months and no autologous stem cell transplant within the past 12 weeks</td></tr>
<tr><td>1.2</td><td>Effective Date: 10/12/2023</td><td>Updated to align criteria with the other bispecific BCMA directed CD3 T-cell engager therapies including adding liver enzymes tests to be less than or equal to 3 times the ULN, creatinine clearance greater than or equal to 40 mL/min, left ventricular ejection fraction greater than 40%, no autoimmune disease, and removed the requirement ensuring there is no HIV infection</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: 12/01/2022</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.*