MONJUVI®
tafasitamab-cxix | 200 mg
for injection, for intravenous use

MEDICAL EXCEPTIONS & PATIENT SUPPORT SERVICES GUIDE

- What is a Medical Exception?
- Information / Document Checklist
- Sample Reimbursement Letters
  - Letter of Medical Necessity
  - Medical Exception Letter
  - Letter of Appeal - Prior Authorization and Claim Denial
- My MISSION Support - Program Overview

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on specific payer guidance and requirements.

WHAT IS A MEDICAL EXCEPTION?

When a product is not covered by an insurance plan, it is sometimes referred to as non-formulary, NDC blocked, or requiring a medical exception. A medical exception describes the process whereby a healthcare professional can request that a payer consider covering a product not approved or covered for a specific patient due to medical necessity.

A medical exception is commonly used when new drugs become available and the payer has not yet determined coverage or established a medical policy. When a healthcare professional has determined that a drug is medically necessary, he or she can submit a medical exception requesting that the payer approve the treatment.

Prior authorizations are standard for many oncology therapies. If a prior authorization is denied, the medical exception request process can be used as a prior authorization appeal, and the same forms and processes can typically be used.

Similar to a traditional prior authorization process, the medical exception request process varies by payer. Therefore, it is important to follow the steps required, submit all requested documentation, and use the correct forms.

The medical exception request process specific to a given payer may be obtained by contacting the payer's provider relations department, and may also be available online.

Additionally, **My MISSION Support** may be able to provide payer-specific details as needed.

For Medicare Part B plans, instructions for submitting a request, as well as downloadable model request forms, are available from CMS at **www.cms.gov**.

Part B plans do not require specific forms, so the use of the model form is optional.

NCCN PREFERRED

National Comprehensive Cancer Network® (NCCN®) Preferred Treatment Option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend tafasitamab-cxix (MONJUVI) in combination with lenalidomide as a preferred second-line or subsequent therapy option (if not previously used) for DLBCL in patients who are not candidates for transplant (Category 2A)[1*]

*It is unclear if tafasitamab or loncastuximab tesirine or if any other CD-19 directed therapy would have a negative impact on the efficacy of subsequent anti-CD19 CAR T-cell therapy.
NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

INDICATION

MONJUVI (tafasitamab-cxix), in combination with lenalidomide, is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Contraindications: None.

Warnings and Precautions:

- **Infusion-Related Reactions (IRRs).** MONJUVI can cause IRRs, including fever, chills, rash, flushing, dyspnea, and hypertension. Premedicate patients and monitor frequently during infusion. Based on the severity of the IRR, interrupt or discontinue MONJUVI and institute appropriate medical management.

(continued on page 10)

Please see additional Important Safety Information on page 10 and full Prescribing Information.

INFORMATION / DOCUMENT CHECKLIST

Patients' health plans may request additional information before approving coverage for treatment. In your efforts to secure MONJUVI coverage for individual patients, you may need to provide one or more supporting letters. For your reference, we've provided sample reimbursement letters as well as the following checklist to help you generate accurate payer correspondence to support your MONJUVI patients.

CHECKLIST

Patient Information

- ☐ Patient Name
- ☐ Date of Birth
- ☐ Insurance Carrier
- ☐ Insurance ID
- ☐ Insurance Group Number
- ☐ Case ID Number (if applicable)

Clinical Rationale

- ☐ Patient's diagnosis for a condition MONJUVI is FDA-approved to treat
- ☐ Severity of patient's condition, patient's performance status
- ☐ Summary of patient's previous treatments, including the duration of each treatment, response to past treatments, the rationale for discontinuation, and recent symptoms / condition. Include coding information for prior treatments / services if available
- ☐ Patient's disease progression and scan history
- ☐ Clinical rationale for MONJUVI treatment, including clinical trial data supporting FDA approval, administration, and dosage information

Additional Enclosures

- ☐ MONJUVI Prescribing Information (**www.MONJUVI.com/PI/MONJUVI-PI.pdf**)
- ☐ FDA Approval Information (**www.FDA.gov/drugsatfda**)
- ☐ Clinical Notes / Medical Records

If you have questions about appeals or medical exceptions, **My MISSION Support** may be able to help – **855-421-6172**

Access more information online at **www.MyMISSIONSupport.com**

Please see Important Safety Information on pages 2 and 10 and full Prescribing Information.

SAMPLE REIMBURSEMENT LETTERS

The following sample letters are included to help support the development of payer-specific communications in the event of medical policy restrictions, prior authorizations, and/or denials.

Please note, the sample letters included here are for reference and should be used for guidance only.

