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

Pursuing coverage for LYNOZYFIC™ (linvoseltamab-gcpt)

A guide to provide education for HCPs and office staff on submitting complete CMS-1500 and UB-04 forms and pursuing coverage through medical necessity or exceptions based on their independent clinical judgment

CMS=Centers for Medicare and Medicaid Services; HCP=healthcare provider.

INDICATION AND USAGE[1]

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 coverage support

Use this resource to access coverage support for LYNOZYFIC, including:

Forms that support reimbursement, with annotated samples of the 2 most common CMS claim forms used for billing drugs and services:

- CMS-1500 (print) or 837P (electronic) forms for billing for physician office
- CMS-1450 (print), also referred to as CMS UB-04, or 837I (electronic) forms for hospital outpatient

Checklists and sample letter templates that may be used to pursue coverage for LYNOZYFIC:

- Prior authorization (PA) checklist
- Sample letter of medical necessity
- Sample letter of medical exception
- Appeal checklist and sample letter of appeal

Scan the QR code or visit LYNOZYFIChcp.com for letter templates, available in the resources section of the website

Questions about coverage 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.

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

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Sample annotated CMS-1500 form*

The CMS-1500 form is commonly used for billing for LYNOZYFIC when it is administered in physician offices. The annotations in the sample form below are designed to provide you with information about how to populate the critical fields that health plans require for LYNOZYFIC reimbursement.

This sample claim form is intended for use only as a reference. The codes provided are subject to change and should not be construed as legal or billing advice. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient. Please confirm the accuracy of the codes you use to bill for LYNOZYFIC with each payer. If submitting to a Medicare Administrative Contractor (MAC), be sure to refer to the specific MAC's guidelines for completion of the reimbursement forms.

BOX 19

LYNOZYFIC does not currently have a product-specific HCPCS code. When filing claims using a miscellaneous HCPCS code, most payers require additional information to be entered in Box 19, including the drug name, route of administration, total dosage, NDC number, and wastage or lack of wastage.[2] **Please check with the payer to confirm the required additional information.**

BOX 21

Indicate appropriate diagnosis using ICD-10-CM codes.[2]

BOX 24A

Enter a 6-digit or 8-digit (month-date-year) date for each procedure, service, or supply. Include NDC information, if required, in the shaded red areas above each date.[2]

BOX 24B

Enter the appropriate place of service code(s).[2]

BOX 24D

Enter the appropriate CPT® and HCPCS level 2 codes and modifiers for procedures, services, and supplies.[2] Because LYNOZYFIC does not currently have a product-specific HCPCS code, default NOC (Not Otherwise Classified) codes are used instead. Enter miscellaneous HCPCS code J3490, J3590, J9999, or C9399 to represent LYNOZYFIC.

Additionally, CMS and most payers require you to record drug waste. Until LYNOZYFIC is assigned a product-specific code, reports of no wastage can be added to Box 19 and entered here using the miscellaneous HCPCS code and modifier JZ denoting zero waste (ie, JXXXX-JZ). Similarly, reports of wastage can be added to Box 19 and entered here using the miscellaneous HCPCS code and modifier JW denoting drug waste (ie, JXXXX-JW). Please note that when reporting drug wastage, it should be entered on a separate claim line.[2,3]

