

5.21.210

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 1, 2023
<b>Subject:</b>	Elrexfio	<b>Page:</b>	1 of 5

---

**Last Review Date:** June 13, 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. Withhold dose until CRS resolves or permanently discontinue based on severity. Neurotoxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening reactions, can occur. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold 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).

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 1, 2023
<b>Subject:</b>	Elrexio	<b>Page:</b>	2 of 5

---

Elrexio 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).

Elrexio can cause fetal harm when administered 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 Elrexio and for 4 months after the last dose (1).

The safety and effectiveness of Elrexio 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.*

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

Elrexio 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

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 1, 2023
<b>Subject:</b>	Elrexfio	<b>Page:</b>	3 of 5

---

- 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

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 1, 2023
<b>Subject:</b>	Elrexio	<b>Page:</b>	4 of 5

---

## Prior - Approval Limits

**Duration** 12 months

---

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

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

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

### References

1. Elrexio [package insert]. New York, NY: Pfizer Inc.; August 2023.
2. NCCN Drugs & Biologics Compendium® Elranatamab-bcmm 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.

## Policy History

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

## Keywords

---

# 5.21.210

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 1, 2023
<b>Subject:</b>	Elrexio	<b>Page:</b>	5 of 5

---

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.**