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Newly approved relapsed/refractory multiple myeloma drug: Learn more about the product and acquisition information

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Dear Coalition of Hematology and Oncology Practices,

**LYNOZYFIC™ (linvoseltamab-gcpt) is now approved!**

LYNOZYFIC is **now approved** 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 below.

## NDC for LYNOZYFIC

Please ensure that policies and systems are updated to reflect LYNOZYFIC.

LYNOZYFIC dose (mg/mL)	Vial cap color	NDC
5 mg/2.5 mL	White	61755005401
200 mg/10 mL	Blue	61755005601

NDC=National Drug Code.

**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.

## HCPCS Information

Not otherwise classified, antineoplastic	J9999
Unclassified drug	J3490
Unclassified biologic	J3590
Unclassified drug or biologic (limited to ASC or HOPD claims for Medicare beneficiaries)	C9399

ASC=ambulatory surgical center; HCPCS=Healthcare Common Procedure Coding System; HOPD=hospital outpatient department.

**Note:** When using a temporary miscellaneous J-code, it is appropriate to indicate "1" billing unit on the claim form.

## Relevant ICD-10-CM Diagnosis Codes for Relapsed/Refractory Multiple Myeloma (R/R MM)

ICD-10-CM Code	ICD-10-CM Code description
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=*International Classification of Diseases, Tenth Revision, Clinical Modification.*

## ICD-10-CM Diagnosis Codes for R/R MM After At Least 4 Lines of Therapy

ICD-10-CM Code	ICD-10-CM Code description
Z92.22	Personal history of monoclonal drug therapy
Z92.25	Personal history of immunosuppression therapy

LYNOZYFIC is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called LYNOZYFIC REMS. Visit [LYNOZYFICREMS.com](http://LYNOZYFICREMS.com) to learn more.

LYNOZYFIC Surround™ helps eligible patients access LYNOZYFIC and navigate the insurance process. Enrollment is the first step to accessing support for benefits investigation, prior authorizations, claims, and appeals.

For more information or support, please reach out to your Oncology Reimbursement Manager, call 1.844.RGN.HEME (1.844.746.4363), Option 1, Monday–Friday, 8 AM–8 PM Eastern time, or visit [LYNOZYFIChcp.com](http://LYNOZYFIChcp.com).

**This material is provided for informational purposes only, is subject to change, and should not be construed as legal or medical advice. This information may not apply to all patients or to all health plans. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to the specific patient.**

Please contact me if you'd like additional information or if you have questions regarding the attached acquisition guide.

## **IMPORTANT SAFETY INFORMATION (cont'd)**

### **Warnings and Precautions**

**Cytokine Release Syndrome (CRS):** LYNZYFIC can cause CRS, which can be serious or life-threatening. In LINKER-MM1, CRS occurred in 46% (54/117) of patients who received LYNZYFIC 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 LYNZYFIC, 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 LYNZYFIC 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 LYNZYFIC until CRS resolves and modify the next dose or permanently discontinue LYNZYFIC based on severity.

#### *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 LYNZYFIC based on severity of reaction.

#### **Neurologic Toxicity, including Immune Effector Cell Associated Neurotoxicity Syndrome:**

LYNZYFIC 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 LYNZYFIC 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 LYNZYFIC. 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.

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 LYNZYFIC until ICANS resolves and modify the next dose or permanently discontinue LYNZYFIC 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 ( $\geq 10\%$ ) were pneumonia and sepsis. Two cases of progressive multifocal leukoencephalopathy (PML) occurred in patients receiving LYNOZYFIC.

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 ( $\geq 20\%$ ) 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 ( $\geq 30\%$ ) 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 full [Prescribing Information](#), including **Boxed WARNING**, for LYNOZYFIC.**

Sincerely,

Melissa Souders  
Melissa.Souders@regeneron.com  
214-564-3024

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

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