BOX 24E

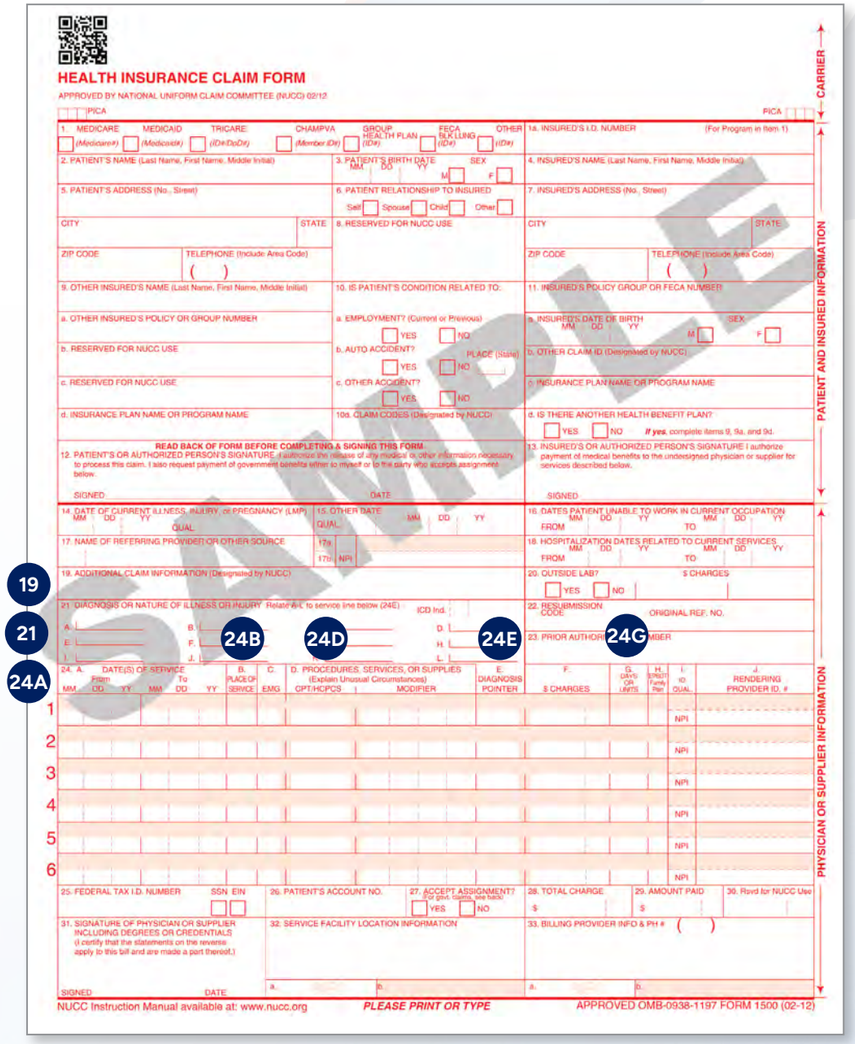
Enter the diagnosis code reference number or letter (as appropriate, per form version) as shown in item 21 to relate the date of service and the procedures performed to the primary diagnosis. Enter only 1 reference number/letter per line item. If multiple services were performed, enter the primary reference number/letter for each service.[2]

BOX 24G

Enter the number of units of LYNOZYFIC administered. **Miscellaneous HCPCS codes are usually reported with a unit of 1.** Use Box 19 to report the total dosage of LYNOZYFIC administered.[2]

*CMS 837P (not shown) is the electronic equivalent of CMS-1500. It should be used if you submit your claims electronically.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; NDC=National Drug Code.



IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

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

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.

Sample annotated UB-04 form*

The CMS UB-04 form is commonly used for billing for LYNOZYFIC when it is administered in hospital outpatient settings. The annotations in the sample form below are designed to provide you with information about how to populate the critical fields that health plans require for LYNOZYFIC reimbursement.

This sample claim form is intended for use only as a reference. The codes provided are subject to change and should not be construed as legal or billing advice. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient. Please confirm the accuracy of the codes you use to bill for LYNOZYFIC with each payer. If submitting to a MAC, be sure to refer to the specific MAC's guidelines for completion of the reimbursement forms.

