Medical Drug Clinical Criteria

Subject:	Elrexfio (elranatamab-bcmm)		
Document #:	CC-0248	**Publish Date:**	~~12/23/2024~~12/22/2025
Status:	Revised	**Last Review Date:**	~~11/15/2024~~11/14/2025

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Overview

This document addresses the use of Elrexfio (elranatamab-bcmm) injection for subcutaneous use. Elrexfio is a bispecific B-cell maturation antigen (BCMA)-directed T-cell engager indicated for the treatment of those 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. Elrexfio has a black box warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS). Elrexfio is only available through a restricted program under a REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Elrexfio is a subcutaneous injection administer as step-up doses of 12 mg, 32 mg, and followed by the first treatment dose of 76 mg and then 76 mg weekly thereafter though week 24.

Those who have received at least 24 weeks of treatment and achieved a response [partial response or better] and maintained this response for at least 2 months, the dose interval should transition to an every two week schedule. Continue treatment until disease progression or unacceptable toxicity.

Definitions and Measures

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Multiple Myeloma: Is an infiltration of plasma cells into the bone or other organs producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Elrexfio (elranatamab-bcmm)

Requests for Elrexfio (elranatamab-bcmm) may be approved if the following criteria are met:

I. Individual is under 19 years of age;

OR

~~I.~~II. Individual has a diagnosis of relapsed or refractory multiple myeloma (Label, NCCN 2A); **AND**
~~II.~~III. Individual has had at least four prior therapies, including an anti-CD38 monoclonal antibody (e.g., daratumumab), a proteasome inhibitor (e.g., bortezomib, ixazomib, or carfilzomib), and an immunomodulatory agent (e.g., lenalidomide or pomalidomide); **AND**
~~III.~~IV. Individual has a current Eastern Cooperative Group (ECOG) performance status of 0-2;

Elrexfio (elranatamab-bcmm) may not be approved for the following when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1323	Injection, elranatamab-bcmm, 1 mg [Elrexfio]

ICD-10 Procedure

XW013L9	Introduction of Elranatamab Antineoplastic into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 9 [Elrexfio]

ICD-10 Diagnosis

C90.00~~-C90.02~~	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

Document History

Reviewed: 11/14/2025
Document History:

- 11/14/2025 – Annual Review: No changes to criteria. Administrative update for age. Coding Reviewed: Added ICD-10 Procedure XW013L9, removed ICD-10-CM C90.01.
- 11/15/2024 – Annual Review: No changes to criteria. Added references. Coding Reviewed: Removed all diagnosis pend. Added ICD-10-CM C90.00-C90.02.
- 09/11/2023 – Select Review: New clinical criteria document for Elrexfio. Coding Reviewed: Added HCPCS J3490, J3590, J9999, C9399. All diagnoses pend. Effective 1/1/2024 Added HCPCS C9165. Removed HCPCS C9399. Effective 4/1/2024 Added HCPCS J1323. Removed HCPCS J3490, J3590, J9999, C9165.

References

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp . Accessed on October 8, 2025.
    a. Multiple Myeloma. V2.2026. Revised July 16, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.