09-J5000-27

Original Effective Date: 09/15/25

Reviewed: 08/13/25

Revised: 04/01/26

Subject: Linvoseltamab-gcpt (Lynozyfic) IV Infusion

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Linvoseltamab-gcpt (Lynozyfic) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engaging antibody approved by the US Food and Drug Administration (FDA) on July 2, 2025, for the treatment of adult patients with relapsed or refractory multiple myeloma (MM) 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 was approved under accelerated approval based on response rate and durability of response, and continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Prior to FDA approval, linvoseltamab was granted orphan drug designation in June 2022 for the treatment of MM. Linvoseltamab is the fourth FDA-approved bispecific T-cell engager (BiTE) for the treatment of MM, and the third BCMA-directed BiTE for the treatment of MM; the first being teclistamab (Tecvayli), a BCMA-directed BiTE, approved in October 2022 for the same patient population. Linvoseltamab binds to the CD3 receptor expressed on the surface of T-cells and BCMA expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. In vitro, linvoseltamab activated T-cells, caused the release of various proinflammatory cytokines, and resulted in the lysis of multiple myeloma cells.

The National Comprehensive Cancer Network (NCCN) Guidelines for MM (Version 2.2026 - July 16, 2025) list linvoseltamab-gcpt under “Relapse/Refractory Disease After 3 Prior Therapies” and under “Preferred Regimens” as a category 2A recommendation for the treatment of previously treated MM. Under this section, the recommendations are further categorized as either “CAR T-cell Therapy” or “After at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor (PI), and an immunomodulatory agent (IMiD)”. Idecabtagene vicleucel (Abecma) and ciltacabtagene autoleucel (Carvykti) are listed under the “CAR T-cell Therapy” section, and the bispecific antibodies of elranatamab (Elrexfio), linvoseltamab, talquetamab (Talvey) and teclistamab (Tecvayli) are list under the “After at least four prior therapies, including an anti-CD38 monoclonal antibody, a PI, and an IMiD” section. The

NCCN also includes footnotes stating (1) “Autologous HCT should be considered in patients who are eligible and have not previously received HCT or had a prolonged response to initial HCT”, (2) “Patients can receive more than one BCMA targeted therapy. Optimal sequencing of sequential BCMA targeted therapies is not known; however accumulated data suggests immediate follow on with second BCMA directed therapy after relapse may be associated with lower response rates”, and (3) “Prophylactic tocilizumab may be considered prior to first dose to reduce the risk of CRS” (applicable to the bispecific antibodies only).

The safety and efficacy of linvoseltamab leading to initial FDA approval was evaluated in patients with relapsed or refractory MM in an open-label, multi-center, multi-cohort study (LINKER-MM1, NCT03761108). The study included patients who had previously received at least 3 prior therapies, including a PI, an IMiD, and an anti-CD38 antibody. The study included patients with an ECOG score of 0 or 1 and adequate baseline hematologic function. The study excluded patients with known MM brain lesions or meningeal involvement, history of a neurodegenerative condition, history of seizure within 12 months prior to study enrollment, active infection, a history of an allogeneic or autologous stem cell transplantation within 12 weeks, prior BCMA-directed bispecific antibody therapy, prior bispecific T-cell engaging therapy, or prior BCMA CAR-T cell therapy.

Patients received a step-up dose of 5 mg on Day 1, 25 mg on Day 8, and the first treatment dose of 200 mg on Day 15 by IV infusion. Then, patients received 200 mg weekly from Week 4 to Week 13, followed by 200 mg every 2 weeks thereafter. After at least 24 weeks, the Phase 2 patients who achieved a very good partial response (VGPR) or greater received 200 mg every 4 weeks. Patients were treated until disease progression or unacceptable toxicity. The efficacy population included 80 patients who had received at least four prior lines of therapy. The median age was 71 (range of 37 to 83) years with 30% of patients 75 years or older; 64% were male and 69% were white. The International Staging System (ISS) at study entry was Stage I in 39%, Stage II in 36%, and Stage III in 19%. High-risk cytogenetics were present in 40% of patients, and 18% of patients had extramedullary disease at baseline. The median number of prior lines of therapy was 5 (range of 4 to 13), 83% of patients were refractory to the last line of therapy, 65% of patients received prior stem cell transplantation, 79% of patients were triple-class refractory, and 13% of patients were previously treated with a BCMA antibody-drug conjugate.

