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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 1, 2023
Subject:	Elrexfio	**Page:**	1 of 4

Last Review Date: March 8, 2024

Elrexfio

Description

Elrexfio (elranatamab-bcmm)

Background
Elrexfio (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. Elrexfio activated T-cells, caused proinflammatory cytokine release, and resulted in multiple myeloma cell lysis (1).

Regulatory Status
FDA-approved indication: 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 (1).

Elrexfio has a boxed warning regarding cytokine release syndrome (CRS) and neurotoxicity. Initiate treatment with Elrexfio step-up dosing schedule to reduce risk of CRS. Withold dose until CRS resolves or permanently discontinue based on severity. Neurotoxicity, including immune effector cell-associated neurotoxcitiy syndrome (ICANS), and serious and life-threatening reactions, can occur. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withold dose until neurologic toxicity resolves or permanently discontinue based on severity. Elrexfio is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Elrexfio REMS (1).

Elrexfio may cause hepatotoxicity, neutropenia, and infections. Monitor liver enzymes, bilirubin, and complete blood count (CBC) at baseline and during treatment as clinically indicated. Signs and symptoms of infection should be monitored and treated appropriately. Do not initiate treatment in patients with active infections (1).

Elrexfio can cause fetal harm when administerd to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Elrexfio and for 4 months after the last dose (1).

The safety and effectiveness of Elrexfio in pediatric patients have not been established (1).

Related Policies
Blenrep, Talvey, Tecvayli

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Elrexfio may be considered **medically necessary** if the conditions indicated below are met.

Elrexfio may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:

a. Patient has received at least 4 prior therapies, including **ALL** of the following:
   i. Anti-CD38 monoclonal antibody

   ii. Proteasome inhibitor
   iii. Immunomodulatory agent
b. Prescriber is certified with the Elrexfio REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin, and complete blood cell counts (CBC) at baseline and during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Elrexfio and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:
a. **NO** disease progression or unacceptable toxicity
b. Prescriber is certified with the Elrexfio REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin, and complete blood cell counts (CBC) during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Elrexfio and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Elrexfio (elranatamab-bcmm) is indicated for the treatment of relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Elrexfio has a boxed warning for cytokine release syndrome and neurologic toxicity. Hepatotoxicity, neutropenia, and infections can occur in patients treated with Elrexfio; therefore liver enzymes, bilirubin, complete blood cell counts, and signs and symptoms of infections must be monitored. The safety and effectiveness of Elrexfio in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Elrexfio while maintaining optimal therapeutic outcomes.

References

1. Elrexfio [package insert]. New York, NY: Pfizer Inc.; August 2023.
2. NCCN Drugs & Biologics Compendium® Elranatamab-bcmm 2024. National Comprehensive Cancer Network, Inc. Accessed on January 30, 2024.

Policy History

Date	Action
September 2023	Addition to PA
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.