BOX 42

List revenue codes in ascending order. Be sure to enter the appropriate numeric revenue code on the adjacent line in Box 42 to explain each charge in Box 47.[4]

BOX 43

Provide a narrative description or standard abbreviation for each revenue code shown in Box 42 on the adjacent line in Box 43. If an NDC is required, submit "N4" followed by the 11-digit NDC.[4]

BOX 44

Enter the appropriate CPT code for LYNOZYFIC injection: 96314 or 96415, and the payer's preferred miscellaneous HCPCS code to represent LYNOZYFIC. CMS and most payers require you to record drug waste. Until LYNOZYFIC is assigned a product-specific code, reports of no wastage can be added to Box 80 and entered here using the miscellaneous HCPCS code and modifier JZ denoting zero waste (ie, JXXXX-JZ). Similarly, reports of wastage can be added to Box 80 and entered here using the miscellaneous HCPCS code and modifier JW denoting drug waste (ie, JXXXX-JW). Please note that when reporting drug wastage, it should be entered on a separate claim line.[3,4]

BOX 46

Enter the number of units of LYNOZYFIC administered. **Miscellaneous HCPCS codes are usually reported with a unit of 1.** If drug wastage was reported in Box 44 on a separate claim line with the JW modifier, please indicate the amount of drug wasted here.[4]

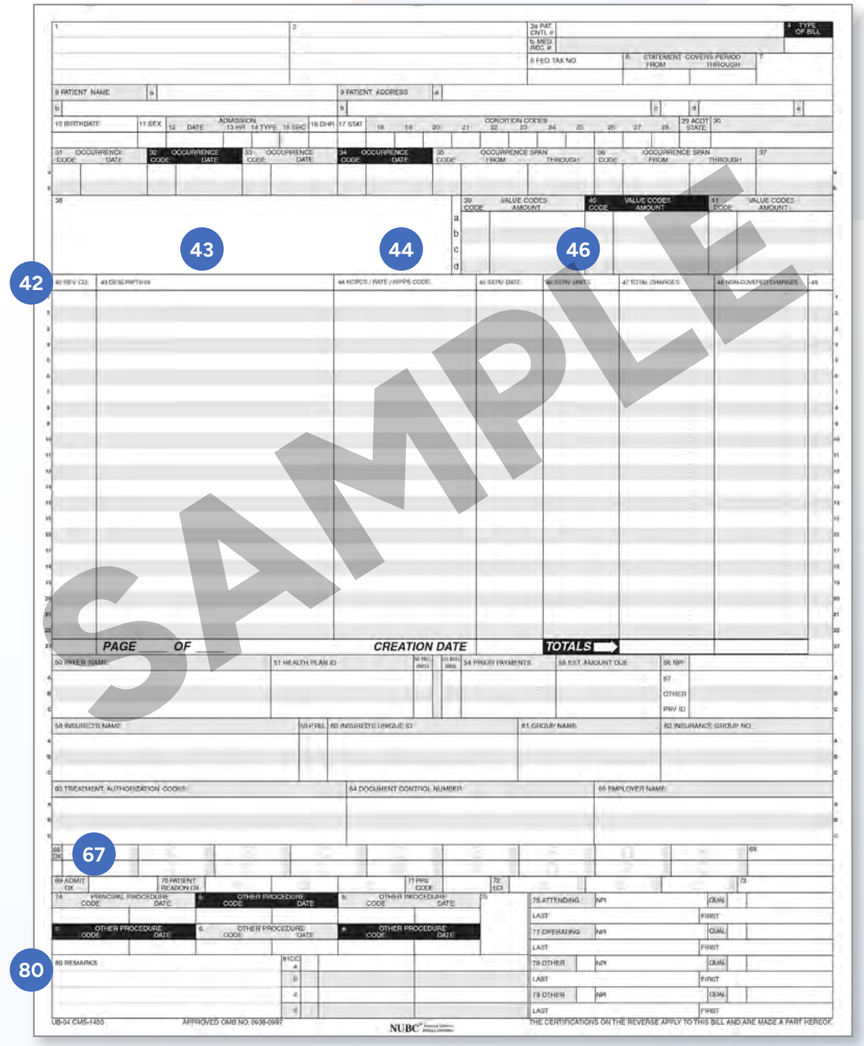
BOX 67

Enter the specific ICD-10-CM diagnosis code(s).[4]

BOX 80

When filing claims using a miscellaneous HCPCS code, most payers require additional information to be entered in Box 80, including the drug name, route of administration, total dosage, NDC number, and wastage or lack of wastage.[4] **Please check with the payer to confirm the required additional information.**

*CMS 837I (not shown) is the electronic equivalent of CMS-1450/UB-04. It should be used if you submit your claims electronically.



