

Medical Policy:

Elrexfio (elranatamab-bcmm) injection solution

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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	Elrexio 40mg/mL 1.1mL
00069-4494-xx	Elrexio 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.