

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Elrexfio Prior Authorization Policy

- Elrexfio™ (elranatamab-bcmm subcutaneous injection – Pfizer)

REVIEW DATE: 09/11/2024

OVERVIEW

Elrexfio, a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, is indicated for the treatment of relapsed or refractory **multiple myeloma** in adults who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.¹

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for multiple myeloma (version 4.2024 – April 26, 2024) recommend Elrexfio as a “Preferred Regimen” for the treatment of relapsed or refractory multiple myeloma in patients who have received at least four prior lines of therapy including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (category 2A).^{2,3}

Safety

Elrexfio has a Boxed Warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS).¹ In addition, Elrexfio was approved with a Risk Evaluation and Mitigation Strategy (REMS) program due to the risk of CRS and neurologic toxicity, including ICANS.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Elrexfio. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Elrexfio as well as the monitoring required for adverse events and long-term efficacy, approval requires Elrexfio to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Elrexfio is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has tried at least four systemic regimens; AND
 - C) Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii):
 - i. Proteasome inhibitor; AND

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Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).

ii. Immunomodulatory drug; AND

Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), and Thalomid (thalidomide capsules).

iii. Anti-CD38 monoclonal antibody; AND

Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), and Sarclisa (isatuximab-irfc intravenous infusion).

D) The medication will be prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Elrexio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Elrexio™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; August 2023.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 4, 2024. Search term: elranatamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 4.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 4, 2024.