09-J4000-64

Original Effective Date: 11/15/23

Reviewed: 06/12/24

Revised: 07/15/24

Subject: Elranatamab-bcmm (Elrexfio) Subcutaneous Injection

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Elranatamab (Elrexfio) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engaging antibody approved by the US Food and Drug Administration (FDA) on August 14, 2023, for the treatment of adult patients with relapsed or refractory multiple myeloma (MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. This indication was approved under accelerated approval based on response rate and durability of response, and continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s). Prior to FDA approval elranatamab was granted orphan drug designation in October 2021 for the treatment of MM. Elranatamab is the third FDA-approved bispecific T-cell engager (BiTE) and the second BCMA-directed BiTE for the treatment of MM; the first being teclistamab (Tecvayli), a BCMA-directed BiTE, approved in October 2022 for this same patient population. Elranatamab binds to the CD3 receptor expressed on the surface of T-cells and BCMA expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. In vitro, elranatamab activated T-cells, caused the release of various proinflammatory cytokines, and resulted in the lysis of multiple myeloma cells.

The National Comprehensive Cancer Network (NCCN) Guidelines for MM (Version 4.2024 – April 26, 2024) list elranatamab under “Relapse/Refractory Disease After 3 Prior Therapies” and under “Preferred Regimens” as a category 2A recommendation for the treatment of previously treated MM. Under this section, the recommendations are further categorized as “After at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor (PI), and an immunomodulatory agent (IMiD)”. The other treatments listed in this same “Preferred Regimens” section include the CAR-T cell therapies of idecabtagene vicleucel (Abecma) and ciltacabtagene autoleucel (Carvykti), and the bispecific antibodies of talquetamab (Talvey) and teclistamab (Tecvayli). The NCCN also includes

footnotes stating “Autologous HCT should be considered in patients who are eligible and have not previously received HCT or had a prolonged response to initial HCT” and “Patients can receive more than one BCMA targeted therapy, but optimal sequencing is unclear”.

The safety and efficacy of elranatamab leading to initial FDA approval was evaluated in patients with relapsed or refractory MM in an open-label, single arm, multi-center study (MagnetisMM-3, NCT04649359). The study included patients who were refractory to at least one PI, one IMiD, and one anti-CD38 monoclonal antibody. MagnetisMM-3 included 123 patients naïve to prior BCMA-directed therapy (pivotal Cohort A) and 64 patients with prior BCMA-directed antibody drug conjugate (ADC) or CAR T-cell therapy (supportive Cohort B). Patients had measurable disease by International Myeloma Working Group (IMWG) criteria at enrollment. The study included patients with an ECOG score of ≤2, adequate baseline bone marrow (ANC ≥1.0 x 10^9/L, platelet count ≥25 x 10^9/L, hemoglobin level ≥8 g/dL), renal (CrCL ≥30 mL/min), and hepatic (AST and ALT ≤2.5 x ULN, total bilirubin ≤2 x ULN) function, and left-ventricular ejection fraction ≥40%. Patients with a stem cell transplant within 12 weeks prior to enrollment and active infections were excluded from the study. Eligible patients received subcutaneous elranatamab step-up doses of 12 mg on Day 1 and 32 mg on Day 4 of treatment, followed by the first treatment dose (76 mg) on Day 8 of treatment. Thereafter, patients received 76 mg once weekly. After 24 weeks, in patients who achieved an IMWG response category of partial response or better with responses persisting for at least 2 months, the dose interval was changed from every week to every 2 weeks.

The 123 patients enrolled in pivotal Cohort A had received a median of 5 prior lines of therapy (range: 2 to 22). Ninety-seven patients who were not exposed to prior BCMA-directed therapy and received at least four prior lines of therapy comprised the efficacy population. Among the 97 patients in the efficacy population, the median age was 69 (range: 46 to 89) years with 18.6% of patients ≥75 years of age. Forty percent were female; 59.8% were White, and 13.4% were Asian. Disease stage (R-ISS) at study entry was 20.6% in Stage I, 53.6% in Stage II, and 17.5% in Stage III. The median time since initial diagnosis of MM to enrollment was 79.6 (range: 16 to 228) months. 96.9% were triple-class refractory, and 94.8% were refractory to their last line of therapy. 69.1% received prior autologous stem cell transplantation, and 7.2% received prior allogenic stem cell transplantation. High-risk cytogenetics were present in 22.7% of patients. 34.0% of patients had extramedullary disease at baseline by BICR. Efficacy was based on response rate and duration of response (DOR), as assessed by BICR based on IMWG criteria. Efficacy results from BCMA-directed therapy naïve patients are displayed in Table 1 below. The median (range) time to first response (TTR) was 1.22 (0.9 to 6.5) months. With a median follow-up of 11.1 months (95% CI: 10.6, 12.0) among responders, the DOR rate at 6 months was 90.4% (95% CI: 78.4%, 95.9%) and at 9 months was 82.3% (95% CI: 67.1%, 90.9%).