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.

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

PA checklist

LYNOZYFIC is likely to require a PA from the patient's health plan. When submitting a PA request for LYNOZYFIC, you can use the following PA checklist to help ensure you provide the essential information requested by the health plan.

It is important to review each health plan's guidelines for obtaining PA, as elements and requirements vary by plan. Please note that following a health plan's guidelines does not guarantee the patient's health plan will provide reimbursement for LYNOZYFIC, and the guidelines are not intended to substitute or influence the physician's independent medical judgment.

Tips for handling PA requirements

- ☐ **Complete a PA form**. Some health plans accept a standardized form; others require you to complete a form they provide
- ☐ **Write** a letter of medical necessity, if required
- ☐ **Attach copies** of the front and back of the patient's health plan card
- ☐ **Provide additional documentation**, where applicable, that supports your treatment rationale, such as:
  - Patient's medical records
  - Peer-reviewed literature
  - Supporting clinical studies
  - Prescribing Information for LYNOZYFIC
  - Clinical notes and laboratory tests
  - Letter of medical necessity

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

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.

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

Sample letter of medical necessity

You can use this sample letter of medical necessity to provide the reasons that, in your clinical judgment, LYNOZYFIC is necessary for your patient. The letter should explain why LYNOZYFIC is being requested and give health plans additional information they can use to assess whether the medication may be approved. The sample letter is provided for your reference and should be adapted as you see fit.

Please note that taking the steps recommended in this resource does not guarantee the health plan will provide reimbursement for LYNOZYFIC, and the information is not intended to substitute or influence the physician's independent medical judgment.

Some key reminders:

- You may consider including a letter of medical necessity with your PA request to emphasize the medical necessity for LYNOZYFIC or in addition to your appeal letter, as needed
- Letters of medical necessity should only be signed by the physician
- Be sure to include an appropriate ICD-10-CM code matching your patient's diagnosis

Some health plans require a letter of medical necessity along with supporting documentation, which may include:

- Patient's medical records
- Peer-reviewed literature
- Supporting clinical studies
- Prescribing Information for LYNOZYFIC
- Clinical notes and laboratory results

A sample letter of medical necessity template is available at **LYNOZYFIChcp.com**

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.

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

Sample letter of medical necessity

NOTE: *You can use this sample letter of medical necessity to provide the reasons that, in your clinical judgment, this product is necessary for your patient. The letter should explain why the product is being requested and give health plans additional information they can use to assess whether the medication is approvable. This letter offers no guarantees. This sample letter is provided for your guidance and may be adapted as you see fit, please be sure to use your own letterhead.*

[Date]
[Health Plan Contact Name]
[Title]
[Health Plan Organization Name]
[Address]
[City, State ZIP]

Re: [Patient Name], Insurance Policy ID Number: [Policy ID Number], Group Number: [Group Number], Claim Number: [Claim Number]

Dear [Health Plan Contact Name],

I am writing on behalf of my patient, [Patient full name], to document the medical necessity of [product]. Included below is additional information about the patient's medical history and diagnosis, as well as a statement summarizing my treatment rationale.

[Include a detailed overview of the patient's condition and specific diagnosis. Include the patient's history related to the condition and the length of time you think the patient will need to take the medication.]

In summary, [product] is medically necessary for this patient's medical condition, and [health plan name] should cover this product for my patient without delay. Please contact me at [phone number] if additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician's name, degree(s), and signature]
Enclosures: [Attach any additional documentation, as appropriate]

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Sample letter of medical exception

This letter provides an example of the types of information that may be required when writing a letter of medical exception for LYNOZYFIC. It is important to note that supplying the information listed in this letter does not guarantee the health plan will provide reimbursement for LYNOZYFIC, and this information is not intended to substitute or influence the physician's independent medical judgment. The sample letter is provided for your reference only and should be adapted as you see fit.

