April 2026

LYNOZYFIC™ (linvoseltamab-gcpt) Injection 5mg | 200mg

Billing and coding guide

An overview of the key coding descriptors that capture diagnoses, medical procedures, and product information needed for billing and coding for LYNOZYFIC and helping payers recognize, process, and pay claims

INDICATION AND USAGE

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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

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.**

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING, for LYNOZYFIC.

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Key resources for reimbursement support

Use this resource to access potential billing codes for LYNOZYFIC, including:

- *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) codes
- Current Procedural Terminology (CPT) codes
- Revenue codes for hospital-based infusions
- Healthcare Common Procedure Coding System (HCPCS) level 2 codes
- Product information

Scan the QR code or visit LYNOZYFIChcp.com for additional helpful resources, including:

- Annotated samples of the 2 most common Centers for Medicare & Medicaid Services (CMS) claim forms used to bill for drugs and services
  - CMS-1500 (print) or 837P (electronic) forms for billing for physician office reimbursement
  - CMS-1450 (print), also referred to as CMS UB-04, or 837I (electronic) forms for hospital outpatient reimbursement

Questions about billing and coding for LYNOZYFIC? Please contact **LYNOZYFIC Surround™** at **1.844.RGN.HEME** (1.844.746.4363), **Option 1**, Monday–Friday, 8 AM–8 PM Eastern time.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

Cytokine Release Syndrome (CRS): LYNOZYFIC can cause CRS, which can be serious or life-threatening. In LINKER-MM1, CRS occurred in 46% (54/117) of patients who received LYNOZYFIC at the recommended dose, with Grade 1 CRS occurring in 35% (41/117) of patients, Grade 2 in 10% (12/117), and Grade 3 in 0.9% (1/117). Thirty-eight percent (45/117) of patients had CRS following step-up dose 1, including 1 patient who experienced Grade 3 CRS; 8% (9/117) had an initial CRS event following a subsequent dose. Seventeen percent (19/113) of patients developed CRS after step-up dose 2, 10% (11/111) developed CRS after the first full 200-mg dose of LYNOZYFIC, and 3.6% (4/110) developed CRS after the second full dose. Recurrent CRS occurred in 20% (23/117) of patients. The median time to onset of CRS from the end of infusion was 11 (range: -1 to 184) hours after the most recent dose, with a median duration of 15 (range: 1 to 76) hours.

Clinical signs and symptoms of CRS included, but were not limited to pyrexia, chills, hypoxia, tachycardia, and hypotension. Administer pretreatment medications and initiate therapy according to LYNOZYFIC step-up dosing to reduce the incidence and severity of CRS. Monitor patients for signs and symptoms of CRS after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur.

At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care; withhold LYNOZYFIC until CRS resolves and modify the next dose or permanently discontinue LYNOZYFIC based on severity.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING, for LYNOZYFIC.

Billing codes for LYNOZYFIC

The coding information discussed in this document is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed herein may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients. Providers should follow payer-specific coding requirements and exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

Indication and usage for relapsed/refractory multiple myeloma (R/R MM)

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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

ICD-10-CM codes* for R/R MM

C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma 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-CM codes* for R/R MM after at least 4 lines of therapy

Z92.22	Personal history of monoclonal drug therapy
Z92.25	Personal history of immunosuppression therapy

*Be as specific as possible when selecting a code.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Cytokine Release Syndrome (CRS): (cont'd)
Infusion Related Reactions

Infusion-related reactions (IRR) may be clinically indistinguishable from manifestations of CRS. In the patients who were treated with the recommended step-up dosing regimen and pretreatment medications, the rate of IRR was 9% [11/117 including Grade 2 IRR (4.3%) and Grade 3 IRR (1.7%)]. For IRR, interrupt or slow the rate of infusion or permanently discontinue LYNOZYFIC based on severity of reaction.

Neurologic Toxicity, including Immune Effector Cell Associated Neurotoxicity Syndrome: LYNOZYFIC can cause serious or life-threatening neurologic toxicity, including ICANS. In LINKER-MM1, neurologic toxicity occurred in 54% of patients, with Grade 3 or 4 neurologic toxicity occurring in 8%, at the recommended dose. Neurologic toxicities included ICANS, depressed level of consciousness, encephalopathy, and toxic encephalopathy. ICANS occurred in 8% of patients who received LYNOZYFIC with the recommended dosing regimen, including Grade 3 events in 2.6%. Most patients experienced ICANS following step-up dose 1 (5%). Two patients (1.8%) experienced initial ICANS following step-up dose 2 and one patient developed the first occurrence of ICANS following a subsequent full dose of LYNOZYFIC. Recurrent ICANS occurred in one patient. The median time to onset of ICANS was 1 (range: 1 to 4) day after the most recent dose with a median duration of 2 (range: 1 to 11) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

CPT codes

96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
G0463	Hospital outpatient clinic visit for assessment and management of a patient
G0378	Hospital observation service, per hour
G0379	Direct admission of patient for hospital observation care

Note: LYNOZYFIC, when administered in the hospital outpatient setting, may require observation services. Observation requires a series of clinically appropriate services like short-term treatment, assessment, and reassessment of the patient. Claims reporting observation services must also include an initial service CPT such as a clinic or emergency department visit. Medical observation records should contain dated and timed physician's orders describing the observation services the patient is to receive. Please refer to payer requirements before reporting observation codes.