1. **Letter of Medical Necessity**
   - If the payer's medical policy includes a prior authorization for the patient to be treated with MONJUVI, you can submit a Letter of Medical Necessity
2. **Medical Exception Request**
   - If MONJUVI is not available on the payer's medical policy, you may want to submit a Medical Exception Request
3. **Prior Authorization and Claim Denial**
   - If you have experienced a health plan's denial of MONJUVI and would like to appeal the denial, you can submit a Letter of Appeal - Prior Authorization and Claim Denial

Sample Reimbursement Letters Can Also Be Obtained by Calling My MISSION Support at 855-421-6172 or Visiting www.MyMISSIONSupport.com

Some health plans will require supporting documentation with your outreach. This documentation could include:

- Chart documentation
- Data from MONJUVI clinical trials (included in the Prescribing Information) supporting use in adult patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL)
- Patient treatment plan

To avoid delays in a coverage decision, it is recommended that you provide as much documentation as possible when submitting your requests. It is important to note that supplying information in your request does not guarantee coverage for MONJUVI and this information is not intended to substitute or influence a physician's independent medical judgment.

The My MISSION Support Team Can Assist in Obtaining Payer-Specific Forms and Further Describe Payer Processes

MEDICAL NECESSITY

This sample letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient, as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the procedure.

SAMPLE LETTER OF **MEDICAL NECESSITY**

[Date]
[Payer Name]
[Payer Street Address]
[Payer City, State, and Zip Code]

Patient Name: [Patient Full Name]
Date of Birth: [Patient Birth Date]
Member ID: [Patient Member ID Number]
Policy or Group Number: [Patient Policy or Group Number]
Case ID Number: [Case ID Number (if available)]

To Whom It May Concern,

I am writing on behalf of my patient, (patient name), to provide information supporting medical necessity for MONJUVI® (tafasitamab-cxix) treatment. In this letter, I am providing my patient's medical history, diagnosis, and a summary of their treatment plan. I have also provided a brief description of the patient's previous treatments and a clinically-based treatment rationale supporting the medical necessity for MONJUVI.

Patient's Clinical / Medical History

- [Patient's ICD-10-CM diagnosis code and date of diagnosis]
- [Patient's first visit date and date of referral]
- [Patient's performance status]
- [Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation]
- [Patient's disease progression and scan history]
- [Any additional factors impacting MONJUVI treatment selection]

Treatment Plan

- [Include plan of treatment: dosage, frequency, and length of treatment]
- [Clinical rationale for the use of MONJUVI]

Summary

Based on the provided information, I believe MONJUVI is medically necessary for [Patient name]. Please find the enclosed additional documents [list any attachments] that support my clinical decision. If you need additional information for a timely approval, please contact my office at [insert office phone number].

Sincerely,

[Physician Name]
[Physician Address]
[Physician Phone]

Enclosures: [List any applicable enclosures such as prescribing information, patient medical history, relevant peer-reviewed articles, FDA approval letter, etc.]

IMPORTANT! You must include your patient's medical history, diagnosis, and treatment plan or the health plan cannot make a coverage determination

In order to substantiate your request for MONJUVI coverage, you should include any supporting documents that will assist the health plan in making a decision

It is highly recommended you include the FDA approval letter to support your clinical decision

This sample letter is also available on **www.MyMISSIONSupport.com**

MEDICAL EXCEPTION

This sample letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient, as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the procedure.

SAMPLE LETTER OF **MEDICAL EXCEPTION**

[Date]
[Payer Name]
[Payer Street Address]
[Payer City, State, and Zip Code]

Patient Name: [Patient Full Name]
Date of Birth: [Patient Birth Date]
Member ID: [Patient Member ID Number]
Policy or Group Number: [Patient Policy or Group Number]
Case ID Number: [Case ID Number (if available)]

To Whom It May Concern,

I understand that the [plan name] policy for [patient name] requires [restriction description] prior to approving MONJUVI® (tafasitamab-cxix) treatment. However, I believe that [patient name] requires MONJUVI without [restriction description] due to clinical and medical circumstances. Please see below for details about symptoms, previous treatments, medical history, and treatment rationale that supports the claim for medical exception for [patient name].

Patient's Clinical / Medical History

- [Patient's ICD-10-CM diagnosis code and date of diagnosis]
- [Patient's first visit date and date of referral]
- [Patient's performance status]
- [Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation]
- [Patient's disease progression and scan history]
- [Any additional factors impacting MONJUVI treatment selection]

Justification for Medical Exception

- [State the clinical rationale for treatment with MONJUVI]
- [Describe why the plan requirement is not appropriate for your patient]
- [List concerns that may include experience on similar therapies, drug side effects, and any other patient-specific considerations]

Treatment Plan

- [Include plan of treatment: dosage, frequency, and length of treatment]
- [Clinical rationale for the use of MONJUVI]

Summary

Based on the above, I am certain that you will agree MONJUVI is an appropriate treatment for [patient name]. A timely approval of MONJUVI by [plan name] without [restriction description] would be greatly appreciated by both myself and my patient. Please contact me at [phone number] if you need more information to approve a medical exception for [patient name].