Please note that taking the steps recommended in this resource does not guarantee the health plan will provide reimbursement for LYNOZYFIC, and this information is not intended to be a substitute for or influence on the physician's independent medical judgment.

Some key reminders:

- You may consider including a letter of medical exception if coverage for LYNOZYFIC is denied because of the health plan's policy or if LYNOZYFIC is subject to a National Drug Code block
- Be sure to populate an appropriate ICD-10-CM code matching your patient's diagnosis

Some health plans require a medical exception letter along with supporting documentation, which may include:

- Patient's medical records
- Peer-reviewed literature
- Supporting clinical studies
- Prescribing Information for LYNOZYFIC
- Clinical notes and laboratory results
- Letter of medical necessity

A sample letter of medical exception template is available at **LYNOZYFIChcp.com**

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

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

Sample letter of medical exception

NOTE: *This letter provides an example of the types of information that may be required when writing a letter of medical exception for this product. It is important to note that supplying the information listed in this letter does not guarantee the health plan will provide reimbursement for the product, and this information is not intended to substitute or influence the physician's independent medical judgment. This sample letter is provided for your guidance only and may be adapted as you see fit. Please be sure to use your own letterhead.*

[Date]
[Health Plan Contact Name]
[Title]
[Health Plan Organization Name]
[Address]
[City, State ZIP]

Re: [Patient Name], Insurance Policy ID Number: [Policy ID Number], Group Number: [Group Number], Claim Number: [Claim Number]

Dear [Health Plan Contact Name],

I am writing to request a medical exception for [Patient full name] for the treatment of [diagnosis] with [product]. It is my professional opinion that [product] is medically appropriate and necessary, and should be covered and reimbursed for this patient.

[Patient full name] has been under my care for [insert diagnosis] since [date of onset/diagnosis]. Included for your consideration is [Patient first name]'s medical history and diagnosis (ICD-10-CM code: [insert code]), a statement summarizing my reasons for treating [Patient full name] with [product], and a copy of the Prescribing Information for [product].

[Insert summary of patient history, including treatment history, response to past therapies, and recent symptoms and conditions.]

In summary, it is my professional judgment that it is in the best interest of [Patient full name] to be treated with [product], and I am requesting approval for treatment with [product]. Please call me at [phone number] if I can be of further assistance or if you require additional information.

Sincerely,

[Physician's name, degree(s), and signature]
Enclosures: [Attach any additional documentation, as appropriate]

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Appeal checklist and sample letter of appeal

If a health plan receives a PA request and denies coverage for LYNOZYFIC for your patient, you may appeal the decision. You can use the checklist included in this resource to help support an appeal.

Please note that taking the steps recommended in this resource does not guarantee the health plan will offer reimbursement for LYNOZYFIC, and this information is not intended to substitute for or influence the physician's independent medical judgment. It is important to review each health plan's guidelines for appeals, as elements and requirements vary by plan. The sample letter is provided for your reference only and should be adapted as you see fit.

Some health plans require an appeal letter along with additional documentation, which may include:

- Appeal form, if provided by the plan
- Clinical notes and laboratory results
- Supporting clinical studies
- Peer-reviewed literature
- Prescribing Information for LYNOZYFIC

There are numerous reasons why health plans may deny a PA for LYNOZYFIC. Although the reasons vary by plan, some of the most common include:

- Errors in ICD-10-CM coding on the PA request
- Insufficient documentation on the PA request
- Health plan claims lack of medical necessity for LYNOZYFIC
- LYNOZYFIC is not covered by patient's health plan

Please keep in mind, just as reasons for denial vary, so do each health plan's requirements for an appeal. It is important to check with the patient's health plan to ensure you have all the information you need to proceed with an appeal.

