Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Elrexfio™ (elranatamab-bcmm)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Accelerated approval of Elrexfio is based on the Phase 2 MagnetisMM-3, open label, single arm trial where 187 patients fell into two different cohorts. Cohort A were B-cell maturation antigen (BCMA)-directed therapy naïve patients. Cohort B were BCMA-treatment experienced patients. The results for Cohort A were an objective response rate of 58% after a median follow up of about 11 months. The duration of response was not reached and the median time to first response was 1.2 months. The results for Cohort B showed a lower objective response rate of 33% after a median follow up of about 10 months.

There are no guidelines for sequencing the options that can be used in the fifth line setting for multiple myeloma. Providers will consider patient comorbidities, ability to tolerate side effects, ECOG score, prior exposure to agents, and availability of therapies in the specific area.

Food and Drug Administration–Approved Indications

Elrexfio (elranatamab-bcmm) is a bispecific B-cell maturation antigen (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.

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 and description of clinical benefit in a confirmatory trial(s).

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Elrexfio for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of relapsed or refractory multiple myeloma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the patient has received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1323	Injection, elranatamab-bcmm, 1 mg

References

1. Elrexfio (elranatamab-bcmm) [prescribing information]. New York, NY: Pfizer, Inc.; 2023 Aug.

Approval And Revision History

November 14, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- January 1, 2024: Administrative updated: Added new C Code C9165 to Medical Necessity Guideline.
- April 1, 2024: Administrative updated: Removed C Code C9165 and added J Code J1323 to Medical Necessity Guideline.
- November 12, 2024: No changes (eff 1/1/25)
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25)
- December 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.