Efficacy was established based on objective response rate (ORR) as determined by blinded independent review committee (IRC), as measured using the International Myeloma Working Group (IMWG) criteria. Result are found in the Table below. The median time to first response was 0.95 months (range: 0.5 to 6 months). With a median follow-up of 11.3 months among responders, the estimated duration of response (DOR) rate was 89% (95% CI: 77, 95) at 9 months and 72% (95% CI: 54, 84) at 12 months.

Table: Efficacy Results for LINKER-MM1

	N=80
Objective response rate (ORR: sCR+CR+VGPR+PR)	56 (57.7%)
95% CI	(47.3, 67.7)
Complete response (CR) or better*	25 (25.8%)
Very good partial response (VGPR)	25 (25.8%)
Partial response (PR)	6 (6.2%)
Duration of Response (DOR) (months)	

Median (95% CI)	NR (12, NE)

NE = not estimable, NR = Not reached

*Complete response or better = Stringent complete response (sCR) + complete response (CR)

The safety of linvoseltamab was also evaluated in LINKER-MM1. The safety population includes patients (n=117) who received the recommended dosage regimen. Serious adverse reactions occurred in 74% of patients. Serious adverse reactions that occurred in >5% of patients included cytokine release syndrome (27%), pneumonia (13%), COVID-19 (7%), and acute kidney injury (5%). Fatal adverse reactions occurred in 7% of patients, and included sepsis (3.4%), chronic kidney disease (0.9%), pneumonia (0.9%), tumor lysis syndrome (0.9%), and encephalopathy (0.9%). Permanent discontinuation due to adverse reactions occurred in 16% of patients. Adverse reactions leading to discontinuation that occurred in at least 2 patients included sepsis, pneumonia, and encephalopathy. Dosage interruptions or delays due to adverse reactions occurred in 74% of patients. Adverse reactions which required a dosage interruption or delay in >10% of patients included neutropenia (29%), upper respiratory tract infection (18%), pneumonia (15%), and COVID-19 infection (11%). The most common adverse reactions (≥20%) were musculoskeletal pain, cytokine release syndrome, cough, upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache, and dyspnea. The most common Grade 3 to 4 laboratory abnormalities (≥30%) were decreased lymphocyte count, decreased neutrophil count, decreased hemoglobin, and decreased white blood cell count. Refer to the package labeling for the specific percentages.

POSITION STATEMENT:

Initiation of linvoseltamab-gcpt (Lynozyfic) **meets the definition of medical necessity** when **EITHER** of the following criteria are met ("1" or "2"):

1. Member has a diagnosis of relapsed or refractory multiple myeloma (MM) and **ALL** of the following ("a" to "f") - *medical record documentation confirming the patient's diagnosis and complete treatment history must be submitted*:
    a. Member has received **FOUR or more** appropriate prior lines of therapy of adequate duration for the treatment of their MM

       NOTE: Primary therapy, with or without subsequent hematopoietic cell transplant, followed by maintenance therapy is considered a single line of therapy

    b. Member's prior MM treatments have included **ALL** of the following ("i", "ii", and "iii"):
        i. An anti-CD38 monoclonal antibody [for example - daratumumab (Darzalex), daratumumab-hyaluronidase (Darzalex Faspro), or isatuximab (Sarclisa)]
        ii. A proteasome inhibitor [for example - bortezomib, carfilzomib (Kyprolis), or ixazomib (Ninlaro)]
        iii. An immunomodulatory agent [for example - lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid)]
    c. Member's MM was **NOT** previously refractory (i.e., disease progression on treatment or progression within 60 days after the last dose of a given therapy) to a BCMA-directed bispecific

T-cell engager (BiTE) treatment regimen [such as elranatamab (Elrexfio), linvoseltamab, and teclistamab (Tecvayli)]

d. Linvoseltamab will be used as single-agent therapy for the member's MM (i.e., not used in combination with other MM treatments)

e. The ordering provider and the infusing healthcare facility is certified in the LYNOZYFIC REMS program

f. Dosage of linvoseltamab does not exceed the following:

- Day 1 (Step-up dose 1) – 5 mg
- Day 8 (Step-up dose 2) – 25 mg
- Day 15 (First treatment dose) – 200 mg
- One week after first treatment dose (Day 15) from Week 4 to Week 13 – 200 mg once weekly for 10 treatment doses
- Week 14 and thereafter – 200 mg once every two weeks

2. Member has another FDA-approved or NCCN-supported diagnosis, and **ALL** of the following are met ("a" to "d"):

a. **EITHER** of the following ("i" or "ii"):

i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

ii. Indication **AND** usage are recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

b. Linvoseltamab is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis

c. The ordering provider and the infusing healthcare facility is certified in the LYNOZYFIC REMS program

d. Dosage of linvoseltamab does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