A sample letter of appeal template is available at **LYNOZYFIChcp.com**

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Hepatotoxicity: (cont'd)

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

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

Appeal checklist

- ☐ **Confirm** that LYNOZYFIC is covered by the patient's health plan for the appropriate diagnosis
- ☐ **Double-check** the accuracy of the information provided on the initial PA request
  - Patient Information
  - Coding (it is recommended to use the most specific applicable codes as possible)
- ☐ **Identify** the reason for the denial—it is often included in the Explanation of Benefits letter
- ☐ **Review** the plan's appeal guidelines
  - Deadline to submit appeal
  - Timeline of review by health plan
  - Number of appeals permitted
  - Fax number or email address to be used to submit the appeal letter and any additional required information
  - Required additional supporting documentation, such as:
    - Supporting clinical studies
    - Prescribing Information for LYNOZYFIC
    - Appeal form, if provided by the plan
    - Clinical notes and laboratory results
- ☐ **Clarify** any aspect of the appeal process with the health plan's review department
- ☐ **Gather** all required supporting documentation needed to help defend your rationale for coverage of LYNOZYFIC
- ☐ **Prepare** a written appeal. The appeal should be written by the physician. In some cases, the patient may write the appeal **(see page 16 for a sample letter of appeal template)**
- ☐ **Send** the written appeal, along with the supporting documentation, to the health plan for review
- ☐ **Follow up** with the plan on the status of the appeal
- ☐ **Save** copies of all appeal-related documentation, including:
  - Documents submitted with the appeal letter
  - Documents received from the patient's health plan
  - Health plan representative's contact information

Sample letter of appeal

Sample appeal letter

NOTE: *If a health plan receives a PA request and denies coverage of this product for your patient, you may appeal the decision. This sample letter is provided for your guidance only and doesn't ensure your appeal will be overturned. Please use your own letterhead.*

[Date]
[Health Plan Contact Name]
[Title]
[Health Plan Organization Name]
[Address]
[City, State ZIP]

Re: [Patient Name], Insurance Policy ID Number: [Policy ID Number], Group Number: [Group Number], Claim Number: [Claim Number]

Dear [Health Plan Contact Name],

I am writing to request a medical exception for [Patient full name] to appeal your denial of coverage for [product]. It is my understanding that [product] was denied because [state the specific reason the PA was denied].

I would like to explain why [product] should be covered for [Patient name]. Along with this letter, I am providing information about the patient's medical history and diagnosis (ICD-10-CM code: [insert code]), a statement summarizing my treatment rationale, and other documents that support the medical necessity of [product] in this clinical case.

[Patient name] was diagnosed with [disease] on [date]. I believe [product] is needed for the treatment of this patient. The patient's medical history includes [insert information that summarizes the patient's treatment history, response to past therapies, recent symptoms and conditions, and opinion of the patient's prognosis with and without treatment with [product]].

Given [Patient name]'s clinical condition and the information included in the supporting documentation, I ask you to reconsider your previous decision and approve coverage for [product], which is indicated by the US Food and Drug Administration for this condition.

On behalf of [Patient name], I appreciate your reconsideration. If you require additional information, please contact me at [phone number]. Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name, degree(s), and signature]
Enclosures: [Attach any additional documentation, as appropriate]

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Notes

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

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

LYNOZYFIC SURROUND™

LYNOZYFIC Surround helps eligible patients access LYNOZYFIC and navigate the insurance process

For more information, 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)

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.

References: 1. LYNOZYFIC™ (linvoseltamab-gcpt) full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 26: completing and processing form CMS-1500 data set. Updated August 9, 2024. Accessed February 21, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf **3.** Centers for Medicare & Medicaid Services. Medicare program. Discarded drugs and biologicals JW modifier and JZ modifier policy. Frequently asked questions. Accessed February 21, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **4.** Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 25: completing and processing the form CMS-1450 data set. Updated December 20, 2023. Accessed February 21, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

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