CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Bispecific – BCMA-Directed) – Elrexfio Utilization Management Medical Policy
- Elrexfio® (elranatamab-bcmm subcutaneous injection – Pfizer)

REVIEW DATE: 09/23/2026

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]

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

Dosing Information

Elrexfio is administered by subcutaneous injection.[1] Dosing begins with step-up doses of 12 mg on Day 1 and 32 mg on Day 4, followed by the first full treatment dose of 76 mg on Day 8. Treatment with the 76 mg dose is continued once weekly through Week 24. Beginning at Week 25, patients with a response to therapy can transition to a once every 2 weeks dosing regimen through Week 48. At Week 49, patients who have maintained the response following 24 weeks of treatment at the biweekly dosing schedule can extend the dosing interval to every 4 weeks. Treatment can continue until disease progression or unacceptable adverse events. Patients with light chain amyloidosis received Elrexfio according to the prescribing information.[3]

Guidelines

Elrexfio is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Multiple Myeloma:** NCCN guidelines (version 1.2027 – September 9, 2026) 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).[2,4]
- **Systemic Light Chain Amyloidosis:** NCCN guidelines (version 1.2027 – August 19, 2026) recommend Elrexfio for the treatment of relapsed or refractory previously treated disease as a single agent as "Useful in Certain Circumstances" (category 2A).[2,5]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Elrexfio. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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.

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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
       Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).
     - **ii.** Immunomodulatory drug; AND
       Note: Examples include lenalidomide, pomalidomide, 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), Sarclisa (isatuximab-irfc intravenous infusion), and Sarclisa Escena (isatuximab-irfc subcutaneous injection).
   - **D)** The medication will be prescribed by or in consultation with an oncologist or hematologist.

   Dosing. Approve the following dosing regimens (A and B):
   - **A)** Step-up dosing (i, ii, and iii):
     - **i.** Dose 1: Approve 12 mg given by subcutaneous injection on Day 1; AND
     - **ii.** Dose 2: Approve 32 mg given by subcutaneous injection, 2 to 14 days after Dose 1; AND
     - **iii.** Dose 3: Approve 76 mg given by subcutaneous injection, 3 to 14 days after Dose 2; AND
   - **B)** Approve 76 mg given by subcutaneous injection no more frequently than once weekly.

Other Uses With Supportive Evidence

2. **Systemic Light Chain Amyloidosis.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one systemic regimen; AND
     Note: Examples of systemic regimens include those containing one or more of the following products: Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Darzalex (daratumumab intravenous infusion), bortezomib, lenalidomide, cyclophosphamide, and melphalan.
   - **C)** The medication will be prescribed by or in consultation with an oncologist or hematologist.

   Dosing. Approve the following dosing regimens (A and B):
   - **A)** Step-up dosing (i, ii, and iii):
     - **i.** Dose 1: Approve 12 mg given by subcutaneous injection on Day 1; AND
     - **ii.** Dose 2: Approve 32 mg given by subcutaneous injection, 2 to 14 days after Dose 1; AND
     - **iii.** Dose 3: Approve 76 mg given by subcutaneous injection, 3 to 14 days after Dose 2; AND

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B) Approve 76 mg given by subcutaneous injection no more frequently than once weekly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Elrexfio 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. Elrexfio® subcutaneous injection [prescribing information]. New York, NY: Pfizer; February 2026.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 21, 2026. Search term: elranatamab.
3. Vianna P, Chakroborty R, Hossain S, et al. Safety and efficacy of elranatamab in patients with relapsed and/or refractory immunoglobulin light-chain amyloidosis. *Blood*. 2025; 146(16):1929-1935.
4. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2027 – September 9, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 21, 2026.
5. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 1.2027 – August 19, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 21, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/11/2024
Update	04/08/2025: The policy name was changed from "Oncology (Injectable) – Elrexfio UM Medical Policy" to "Oncology (Injectable – Bispecific – BCMA-Directed) – Elrexfio UM Medical Policy".	N/A
Annual Revision	No criteria changes.	09/10/2025
Annual Revision	**Multiple Myeloma:** Sarclisa Escena (isatuximab-irfc subcutaneous injection) was added to the Note of examples of an anti-CD38 monoclonal antibody. The specialist requirement was updated to include a hematologist. **Systemic Light Chain Amyloidosis:** Condition of approval and criteria were added to Other Uses with Supportive Evidence.	09/23/2026

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