Medical Policy:

Elrexfio (elranatamab-bcmm) injection solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.394	April 3, 2025	October 3, 2023

Definitions

ELREXFIO is 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. Elranatamab-bcmm is a bispecific B-cell maturation antigen (BCMA)-directed T-cell engaging antibody that binds BCMA on plasma cells, plasmablasts, and multiple myeloma cells and CD3 on T-cells leading to cytolysis of the BCMA-expressing cells. Elranatamab-bcmm activated T-cells, caused proinflammatory cytokine release, and resulted in multiple myeloma cell lysis.

Length of Authorization

Initial Approval: 6 months
Continuation: 12 months

Dosing Limits [Medical Benefit]

The recommended dosing schedule for ELREXFIO is provided in Table 1. The recommended dosages of ELREXFIO subcutaneous injection are: step-up dose 1 of 12 mg on Day 1, step-up dose 2 of 32 mg on Day 4, followed by the first treatment dose of 76 mg on Day 8, and then 76 mg weekly thereafter through week 24.

Max Units (per dose and over time) [HCPCS Unit]:

- Titration: 44 mg on day one, 44 mg on day four and 76 mg on day eight
- Maintenance: 76 mg weekly through week 24 then 76 mg every two weeks thereafter

Table 1. ELREXFIO Dosing Schedule

Dosing Schedule	Day	ELREXFIO Dose	
Step-up Dosing Schedule	Day 1*	Step-up dose 1	12 mg
	Day 4*‡	Step-up dose 2	32 mg
	Day 8*‡	First treatment dose	76 mg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter§ through week 24	Subsequent treatment doses	76 mg
Biweekly (Every 2 Weeks) Dosing Schedule *Responders only week 25 onward	Week 25 and every 2 weeks thereafter§	Subsequent treatment doses	76 mg

Guideline

I. INITIAL CRITERIA

1. **Multiple Myeloma**
   A. Patient is 18 years of age or older; **AND**
   B. Patient has tried and failed at least four prior therapies including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 Antibody

II. RENEWAL CRITERIA

1. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
2. Member has not experienced unacceptable toxicity from the drug.

Applicable Procedure Codes

Code	Description
J1323	Injection, elranatamab-bcmm, 1 mg

Applicable NDCs

Code	Description
00069-2522-xx	Elrexfio 40mg/mL 1.1mL
00069-4494-xx	Elrexfio 40mg/mL 1.9mL

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/3/2025	Annual Review: updated diagnosis codes.
EmblemHealth & ConnectiCare	3/18/2024	Annual Review: removed C9399 and J9999, added C9165 and J1323, updated dosing limits, no criteria changes
EmblemHealth & ConnectiCare	10/3/2023	New Policy

References

1. Product Information: Elrexfio injection solution, elranatamab-bcmm injection solution. Pfizer Laboratories Div Pfizer, Inc (per FDA), New York, NY. 2023.