Example revenue codes for hospital-based infusions

0636	Pharmacy - Drugs Requiring Detailed Coding
025X	Pharmacy
0335	Radiology Therapeutic and/or Chemotherapy Administration - Chemotherapy Admin - IV
0762	Specialty Services - Observation Hours; Hospital Outpatient

Note: CMS requires Revenue Code 0636 to be billed on hospital outpatient claims for Medicare beneficiaries. Requirements for other payers may vary; some require 0636, others another pharmacy revenue code, such as 025X. Please consult with the appropriate payer before reporting a revenue code to determine the appropriate choice.

HCPCS level 2 code (J-code)

J-codes are permanent codes that are used by hospitals, physicians, and other health professionals who bill Medicare and commercial payers for non–orally-administered medication and chemotherapy drugs.

J9601

Injection, linvoseltamab-gcpt, 1 mg

LYNOZYFIC is billed in 1-mg units, per its HCPCS code.

Five units are billed for the 5-mg dose;
200 units are billed for the full 200-mg dose.

Note: Effective July 1, 2023, CMS and most payers require prescribers to record drug wastage, or lack thereof. A "-JW" modifier may be required for reporting that there was discarded drug (ie, JXXXX-JW). A "-JZ" modifier may be required for reporting there was no discarded drug (ie, JXXXX-JZ).

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; IV=intravenous infusion.

LYNOZYFIC product information

LYNOZYFIC is supplied in either a 5 mg/2.5 mL (2 mg/mL) single-dose vial or a 200 mg/10 mL (20 mg/mL) single-dose vial

LYNOZYFIC dose (mg/mL)	NDC	GTIN	UPC
5 mg/2.5 mL	61755**0**05401	Carton: 50361755054010 Case: 00361755054015	361755054015
200 mg/10 mL	61755**0**05601	Carton: 50361755056014 Case: 00361755056019	361755056019

Please refer to the full Prescribing Information for the recommended dosage of LYNOZYFIC. Coding requirements may vary by payer; please verify coding requirements before submitting claims.

NOTE: The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in bold above.

GTIN=Global Trade Item Number; NDC=National Drug Code; UPC=Universal Product Code.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Neurologic Toxicity, including Immune Effector Cell Associated Neurotoxicity Syndrome: (cont'd)
The most common clinical signs and symptoms of ICANS are confusion, depressed level of consciousness, and lethargy. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient; provide supportive therapy and consider further management per current practice guidelines. Withhold LYNOZYFIC until ICANS resolves and modify the next dose or permanently discontinue LYNOZYFIC based on severity. Counsel patients to seek immediate medical attention should signs or symptoms of neurologic toxicity, including ICANS occur at any time.

Due to the potential for neurologic toxicity, including ICANS, patients receiving LYNOZYFIC are at risk of confusion and depressed consciousness. Advise patients to refrain from driving, or operating heavy or potentially dangerous machinery, for 48 hours after completion of each of the step-up doses and in the event of new onset of any neurological symptoms, until symptoms resolve.

LYNOZYFIC REMS: LYNOZYFIC is available only through a restricted program under a REMS called the LYNOZYFIC REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Infections: LYNOZYFIC can cause serious, life-threatening, or fatal infections. In patients who received LYNOZYFIC at the recommended dose in LINKER-MM1, serious infections, including opportunistic infections, occurred in 42% of patients, with Grade 3 or 4 infections in 38% and fatal infections in 4%. The most common serious infection reported (≥10%) were pneumonia and sepsis. Two cases of progressive multifocal leukoencephalopathy (PML) occurred in patients receiving LYNOZYFIC.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING, for LYNOZYFIC.

LYNOZYFIC is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called LYNOZYFIC REMS.

Visit LYNOZYFICREMS.com

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Infections: (cont'd)
Monitor patients for signs and symptoms of infection and immunoglobulin levels prior to and during treatment with LYNOZYFIC and treat appropriately. Administer prophylactic antimicrobials, antibiotics, antifungals, antivirals, vaccines, and subcutaneous or intravenous immunoglobulin (IVIG) according to guidelines, including prophylaxis for PJP and herpesviruses. Withhold LYNOZYFIC or consider permanent discontinuation of LYNOZYFIC based on severity of the infection.

Neutropenia: LYNOZYFIC can cause neutropenia and febrile neutropenia. In patients who received LYNOZYFIC at the recommended dose in LINKER-MM1, decreased neutrophil count occurred in 62% of patients with Grade 3 or 4 decreased neutrophil count in 47%. Febrile neutropenia occurred in 8% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local guidelines. Monitor patients with neutropenia for signs of infection. Withhold LYNOZYFIC based on severity.

Hepatotoxicity: LYNOZYFIC can cause hepatotoxicity. In LINKER-MM1, elevated ALT occurred in 46% of patients, with Grade 3 or 4 ALT elevation occurring in 6%; elevated AST occurred in 61% of patients, with Grade 3 or 4 AST elevation occurring in 10% of patients who received the recommended dose. Grade 3 or 4 total bilirubin elevations occurred in 1.7% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold LYNOZYFIC or consider permanent discontinuation of LYNOZYFIC based on severity.

Embryo-Fetal Toxicity: Based on its mechanism of action, LYNOZYFIC may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with LYNOZYFIC and for 3 months after the last dose.

Adverse Reactions

The most common adverse reactions (≥20%) are musculoskeletal pain, cytokine release syndrome, cough, upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache, and dyspnea. The most common Grade 3 or 4 laboratory abnormalities (≥30%) are decreased lymphocyte count, decreased neutrophil count, decreased hemoglobin, and decreased white blood cell count.

Use in Specific Populations

Lactation: Advise not to breastfeed.

Please see accompanying full Prescribing Information, including Boxed WARNING, for LYNOZYFIC.

Reference: LYNOZYFIC™ (linvoseltamab-gcpt) full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

REGENERON®

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(linvoseltamab-gcpt) Injection 5mg | 200mg