Approval duration: 6 months

Continuation* of linvoseltamab-gcpt (Lynozyfic) meets the definition of medical necessity when **ALL** of the following criteria are met ("1" to "3"):

1. An authorization or reauthorization for linvoseltamab has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of multiple myeloma or other FDA-approved or NCCN-supported diagnosis (if another health plan, documentation of a health plan-paid claim for linvoseltamab during the 90 days immediately before the authorization request must be provided); **OR** the member previously met **ALL** indication-specific initiation criteria

2. The ordering provider and the infusing healthcare facility is certified in the LYNOZYFIC REMS program
3. **EITHER** of the following based on the member's diagnosis ("a" or "b"):
    a. Multiple myeloma, and **ALL** of the following ("i", "ii", and "iii"):
        i. Linvoseltamab is being used as single-agent therapy for the member's MM (i.e., not used in combination with other MM treatments)
        ii. Dosage of linvoseltamab does not exceed the following:
            - One week after first treatment dose (Day 15) from Week 4 to Week 13 – 200 mg once weekly for 10 treatment doses
            - Week 14 to Week 24 - 200 mg once every two weeks
            - Week 25 and thereafter
                - If the member has **NOT** achieved and maintained a VGPR or better at or after Week 24 and received at least 17 doses of 200 mg - 200 mg once every two weeks [*medical record documentation confirming the member has not achieved and maintained a VGPR or better must be submitted*]
                - If the member has achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg - 200 mg once every four weeks
        iii. Provider attestation that the member has not had disease progression during linvoseltamab treatment
    b. Other FDA-approved or NCCN-supported diagnosis, and **ALL** of the following ("i", "ii", and "iii"):
        i. Dosage of linvoseltamab does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guideline for the specific diagnosis
        ii. Linvoseltamab is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis
        iii. Member has had a beneficial response to treatment with linvoseltamab

Approval duration: 1 year

**For members that may have only completed the initial step-up dosing schedule during an inpatient admission, please refer to the initiation criteria*

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 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 of clinical benefit in a confirmatory trial(s).

- The recommended dosing schedule* is as follows:
  - Step-up dosing schedule:
    - Day 1 (Step-up dose 1) – 5 mg
    - Day 8* (Step-up dose 2) – 25 mg
    - Day 15 (First treatment dose) – 200 mg
  - Weekly dosing schedule:
    - One week after the first treatment dose (Day 15) and once weekly from Week 4 to Week 13 for 10 treatment dose – 200 mg
  - Biweekly (every 2 weeks) dosing schedule:
    - Week 14 and every 2 weeks thereafter – 200 mg
  - Every 4 Weeks Dosing Schedule (only for patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg)
    - Week 24 or after and every 4 weeks thereafter – 200 mg

    **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.*

- Linvoseltamab 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 ICAN
- Due to the risk of CRS and neurologic toxicity, including ICANS, patients 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.
- Administer only as an intravenous infusion after dilution in 0.9% Sodium Chloride Injection.
  - Administer the following pre-treatment medications before each dose of the step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose, the second treatment dose, and if indicated, subsequent treatment doses to reduce the risk of CRS and/or IRR:
    - acetaminophen (or equivalent) 650 mg to 1,000 mg orally 30 to 60 minutes prior to infusion
    - diphenhydramine (or equivalent) 25 mg orally or intravenously 30 to 60 minutes prior to infusion
    - dexamethasone (or equivalent) intravenously 1 to 3 hours prior to infusion
      - 40 mg dexamethasone (or equivalent) before step-up dose 1, step-up dose 2, and the first full treatment dose
      - Once a treatment dose is tolerated without CRS and/or IRR with 40 mg dexamethasone (or equivalent), administer 10 mg dexamethasone (or equivalent) prior to the subsequent treatment dose
    - Pre-treatment medications may be discontinued once a treatment dose is tolerated without CRS and/or IRR following pre-treatment with 10 mg dexamethasone (or equivalent), acetaminophen (or equivalent), and diphenhydramine (or equivalent) as described.

Dose Adjustments

- Hepatic Impairment - Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no initial dosage adjustments are needed. Therapy interruption or permanent discontinuation may be necessary in patients who develop hepatotoxicity based on severity.
- Renal Impairment - Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no initial dosage adjustments are needed.
- Adverse Effects - Dosage reductions of linvoseltamab are not recommended. However, dosage delays and/or decreasing the infusion rate may be required to manage adverse effects such as CRS, neurologic toxicity, and ICANS. Refer to the product labeling for the specific recommendations.

