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

Elrexfio™ (elranatamab-bcmm)

HCPCS: J1323

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. Left ventricular ejection fraction greater than or equal to 40%
      iii. No stem cell transplant within 12 weeks of Elrexfio administration
   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:

- Elrexfio 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 MagnetisMM-3 study, a single-arm, multi-center, open-label, phase I/II trial of 123 patients in cohort A and 64 patients in cohort B 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 in cohort A had not received prior BCMA-targeted therapy while those in cohort B had prior BCMA-targeted therapy. The study excluded patients who had stroke or significant cardiovascular disease within the past 6 months, an ECOG performance score of 2 or higher, or active or documented history of autoimmune disease. The primary endpoints were overall response rate (ORR) and duration of response (DoR). In cohort A, the ORR was 58% with an estimated 82% maintaining the response for at least nine months. The median time to first response in cohort A was 1.2 months. In cohort B, the ORR was 33% after a median follow-up of 10.2 months with an estimated 84% maintaining the response for at least nine months. In longer-term efficacy data for cohort A presented at the 2023 European Hematology Association meeting, the objective response rate was 61%, and median duration of response, overall survival, and progression-free survival had not yet been reached at 14.7 months median follow-up. For the responding patients, the probability of maintaining a response at 15 months was 72%. Among responding patients who switched to every-other-week dosing at least 6 months prior to the data cut-off date (n=50), 80% maintained or improved their response after the switch with 38% attaining a complete response or better after the switch.

- Due to the risk of cytokine release syndrome and neurological toxicities, the step-up doses of Elrexfio are required to be administered in an inpatient setting.

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

References:

1. Elrexfio [prescribing information]. New York, NY: Pfizer Inc.; August 2023.
2. Clinicaltrial.gov. MagnetisMM-3: study of elranatamab (PF-06863135) monotherapy in participants with multiple myeloma who are refractory to at least one PI, one IMiD and one anti-CD38 mAb. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04649359. Accessed on August 16, 2023.
3. Lesokhin AM, Tomasson MH, Arnulf B, et al. Elranatamab in relapsed or refractory multiple myeloma: phase 2 MagnetisMM-3 trial results. Nat Med. 2023 Aug 15. doi: 10.1038/s41591-023-02528-9.
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 7, 2024.

<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: 10/03/2024</td><td>Updated to remove the requirements of active disease, no known central nervous system involvement with myeloma, liver function, kidney function, no uncontrolled infection, no detectable hepatitis B or C viral load, 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 requirement that the patient has not had a stem cell transplant within 12 weeks of Elrexfio administration</td></tr>
<tr><td>1.1</td><td>Effective Date: 06/20/2024</td><td>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></td></tr>
<tr><td>1.0</td><td>Effective Date: 10/12/2023</td><td>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></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.*