Table 1: Efficacy Results for MagnetisMM-3

	N=97
Objective response rate (ORR: sCR+CR+VGPR+PR)	56 (57.7%)
95% CI	(47.3, 67.7)
Complete response (CR) or better*	25 (25.8%)
Very good partial response (VGPR)	25 (25.8%)
Partial response (PR)	6 (6.2%)
Duration of Response (DOR) (months)	

Median (95% CI)	NR (12.0, NE)

NE = not estimable, NR = Not reached

*Complete response or better = Stringent complete response (sCR) + complete response (CR)

Among the 64 patients enrolled in Cohort B who previously received a PI, an IMiD, an anti-CD38 monoclonal antibody, and a BCMA-directed therapy, 63 patients received at least four prior lines of therapy. Patients had received a median of 8 prior lines of therapy (range: 4 to 19); 73% and 32% received prior BCMA-directed ADC and CAR T-cell therapy, respectively. Confirmed ORR by BICR was 33.3% (95% CI: 22.0, 46.3). After a median (95% CI) follow-up of 10.2 (9.9, 11.0) months among responders, median DOR was not reached (95% CI: NE, NE) and the DOR rate at 9 months was 84.3% (95% CI: 58.7, 94.7).

The safety of elranatamab was also evaluated in MagnetisMM-3. The safety population described (n=183) includes patients who received the recommended dosage regimen of 12 mg subcutaneously on Day 1, 32 mg on Day 4, and 76 mg once weekly starting on Day 8. Among patients who received elranatamab, 42% were exposed for 6 months or longer and 9% were exposed for one year or longer. Serious adverse reactions occurred in 68% of patients at the recommended dosing schedule. Serious adverse reactions in >2% of patients included pneumonia (25%), sepsis (13%), CRS (13%), upper respiratory tract infection (4.4%), acute kidney injury (3.8%), urinary tract infection (3.3%), COVID-19 (3.3%), encephalopathy (3.3%), pyrexia (2.2%), and febrile neutropenia (2.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.3%), sepsis (2.7%), acute respiratory distress syndrome (0.5%), cardio-respiratory arrest (0.5%), cardiogenic shock (0.5%), cardiopulmonary failure (0.5%), COVID-19 (0.5%), failure to thrive (0.5%), and pulmonary embolism (0.5%). Permanent discontinuations due to an adverse reaction occurred in 17% of patients. Adverse reactions which resulted in permanent discontinuation of elranatamab in >2% of patients included septic shock (2.2%). Dosage interruptions of due to an adverse reaction occurred in 73% of patients. Adverse reactions which resulted in dose interruptions in >5% of patients included neutropenia, pneumonia, COVID-19, upper respiratory tract infection, thrombocytopenia, and anemia. The most common adverse reactions (≥20%) were CRS, fatigue, injection site reaction, diarrhea, upper respiratory tract infection, musculoskeletal pain, pneumonia, decreased appetite, rash, cough, nausea, and pyrexia. The most common Grade 3 to 4 laboratory abnormalities (≥30%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased white blood cells, and decreased platelets. Refer to the package labeling for the specific percentages.

POSITION STATEMENT:

Initiation of elranatamab (Elrexfio) **meets the definition of medical necessity** when **EITHER** of the following criteria are met ("1" or "2"):

1. Member has a diagnosis of relapsed or refractory multiple myeloma (MM) and **ALL** of the following ("a" to "f") - *medical record documentation confirming the patient's diagnosis and complete treatment history must be submitted*:
    a. Member has received **FOUR or more** appropriate prior lines of therapy of adequate duration for the treatment of their MM

