Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Linvoseltamab-gcpt (LYNOZYFIC)	MP-RX-FP-178-25	☒ 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 Drug

Service Description

This document addresses the use of Linvoseltamab-gcpt (LYNOZYFIC) , a drug approved by the Food and Drug Administration (FDA) for the treatment of 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

Linvoseltamab-gcpt (LYNOZYFIC) 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, with continued approval contingent upon confirmatory trials verifying clinical benefit.[1]

Mechanistically, linvoseltamab-gcpt binds to CD3 on T-cells and BCMA on multiple myeloma cells, leading to T-cell activation, cytokine release, and lysis of myeloma cells. In vitro and animal models have demonstrated anti-tumor activity.[1]

The pivotal clinical study (LINKER-MM1) enrolled patients with a median of 5 prior lines of therapy; 79% were triple-class refractory. Efficacy was measured by objective response rate (ORR) per IMWG criteria, with a median time to first response of 0.95 months. Among responders, the estimated duration of response was 89% at 9 months and 72% at 12 months (median follow-up 11.3 months).[1]

The recommended dosing involves step-up intravenous infusions (5 mg on Day 1, 25 mg on Day 8, 200 mg on Day 15), followed by weekly dosing for 10 doses, then biweekly or every 4 weeks based on response. Hospitalization is required after the first two step-up doses due to the risk of cytokine release syndrome (CRS).[1]

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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
J9999	Not otherwise classified, antineoplastic drugs

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
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Linvoseltamab-gcpt (LYNOZYFIC)

A. Criteria For Initial Approval

i. Individual is using therapy for previously treated multiple myeloma for relapsed/refractory disease and has received at least four prior therapies, including:
   a. an anti-CD38 monoclonal antibody
   b. a proteasome inhibitor
   c. an immunomodulatory agent

OR

ii. Individual is using regimen for the treatment of (NCCN 2A recommended use):
   a. Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS) (useful in certain circumstances)
   b. Monoclonal Immunoglobulin Deposition Disease (MIDD)
   c. plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Linvoseltamab-gcpt (LYNOZYFIC) 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 recommended 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

a. Initial Approval Duration: 6 months
b. Reauthorization Approval Duration: 12 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. When the above criteria are not met.

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Limits or Restrictions

A. 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.

Drug	Related dosage form
Lynozyfic (Linvoseltamab-gcpt)	Lynozyfic Intravenous Solution 5 MG/2.5ML
	Lynozyfic Intravenous Solution 200 MG/10ML

B. Dosage Regimen:

Dosing Schedule	Day/Week	LYNOZYFIC Dose		Duration of Infusion
Step-up Dosing Schedule	Day 1	Step-up dose 1	5 mg	4 hours
	Day 8	Step-up dose 2	25 mg	
	Day 15	First treatment dose	200 mg	
Weekly Dosing Schedule	One week after Day 15 treatment dose and once weekly from Week 4 to Week 13 for 10 treatment doses	Second and subsequent treatment doses	200 mg	1 hour for the second treatment dose, and 30 minutes for subsequent doses
Biweekly (Every 2 Weeks) Dosing Schedule	Week 14 and every 2 weeks thereafter	Subsequent treatment doses	200 mg	30 minutes
Patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg				
Every 4 Weeks Dosing Schedule	At Week 24 or after and every 4 weeks thereafter		200 mg	30 minutes

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Reference Information

1. NCCN drugs & biologics compendium. Available at: https://www.nccn.org/home/store/product-details (Accessed: 14 August 2025).
2. DRUGS@FDA: FDA-approved drugs FDA. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (Accessed: 14 August 2025).
3. *DailyMed - lynozyfic- linvoseltamab-GCPT injection, solution, concentrate* (no date) *U.S. National Library of Medicine*. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e9fd0739-1b3f-4b8b-824a-1f0a902384d3 (Accessed: 14 August 2025).

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception 8/18/2025	MMM Developed Medical Policy	9/22/2025	10/10/2025