April 2026

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

Comprehensive Product Acquisition Guide

Dosing, administration, hospitalization, and acquisition information

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

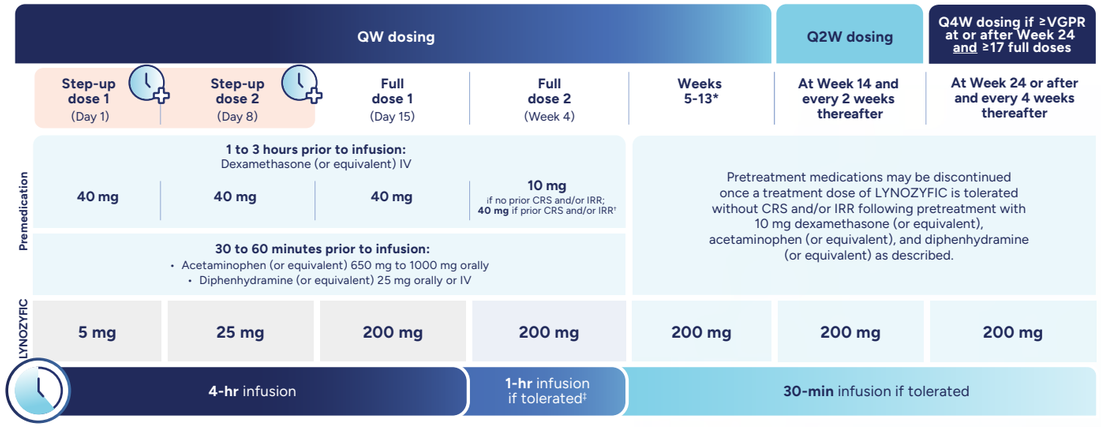
- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving LYNOZYFIC. Initiate treatment with LYNOZYFIC step-up dosing to reduce the risk of CRS. Manage CRS, withhold LYNOZYFIC until CRS resolves, and modify the next dose or permanently discontinue 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.

Dosing and administration

The recommended dosage for LYNOZYFIC is presented below. In patients who experience CRS, ICANS, or neurologic adverse reactions, refer to the approved Prescribing Information for information on management of adverse reactions and recommendations regarding administration of the next LYNOZYFIC dose. Treatment may be continued until disease progression or unacceptable toxicity.

Premedicate and follow the LYNOZYFIC step-up dosing schedule to reduce the risk of CRS and IRR.



Hospitalization information

The 24-hour hospitalizations occur after administration of the first step-up dose on Day 1 and following administration of the second step-up dose on Day 8.

Hospitalization timeline example:

Refer to the Prescribing Information for additional important administration and monitoring instructions.

*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.
†Once full dose is tolerated without CRS and/or IRR with 40 mg dexamethasone IV, administer 10 mg dexamethasone IV and other pretreatment medications as described above until full dose is tolerated without CRS and/or IRR.
‡For patients who experienced CRS with the previous dose of LYNOZYFIC, the duration of infusion should be maintained at the duration of the previous infusion; reduce the duration of infusion sequentially in subsequent doses in patients who do not experience CRS (eg, 4 hours, 1 hour, then 30 minutes).

CRS=cytokine release syndrome; ICANS=immune effector cell-associated neurotoxicity syndrome; IRR=infusion-related reaction; IV=intravenous; QW=weekly; Q2W=every 2 weeks; Q4W=every 4 weeks; VGPR=very good partial response.

Important administration instructions

- **Administer therapy** according to LYNOZYFIC step-up dosing to reduce the incidence and severity of CRS
- 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 **pretreatment medications**
- Administer **only as an IV infusion after dilution in 0.9% Sodium Chloride Injection**
- LYNOZYFIC **should be administered by an HCP** with immediate access to emergency equipment and appropriate medical support to manage severe reactions such as CRS, IRR, and neurologic toxicity, including ICANS

Dosage forms and strengths

LYNOZYFIC dose (mg/mL)	Vial cap color	NDC
5 mg/2.5 mL	White	61755**0**05401
200 mg/10 mL	Blue	61755**0**05601

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.

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 judgment when submitting claims.

HCP=healthcare provider; NDC=National Drug Code.

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.

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

LYNOZYFIC Risk Evaluation and Mitigation Strategy (REMS)

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)

Cytokine Release Syndrome (CRS): (cont'd)
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.

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.

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

Accessing LYNOZYFIC

Authorized distributors

Contact one of our authorized distributors below to order LYNOZYFIC.*

ASD Healthcare
Phone: 1-800-746-6273 | asdhealthcare.com

McKesson Specialty Health
Phone: 1-800-482-6700 | oncology.mckessonspecialtyhealth.com

Oncology Supply
Phone: 1-800-633-7555 | oncologysupply.com

McKesson Plasma and Biologics
Phone: 1-877-625-2566 | connect.mckesson.com

Cardinal Health Specialty Distribution
Phone: 1-866-677-4844 | specialtyonline.cardinalhealth.com

Specialty pharmacy distributor

As an option, or if instructed by the patient's payer, LYNOZYFIC may be obtained through our specialty pharmacy provider.*

Onco360
Phone: 1-877-662-6633 | onco360.com

Regeneron does not recommend the use of any particular distributor or specialty pharmacy. Please refer to LYNOZYFIChcp.com for the authorized specialty pharmacy and a current list of all authorized distributors.

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**

*Orders received prior to 7 PM Eastern time, Monday–Thursday, are typically processed on the same day and scheduled for delivery the next business day. Orders received on Friday will typically be delivered the following Monday. Please contact a specialty distributor for specific order and delivery information.

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.

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

Effective April 1, 2026, the following HCPCS code should be used to bill for LYNOZYFIC:

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.

The billing and coding information discussed in this guide 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. Information provided in this guide is effective as of April 2026.

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**

HCPCS=Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

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.

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

LYNOZYFIC product return/replacement procedure

If LYNOZYFIC is rendered unusable after purchase or receipt, it may be returned to Regeneron and replaced under certain circumstances. Returns are subject to adherence to Regeneron policies and procedures regarding the return of product and Regeneron's right, at its sole discretion, to deny replacement when misuse is suspected.

Information about returning/replacing LYNOZYFIC

- As a condition of replacement, product should be returned.* Proof of purchase/receipt will be required for any product replacements
- Note the condition of the vial:
  - **If vial is intact:** Return to the address provided when you contact the patient support program
  - **If the vial is broken*:** Submit pictures documenting the damage
- **Contact your distributor or specialty pharmacy** if you believe LYNOZYFIC expired or was damaged in shipment

For product complaints and/or product returns, or to obtain appropriate forms and a list of required documents, call **LYNOZYFIC** at **1.844.RGN.HEME** (1.844.746.4363), **Option 4**

*Broken vials do not have to be returned, but pictures documenting the damage should be submitted.

NOTES:

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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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