NOTE: Primary therapy, with or without subsequent hematopoietic cell transplant, followed by maintenance therapy is considered a single line of therapy

b. Member's prior MM treatments have included **ALL** of the following ("i", "ii", and "iii"):
    i. An anti-CD38 monoclonal antibody [for example - daratumumab (Darzalex), daratumumab-hyaluronidase (Darzalex Faspro), or isatuximab (Sarclisa)]
    ii. A proteasome inhibitor [for example - bortezomib, carfilzomib (Kyprolis), or ixazomib (Ninlaro)]
    iii. An immunomodulatory agent [for example - lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid)]
c. Member's MM was **NOT** previously refractory (i.e., disease progression on treatment or progression within 60 days after the last dose of a given therapy) to an elranatamab-containing treatment regimen
d. Elranatamab will be used as single-agent therapy for the member's MM (i.e., not used in combination with other MM treatments)
e. The ordering provider and the infusing healthcare facility is certified in the ELREXFIO REMS program
f. Dosage of elranatamab does not exceed the following:
    - Day 1 (Step-up dose 1) – 12 mg
    - Day 4 (Step-up dose 2) – 32 mg
    - Day 8 (First treatment dose) – 76 mg
    - One week after first treatment dose through week 24 – 76 mg once weekly
    - Week 25 and thereafter – 76 mg once every two weeks

2. Member has another FDA-approved or NCCN-supported diagnosis, and **ALL** of the following are met ("a" to "d"):
    a. **EITHER** of the following ("i" or "ii"):
        i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
        ii. Indication **AND** usage are recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation
    b. Elranatamab is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis
    c. The ordering provider and the infusing healthcare facility is certified in the ELREXFIO REMS program
    d. Dosage of elranatamab does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

Approval duration: 6 months

Continuation* of elranatamab (Elrexfio meets the definition of medical necessity when **ALL** of the following criteria are met ("1" to "3"):

1. An authorization or reauthorization for elranatamab has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of multiple myeloma or other FDA-approved or NCCN-supported diagnosis (if another health plan, documentation of a health plan-paid claim for elranatamab during the 90 days immediately before the authorization request must be provided); **OR** the member previously met **ALL** indication-specific initiation criteria
2. The ordering provider and the infusing healthcare facility is certified in the ELREXFIO REMS program
3. **EITHER** of the following based on the member's diagnosis ("a" or "b"):
    a. Multiple myeloma, and **ALL** of the following ("i", "ii", and "iii"):
        i. Elranatamab is being used as single-agent therapy for the member's MM (i.e., not used in combination with other MM treatments)
        ii. Dosage of elranatamab does not exceed the following:
            - One week after first treatment dose through week 24 – 76 mg once weekly
            - Week 25 and thereafter – 76 mg once every two weeks
        iii. Provider attestation that the member has not had disease progression during elranatamab treatment
    b. Other FDA-approved or NCCN-supported diagnosis, and **ALL** of the following ("i", "ii", and "iii"):
        i. Dosage of elranatamab does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guideline for the specific diagnosis
        ii. Elranatamab is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis
        iii. Member has had a beneficial response to treatment with elranatamab

Approval duration: 1 year

**For members that may have only completed the initial step-up dosing schedule during an inpatient admission, please refer to the initiation criteria*

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 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.
    - This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).
- The recommended dosing schedule is as follows:
    - Step-up dosing schedule:
        - Day 1 (Step-up dose 1) – 12 mg
        - Day 4* (Step-up dose 2) – 32 mg
        - Day 7[#] (First treatment dose) – 76 mg
    - Weekly dosing schedule[†]:
        - One week after first treatment dose and weekly thereafter through week 24 – 76 mg
    - Biweekly (every 2 weeks) dosing schedule (responders only week 25 onward) [†]:
        - Week 25 and every 2 weeks thereafter – 76 mg

      **A minimum of 2 days should be maintained between step-up dose 1 (12 mg) and step-up dose 2 (32 mg)*

      [#]*A minimum of 3 days should be maintained between step-up dose 2 (32 mg) and the first treatment (76 mg) dose*

      [†]*A minimum of 6 days should be maintained between treatment doses*
- Elranatamab should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity, including ICANS.
- Due to the risk of CRS, patients should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.
- Elranatamab 76 mg/1.9 mL (40 mg/mL) vial and 44 mg/1.1 mL (40 mg/mL) vial are supplied as ready-to-use solution that do not need dilution prior to administration.
- Administer the following pre-treatment medications approximately 1 hour before the first three doses of elranatamab in the step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose, to reduce the risk of CRS:
    - acetaminophen (or equivalent) 650 mg orally
    - dexamethasone (or equivalent) 20 mg orally or intravenously
    - diphenhydramine (or equivalent) 25 mg orally
- If a dose of elranatamab is delayed outside of the recommended dosing schedule, a new treatment schedule is required - refer to the product labeling.

Dose Adjustments

- Hepatic Impairment - Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no initial dosage adjustments are needed. Therapy interruption or permanent discontinuation may be necessary in patients who develop severe hepatotoxicity.
- Renal Impairment - Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no initial dosage adjustments are needed.

