Elrexfio® (elranatamab-bcmm)
(Subcutaneous)

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I. Length of Authorization

- Initial: Following initial inpatient administration of 2 doses (step-up dose 1, step-up dose 2), prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 76 billable units weekly through week 24, then 76 billable units every two weeks thereafter

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of step-up dose 1 and step-up dose 2; **AND**
- Member had an absence of unacceptable toxicity while on inpatient administration of step-up doses; **AND**

Universal Criteria [1]

- Member does not have an active infection, including clinically important localized infections; **AND**
- Member will be administered prophylaxis for infection according to local guidelines; **AND**
- Member has not had an allogenic or an autologous stem cell transplant within the previous 12 weeks; **AND**
- Used as single agent treatment; **AND**

Multiple Myeloma* † ‡ Φ [1-3]

- Member has relapsed or refractory disease; **AND**
- Member has received at least 4 prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.)

**The regimens listed for treatment of Multiple Myeloma may also be used for the treatment of Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS), Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infections, neutropenia/febrile neutropenia, severe hepatotoxicity, neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), cytokine release syndrome (CRS), etc.

V. Dosage/Administration [1]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Multiple Myeloma</td><td>The recommended dosages of Elrexfio subcutaneous injection are: step-up dose 1 of 12 mg on Day 1, step-up dose 2 of 32 mg on Day 4, followed by the first treatment dose of 76 mg on Day 8, and then 76 mg weekly thereafter through week 24 (See table below).
• For members who have received at least 24 weeks of treatment with Elrexfio and have achieved a response [partial response (PR) or better] and maintained this response for at least 2 months, the dose interval should transition to an every two-week schedule (See table below).
• For members who have received at least 24 weeks of treatment with Elrexfio at the every two-week dosing schedule and have maintained the response, the dose interval should transition to an every four-week schedule (See table below).

Continue treatment with Elrexfio until disease progression or unacceptable toxicity.
<table>
<tr><th>Dosing Schedule</th><th>Day</th><th colspan="2">Elrexfio Dose</th></tr>
<tr><td rowspan="3">Step-up Dosing Schedule</td><td>Day 1 [a]</td><td>Step-up dose 1</td><td>12 mg</td></tr>
<tr><td>Day 4 [a,b]</td><td>Step-up dose 2</td><td>32 mg</td></tr>
<tr><td>Day 8 [a,c]</td><td>First treatment dose</td><td>76 mg</td></tr>
<tr><td>Weekly Dosing Schedule</td><td>One week after first treatment dose and weekly thereafter [d]</td><td>Subsequent treatment doses</td><td>76 mg</td></tr>
</table>
</td></tr>
</table>

		through week 24		
	Biweekly (Every 2 Week) Dosing Schedule ***Responders only week 25 onward***	Week 25 and every 2 weeks thereafter [d] through week 48	Subsequent treatment doses	76 mg
	Every 4 Week Dosing Schedule **** In members who have maintained the response following 24 weeks of treatment at the biweekly dosing schedule***	Week 49 and every 4 weeks thereafter [d]	Subsequent treatment doses	76 mg
	_ **a.** Administer pre-treatment medications prior to each dose in the Elrexfio step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose. _ **b.** A minimum of 2 days should be maintained between step-up dose 1 (12 mg) and step-up dose 2 (32 mg). _ **c.** A minimum of 3 days should be maintained between step-up dose 2 (32 mg) and the first treatment (76 mg) dose. _ **d.** A minimum of 6 days should be maintained between treatment doses. Note: See the PI for recommendations on restarting Elrexfio after dose delays.			
Note: Elrexfio is intended for subcutaneous use by a healthcare provider only. Administer Elrexfio subcutaneously according to the step-up dosing schedule to reduce the incidence and severity of cytokine release syndrome (CRS). Due to the risk of CRS, members should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.				

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1323 – Injection, elranatamab-bcmm, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Elrexfio 76 mg/1.9 mL solution for injection in a single-dose vial: 00069-4494-xx
- Elrexfio 44 mg/1.1 mL solution for injection in a single-dose vial: 00069-2522-xx

VII. References

1. Elrexfio [package insert]. New York, NY; Pfizer, Inc.; February 2026. Accessed March 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for elranatamab. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2026.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 5.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN

GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed March 2026.

4. BGM Durie, J-L Harousseau, J S Miguel, et al on behalf of the International Myeloma Working Group. International uniform response criteria for multiple myeloma. Leukemia. Sep; 20(9):1467-73.
5. Lesokhin AM, Arnulf B, Niesvizky R, et al. Initial safety results for MagnetisMM-3: A phase 2 trial of elranatamab, a B-cell maturation antigen (BCMA)-CD3 bispecific antibody, in patients (pts) with relapsed/refractory (R/R) multiple myeloma (MM). Journal of Clinical Oncology 2022 40:16_suppl, 8006-8006.
6. Lesokhin AM, Tomasson MH, Arnulf B, et al. Elranatamab in relapsed or refractory multiple myeloma: phase 2 MagnetisMM-3 trial results. Nat Med 2023;29:2259-2267. Available at: https://www.ncbi.nlm.nih.gov/pubmed/37582952.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse

ICD-10	ICD-10 Description
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC