Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Elranatamab-bcmm (Elrexfio®)	MP-RX-FP-120-24	☒ MMM MA ☐ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Elranatamab-bcmm (Elrexfio®)*, a bispecific B-cell maturation antigen (BCMA)-directed T-cell engager approved by the Food and Drug Administration (FDA) for the treatment of 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.

Background Information

Elrexfio indication is approved under accelerated approval based on response rate and durability of response. Elrexfio has a black box warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell- associated neurotoxicity syndrome (ICANS). Elrexfio is only available through a restricted program under a REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Elrexfio is a subcutaneous injection administer as step-up doses of 12 mg, 32 mg, and followed by the first treatment dose of 76 mg and then 76 mg weekly thereafter though week 24.

Those who have received at least 24 weeks of treatment and achieved a response [partial response or better] and maintained this response for at least 2 months, the dose interval should transition to an every two week schedule. Continue treatment until disease progression or unacceptable toxicity.

Definitions and Measures

- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
  - 0 = Fully active, able to carry on all pre-disease performance without restriction
  - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
  - 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

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- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
- 5 = Dead

- Multiple Myeloma: Is an infiltration of plasma cells into the bone or other organs producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.
- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Approved Indications

A. Treatment of 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 pathway pending confirmatory data.

Other Uses

i. None

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J1323	Injection, elranatamab-bcmm, 1 mg [Elrexfio]

ICD-10	Description
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Elranatamab-bcmm (Elrexfio®)

A. Criteria For Initial Approval *Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of relapsed or refractory multiple myeloma; **AND**
ii. Individual has had at least four prior therapies, including an anti-CD38 monoclonal antibody (e.g., daratumumab), a proteasome inhibitor (e.g., bortezomib, ixazomib, or carfilzomib), and an immunomodulatory agent (e.g., lenalidomide or pomalidomide); **AND**
iii. Individual has a current Eastern Cooperative Group (ECOG) performance status of 0-2.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Elranatamab-bcmm (Elrexfio®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the maximum duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
    A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Elrexfio (elranatamab-bcmm) may not be approved for the following when the above criteria (Section A) are not met and for all other indications.

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Elranatamab-bcmm (Elrexfio®) 76 mg/1.9mL (40mg/mL), 44 mg/1.1mL (40mg/mL) SDV

Dosing Schedule	Day	Elrexfio Dose	
Step-up Dosing Schedule	Day 1	Step-up dose 1	12 mg
	Day 4	Step-up dose 2	32 mg
	Day 8	First treatment dose	76 mg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter through week 24	Subsequent treatment doses	76 mg
Biweekly (Every 2 Weeks) Dosing Schedule*	Week 25 and every 2 weeks thereafter	Subsequent treatment doses	
Exceptions			
- For patients 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.			

* Responders only week 25 onward.

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Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 21, 2023
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 12/18/2024	Minor formatting changes. Added drug name and dosage forms to quantity limits table. Coding Reviewed: Added HCPCS J1323. Removed HCPCS J3490, J3590, J9999, C9165. Added ICD-10 C90.00 – C90.02.	3/20/2025	4/2/2025
Policy Inception 01/25/2024	Elevance Health's Medical Policy Adoption	N/A	6/28/2024