- Adverse Effects - Dosage reductions of elranatamab are not recommended. However, dosage delays may be required to manage toxicities related such as CRS, neurologic toxicity, and ICANS. Refer to the product labeling for the specific recommendations.

Drug Availability

- Sterile, preservative-free, clear to slightly opalescent, and colorless to pale brown liquid solution supplied as follows:
  - One 76 mg/1.9 mL (40 mg/mL) single-dose vial in a carton.
  - One 44 mg/1.1 mL (40 mg/mL) single-dose vial in a carton
- Store refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the original carton until time of use to protect from light. Do not freeze or shake the vial or carton.

PRECAUTIONS:

Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY INCLUDING IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving Elrexfio. Initiate treatment with Elrexfio step-up dosing schedule to reduce risk of CRS. Withhold Elrexfio until CRS resolves or permanently discontinue based on severity.
- Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving Elrexfio. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold Elrexfio until neurologic toxicity resolves or permanently discontinue based on severity.
- Because of risk of CRS and neurologic toxicity, including ICANS, Elrexfio is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ELREXFIO REMS.

Contraindications

- None

Precautions/Warnings

- **Cytokine Release Syndrome** – see Boxed Warning
- **Neurologic Toxicity including ICAN** – see Boxed Warning
- **ELREXFIO REMS** – see Boxed Warning
- **Infections**: Can cause severe, life-threatening, or fatal infections. Monitor patients for signs and symptoms of infection and treat appropriately. Do not initiate treatment in patients with active infections.
- **Neutropenia**: Monitor complete blood cell counts at baseline and periodically during treatment.
- **Hepatotoxicity**: Can cause elevated ALT, AST, and bilirubin. Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated.

- **Embryo-Fetal Toxicity**: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

BILLING/CODING INFORMATION:

HCPCS Coding

J1323	Injection, elranatamab-bcmm, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Autologous - cells or tissues obtained from the same individual (as opposed to from a different person).

Heavy chain - the larger component of an immunoglobulin. There are five types: IgG, IgA, IgM, IgD, and IgE.

Immunoglobulins (a.k.a., antibodies) - proteins made by normal plasma cells that have an important role in fighting infection as part of the humoral immune response. Antibodies are composed of two heavy chains and two light chains that form a larger complex. Each plasma cell produces only one type of heavy chain and one type of light chain.

Light chain - the smaller component of an immunoglobulin. There are two types: kappa and lambda.

Myeloma Protein (M-Protein) - a nonfunctional immunoglobulin protein or protein fragment produced by malignant plasma cells (or myeloma cells). Since myeloma cells are monoclonal, the M-proteins for a given patient are structurally identical. Both portions of an immunoglobulin (the heavy chain and light chain) can be found in the serum, while only light chains can be found in the urine.

Plasma cell - a fully differentiated B lymphocyte (a type of white blood cell) that is specialized for immunoglobulin production and is found primarily in bone marrow.

Primary refractory MM - patients who never achieve at least a MR to initial induction therapy and progress while on therapy.

Progressive MM - at least a 25% increase from nadir in the serum M-protein (absolute increase must be ≥0.5 g/dL) or urine M-protein (absolute increase must be ≥200mg/24 hours), or in the difference between involved and uninvolved serum-free light-chain (FLC) levels (with an abnormal FLC ratio and FLC difference >100 mg/L).

Relapsed and refractory MM - patients who never achieve at least a MR or who progress within 60 days of their last therapy.

RELATED GUIDELINES:

Allogeneic Bone Marrow and Stem Cell Transplantation, 02-38240-01
Carfilzomib (Kyprolis) IV, 09-J1000-81
Chimeric Antigen Receptor (CAR) T-Cell Therapies, 09-J3000-94
Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro), 09-J2000-49
Doxorubicin HCl Liposome (Doxil) IV, 09-J0000-91
Elotuzumab (Empliciti) IV, 09-J2000-50
Isatuximab (Sarclisa) Injection, 09-J3000-67
Ixazomib (Ninlaro), 09-J2000-51
Oral Oncology Medications, 09-J3000-65
Talquetamab-tgvs (Talvey) Injection, 09-J4000-63
Teclistamab (Tecvayli) Injection, 09-J4000-46
Thalidomide (Thalomid) Capsules, 09-J1000-56

OTHER:

None

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 06/12/24.

GUIDELINE UPDATE INFORMATION:

11/15/23	New Medical Coverage Guideline.
01/01/24	Revision: Added HCPCS code C9165.
04/01/24	Revision: Added HCPCS code J1323 and deleted codes C9165 and J9999.
07/15/24	Review and revision to guideline consisting of updating the references.