Drug Availability

- Clear to slightly opalescent, colorless to pale yellow solution in a single-dose vial supplied as follows:
  - One 5 mg/2.5 mL (2 mg/mL) single-dose vial
  - One 200 mg/10 mL (20 mg/mL) single-dose vial
- Store unopened vial in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze or shake.

PRECAUTIONS:

Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY INCLUDING IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving Lynozyfic. Initiate treatment with Lynozyfic step-up dosing to reduce the risk of CRS. Manage CRS, withhold Lynozyfic until CRS resolves, and modify the next dose or permanently discontinue based on severity.
- Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including serious or life-threatening reactions, can occur in patients receiving Lynozyfic. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS during treatment. Manage neurologic toxicity, including ICANS, withhold Lynozyfic until neurologic toxicity, including ICANS resolves, and modify the next dose or permanently discontinue based on severity.
- Because of the risk of CRS and neurologic toxicity, including ICANS, Lynozyfic is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the LYNOZYFIC REMS,

Contraindications

- None

Precautions/Warnings

- **Cytokine Release Syndrome** – see Boxed Warning
- **Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome** – see Boxed Warning

- **LYNOZYFIC REMS** – see Boxed Warning
- **Infections**: Can cause serious or fatal infections. Monitor patients for signs or symptoms of infection and treat accordingly.
- **Neutropenia**: Monitor complete blood cell counts at baseline and periodically during treatment.
- **Hepatotoxicity**: Can cause hepatotoxicity. Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated.
- **Embryo-Fetal Toxicity**: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

BILLING/CODING INFORMATION:

HCPCS Coding

J9601	Injection, linvoseltamab-gcpt, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Autologous - cells or tissues obtained from the same individual (as opposed to from a different person).

Heavy chain - the larger component of an immunoglobulin. There are five types: IgG, IgA, IgM, IgD, and IgE.

Immunoglobulins (a.k.a., antibodies) - proteins made by normal plasma cells that have an important role in fighting infection as part of the humoral immune response. Antibodies are composed of two heavy chains and two light chains that form a larger complex. Each plasma cell produces only one type of heavy chain and one type of light chain.

Light chain - the smaller component of an immunoglobulin. There are two types: kappa and lambda.

Myeloma Protein (M-Protein) - a nonfunctional immunoglobulin protein or protein fragment produced by malignant plasma cells (or myeloma cells). Since myeloma cells are monoclonal, the M-proteins for a given patient are structurally identical. Both portions of an immunoglobulin (the heavy chain and light chain) can be found in the serum, while only light chains can be found in the urine.

Plasma cell - a fully differentiated B lymphocyte (a type of white blood cell) that is specialized for immunoglobulin production and is found primarily in bone marrow.

Primary refractory MM - patients who never achieve at least a MR to initial induction therapy and progress while on therapy.

Progressive MM - at least a 25% increase from nadir in the serum M-protein (absolute increase must be ≥0.5 g/dL) or urine M-protein (absolute increase must be ≥200mg/24 hours), or in the difference between involved and uninvolved serum-free light-chain (FLC) levels (with an abnormal FLC ratio and FLC difference >100 mg/L).

Relapsed and refractory MM - patients who never achieve at least a MR or who progress within 60 days of their last therapy.

RELATED GUIDELINES:

Allogeneic Bone Marrow and Stem Cell Transplantation, 02-38240-01
Carfilzomib (Kyprolis) IV, 09-J1000-81
Chimeric Antigen Receptor (CAR) T-Cell Therapies, 09-J3000-94
Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro), 09-J2000-49
Doxorubicin HCl Liposome (Doxil) IV, 09-J0000-91
Elotuzumab (Empliciti) IV, 09-J2000-50
Elranatamab-bcmm (Elrexfio), 09-4000-64
Isatuximab (Sarclisa) Injection, 09-J3000-67
Ixazomib (Ninlaro), 09-J2000-51
Oral Oncology Medications, 09-J3000-65
Talquetamab-tgvs (Talvey) Injection, 09-J4000-63
Teclistamab (Tecvayli) Injection, 09-J4000-46
Thalidomide (Thalomid) Capsules, 09-J1000-56

OTHER:

None

REFERENCES:

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4. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 07/17/25.
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7. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2025 [cited 2025 July 17]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 08/13/25.

GUIDELINE UPDATE INFORMATION:

09/15/25	New Medical Coverage Guideline.
01/01/26	Revision: Added HCPCS code C9307.
04/01/26	Revision: Added HCPCS code J9601 and removed codes C9307 and J9999.