Lynozyfic™ (linvoseltamab-gcpt)
(Intravenous)

-E-

Document Number: IC-0852

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Dates Approved: 06/02/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), following initial inpatient administration of 2 doses (step-up dose 1, step-up dose 2).
- 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]:

- Step-up Dosing
  - Day 1: 5 billable units (5 mg)
  - Day 8: 25 billable units (25 mg)
- Treatment Dosing
  - Day 15: 200 billable units (200 mg)
  - Weekly (starting one week after day 15 through week 13 for ten doses): 200 billable units (200 mg)
  - Bi-weekly (starting week 14 and every 2 weeks thereafter for at least 17 doses): 200 billable units (200 mg)
- Maintenance Dosing
  - Every 4 weeks (starting after at least week 24 and after at least 17 doses): 200 billable units (200 mg)

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 all step-up doses; **AND**
- Member had an absence of unacceptable toxicity while on inpatient administration; **AND**

Universal Criteria [1]

- Member does not have an active infection, including clinically important localized infections; **AND**

- Member will be administered prophylaxis for infection (*e.g., antimicrobials, antibiotics, antifungals, antivirals, vaccines, and subcutaneous or intravenous immunoglobulin (IVIG)*) according to local guidelines; **AND**
- Member immunoglobulin levels will be monitored prior to and during therapy and treated appropriately; **AND**
- Member does not have active CNS involvement or clinical signs of meningeal involvement from multiple myeloma; **AND**
- Member has not had an allogeneic stem cell transplant or an autologous stem cell transplant within the previous 12 weeks; **AND**

Multiple Myeloma † ‡ Φ [1-3]

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

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

† 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: neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), severe administration-related/local injection-site reactions, cytokine release syndrome (CRS), hepatotoxicity, neutropenia/febrile neutropenia, severe infections, etc.

V. Dosage/Administration [1]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Multiple Myeloma</td><td>
The recommended dosage of Lynozyfic is step-up doses of 5 mg, 25 mg, and 200 mg, followed by 200 mg weekly for 10 doses, followed by 200 mg biweekly (every 2 weeks). In members who have achieved and maintained very good partial response (VGPR) or better at or after Week 24 and received at least 17 doses of 200 mg, decrease the dosing frequency to 200 mg every 4 weeks. Continue treatment until disease progression or unacceptable toxicity. (See table below)
<table>
<tr><th>Dosing schedule</th><th>Day [a]</th><th colspan="2">Dose</th></tr>
<tr><td rowspan="3">Step-up dosing schedule</td><td>Day 1</td><td>Step-up dose 1</td><td>5 mg</td></tr>
<tr><td>Day 8</td><td>Step-up dose 2</td><td>25 mg</td></tr>
<tr><td>Day 15</td><td>First treatment dose</td><td>200 mg</td></tr>
<tr><td>Weekly dosing schedule</td><td>One week after Day 15 treatment dose and once weekly from Week 4 to Week 13 for 10 treatment doses</td><td>Second and subsequent treatment doses</td><td>200 mg</td></tr>
<tr><td>Biweekly (Every 2 Weeks) Dosing Schedule</td><td>Week 14 and every 2 weeks thereafter</td><td>Subsequent treatment doses</td><td>200 mg</td></tr>
<tr><td colspan="4">Members who have achieved and maintained very good partial response (VGPR) or better at or after Week 24 and received at least 17 doses of 200 mg</td></tr>
<tr><td>Every 4 Weeks Dosing Schedule</td><td colspan="2">At Week 24 or after and every 4 weeks thereafter.</td><td>200 mg</td></tr>
<tr><td colspan="4">– [a] Weekly doses should be at least 5 days apart. Biweekly doses should be at least 10 days apart. Every 4-week doses should be at least 24 days apart.</td></tr>
</table>
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- *Administer intravenously according to the step-up schedule to reduce the incidence and severity of cytokine release syndrome (CRS).*
- *Lynozyfic should be administered by a healthcare provider with immediate access to emergency equipment and appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS), infusion-related reactions (IRR), and neurologic toxicity, including ICANS.*
- *Due to the risk of CRS and neurologic toxicity, including ICANS, members should be hospitalized for 24 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:

- J9601 – Injection, linvoseltamab-gcpt, 1 mg;

NDC:

- Lynozyfic 5 mg/2.5 mL (2 mg/mL) single-dose vial: 61755-0054-xx
- Lynozyfic 200 mg/10 mL (20 mg/mL) single-dose vial: 61755-0056-xx

VII. References (STANDARD)

1. Lynozyfic [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; July 2025. Accessed April 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for linvoseltamab-gcpt. 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 April 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 April 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. Lee HC, Bumma N, Richter JR, et al. LINKER-MM1 study: Linvoseltamab (REGN5458) in patients with relapsed/refractory multiple myeloma. JCO 41, 8006-8006(2023). DOI:10.1200/JCO.2023.41.16_suppl.8006.

VIII. References (ENHANCED)

1e. Lesokhin, A.M., Tomasson, M.H., Arnulf, B. et al. Elranatamab in relapsed or refractory multiple myeloma: phase 2 MagnetisMM-3 trial results. Nat Med 29, 2259–2267 (2023).

2e. Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2022 Aug 11;387(6):495-505.

3e. Usmani SZ, Garfall AL, van de Donk NWCJ, et al. Teclistamab, a B-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC-1): a multicentre, open-label, single-arm, phase 1 study. Lancet. 2021 Aug 21;398(10301):665-674.

4e. Berdeja JG, Madduri D, Usmani SZ, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b/2 open-label study. Lancet. 2021 Jul 24;398(10297):314-324.

5e. Usmani SZ, Martin T, Berdeja JG, et al. MM-181 CARTITUDE-1: Two-Year Post Last Patient in (LPI) Results From the Phase 1b/2 Study of Ciltacabtagene Autoleucel (Cilta-Cel), a B-Cell Maturation Antigen (BCMA)-Directed Chimeric Antigen Receptor T (CAR-T) Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma (RRMM). Clin Lymphoma Myeloma Leuk. 2022 Oct;22 Suppl 2:S410-S411.

6e. Munshi NC, Anderson LD Jr, Shah N, et al. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2021 Feb 25;384(8):705-716.

7e. Minnema Mc, Chari A, C. Touzeau, Et Al. P29 Phase 1/2 Results Of Talquetamab, A G Protein-Coupled Receptor Family C Group 5 Member D X Cd3 Bispecific Antibody, In Patients With Relapsed/Refractory Multiple Myeloma (Rrmm) (Monumental-1). Hemasphere. 2023;7(S2):26-27.

8e. Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or Standard Regimens in Relapsed and Refractory Multiple Myeloma. New England Journal of Medicine. 2023;388(11):1002-1014.

9e. Prime Therapeutics Management. Lynozyfic Clinical Literature Review Analysis. Last updated April 2026. Accessed April 2026.

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
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		
Jurisdiction	**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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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