LYNOZYFIC SURROUND™

LYNOZYFIC Surround

Commercial Copay Program

This handout provides information about the LYNOZYFIC Surround Commercial Copay Program for eligible, commercially insured patients

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.

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

Commercial Copay Program

Commercially insured patients may be eligible to pay as little as $0 out of pocket for LYNOZYFIC*

Program benefits

Patients may pay as little as $0 out of pocket for LYNOZYFIC, up to $25,000 in assistance per year, which includes copay, coinsurance, and deductibles for LYNOZYFIC product and administration charges*

Patient out-of-pocket responsibility

Patients are responsible for any out-of-pocket costs for LYNOZYFIC that exceed the program assistance limit of $25,000 per year. Patients are also responsible for costs related to supplies for LYNOZYFIC and/or costs as required by their insurance plans

Patient eligibility

Patients are eligible for the LYNOZYFIC Surround Commercial Copay Program if they meet the following criteria:

- Must have **commercial** or **private** insurance
- Must be a resident of the United States or its territories or possessions

There is no income requirement to qualify for this program

Eligible patients can apply for copay assistance through LYNOZYFIC Surround. There are 2 ways to enroll in the Commercial Copay Program:

LYNOZYFIC Surround Enrollment Form

- Fax the completed form to 1.833.853.8362
- Upload the completed form to Docu-Send at DocuSend.org

Phone

Physician offices or patients can call LYNOZYFIC Surround at **1.844.RGN.HEME** (1.844.746.4363), **Option 1**, Monday–Friday, 8 AM–8 PM Eastern time

*Subject to annual maximum copay assistance amount of $25,000 toward out-of-pocket treatment costs for LYNOZYFIC, including deductibles, copays, and coinsurance for LYNOZYFIC drug and administration charges. This program is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, Veterans Affairs/ Department of Defense, TRICARE, or similar federal or state programs. Not a debit card program. The program does not cover or provide support for supplies for LYNOZYFIC. Patients who are residents of Massachusetts or Rhode Island are not eligible for LYNOZYFIC administration assistance. This program only applies to patients who are at least 18 years of age, residents of the United States or its territories or possessions, are prescribed LYNOZYFIC (linvoseltamab-gcpt) for an FDA-approved indication, and are insured by a commercial health plan that requires a copayment, coinsurance, and/or deductible amount for LYNOZYFIC. It is not an insurance benefit. LYNOZYFIC Surround reserves the right to rescind, terminate, or amend this offer, eligibility, and terms and conditions at any time without notice. Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer. This offer is not conditioned on any past, present, or future purchase, including refills. This offer is nontransferable, limited to one per person, and cannot be combined with any other offer or discount. This program is not valid where prohibited by law, taxed, or restricted. Offer has no cash value. Patients are responsible for any out-of-pocket costs for LYNOZYFIC that exceed the program assistance limit of $25,000 per year. Program is not valid for cash-paying customers. Additional program conditions may apply. See LYNOZYFIChcp.com for more information.

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Submitting claims through the LYNOZYFIC Surround Commercial Copay Program

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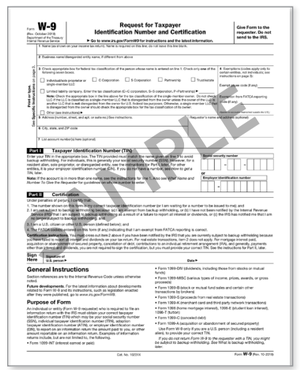
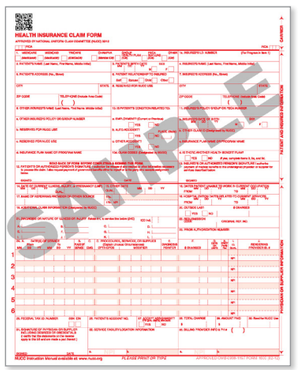
HCPs should submit documents that reflect the charges for the LYNOZYFIC product and administration, as well as reimbursement from the payer, such as:



W-9 form†



CMS-1500 or UB-04 claim form (which includes the NDC)

Explanation of benefits from the patient's health insurer

Once a patient is approved for the LYNOZYFIC Surround Commercial Copay Program, there are 2 ways to submit claims:

Mail

2250 Perimeter Park Drive, Suite 300
Morrisville, NC 27560

Fax

The Commercial Copay Program at 1.866.203.4003

If patients are enrolled in LYNOZYFIC Surround, HCPs can also upload claims through Docu-Send at DocuSend.org or by fax to LYNOZYFIC Surround at 1.833.853.8362

†The completed W-9 form is required for the initial office claim submission into the Commercial Copay Program and may be required for subsequent claim submissions, as requested by LYNOZYFIC Surround.

CMS=Centers for Medicare & Medicaid Services; 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.

Considerations when submitting claims through the Commercial Copay Program

The LYNOZYFIC Surround Commercial Copay Program will **disburse funds once the claim has been approved and processed**

You **must not** have received any **payment from the patient or other third party** for the copayment amount

All requests for reimbursement must be **submitted within 365 days** of the date of service

For more information about reimbursement through the LYNOZYFIC Surround Commercial Copay Program, call **1.844.RGN.HEME** (1.844.746.4363), **Option 1**, Monday–Friday, 8 AM–8 PM Eastern time, or visit **LYNOZYFIChcp.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.

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.

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Notes

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

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For any questions or concerns, or to report side effects with a Regeneron product for patients enrolled in LYNOZYFIC Surround, 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 (cont'd)

Neurologic Toxicity, including Immune Effector Cell Associated Neurotoxicity Syndrome: (cont'd)

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.

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®

777 Old Saw Mill River Road, Tarrytown, NY 10591
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