[Physician Name]
[Physician Address]
[Physician Phone]

Enclosures: [List any applicable enclosures such as prescribing information, patient medical history, relevant peer-reviewed articles, FDA approval letter, etc.]

Be sure to describe the coverage restriction in detail

In this section, include any previous treatment the patient has received so the insurance company does not request a treatment that may not be appropriate for your patient

Be specific in this section so the health plan can make informed and timely decisions

This sample letter is also available on **www.MyMISSIONSupport.com**

PRIOR AUTHORIZATION AND CLAIM DENIAL

This sample letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient, as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the procedure.

SAMPLE LETTER OF APPEAL
PRIOR AUTHORIZATION AND CLAIM DENIAL

[Date]
[Payer Name]
[Payer Street Address]
[Payer City, State, and Zip Code]

Patient Name: [Patient Full Name]
Date of Birth: [Patient Birth Date]
Member ID: [Patient Member ID Number]
Policy or Group Number: [Patient Policy or Group Number]
Case ID Number: [Case ID Number (if available)]

To Whom It May Concern,

I am writing on behalf of my patient, [patient name], to request reconsideration for the coverage of MONJUVI® (tafasitamab-cxix) treatment which was denied on [date] for the following reason: [describe reason given in denial letter]. For your convenience, I have attached documentation supporting my request for reversal of coverage denial:

- The prior authorization request for [patient name] which was denied on [date]
- The patient's relevant medical history, diagnosis, and treatment plan
- Clinical rationale supporting MONJUVI treatment for [patient name]

Patient's Clinical / Medical History

- [Patient's ICD-10-CM diagnosis code and date of diagnosis]
- [Patient's first visit date and date of referral]
- [Patient's performance status]
- [Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation]
- [Patient's disease progression and scan history]
- [Any additional factors impacting MONJUVI treatment selection]

Treatment Plan

- [Include plan of treatment: dosage, frequency, and length of treatment]
- [Clinical rationale for the use of MONJUVI]

Summary

Given the provided evidence, I am confident you will agree treatment with MONJUVI is medically necessary. It is crucial that [plan name] allow the use of MONJUVI and provide coverage so [patient name] receives the care they need. We appreciate your prompt review and reconsideration of this case. If you need additional information, please contact my office at [insert office phone number].

Sincerely,

[Physician Name]
[Physician Address]
[Physician Phone]

Enclosures: [List any applicable enclosures such as prescribing information, patient medical history, relevant peer-reviewed articles, FDA approval letter, etc.]

It is important to include a detailed description of the denial as including specific information may reduce the appeal process timeline and mitigate additional requests for information

By including the patient's detailed history, you highlight the rationale for the insurance plan to cover MONJUVI. It is particularly important to emphasize the severity of your patient's condition, previous treatments, and the patient's failure on prior treatments

This sample letter is also available on **www.MyMISSIONSupport.com**

MY MISSION SUPPORT - PROGRAM OVERVIEW

A ROBUST SUPPORT PROGRAM FOR ELIGIBLE PATIENTS AND CAREGIVERS

My MISSION Support can help you understand health insurance coverage requirements, answer billing and coding questions, and enroll eligible patients in all program services, including financial assistance programs, helping to secure appropriate access to MONJUVI for eligible patients.

My MISSION Support's Program Specialists offer personalized assistance, with the goal of making MONJUVI access simple and streamlined, while providing holistic, compassionate support.

Program Services Include:

- **Call Center 8 AM - 8 PM EST**
- **Program Specialists** Local Market Reimbursement Experts
- **Billing & Coding Resources**
- **Benefit Investigations & Prior Authorization Support**
- **Claims Submission & Appeals Support**
- **Patient Financial Assistance Programs***
- **Patient Support & Education**

Personalized Support to Assist in Accessing MONJUVI:

- Patient-Specific Benefit Verifications
- Prior Authorization Support
- MONJUVI Coding Q&A
- Claim Denial and Appeals Assistance

My MISSION SUPPORT Patient Support Program™

A Suite of Financial Assistance and Program Support Options for Eligible Patients:

- Free Product for Eligible Patients Through the My MISSION Support Patient Assistance Program
- Copay Assistance† for Commercially Insured Patients
- Information About Independent Sources of Assistance That May Be Able to Help Patients

* Other terms and conditions apply. Visit www.MyMISSIONSupport.com for full eligibility criteria.
† The program is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]).

Please see Important Safety Information on pages 2 and 10 and full Prescribing Information.

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GETTING STARTED WITH MY MISSION SUPPORT

1 — **Visit www.MyMISSIONSupport.com and Click on Enroll**

2 — **Download and Complete** a Printable Enrollment Form → **Fax** Enrollment Form to: **866-870-6241**

My MISSION Support

REIMBURSEMENT SUPPORT

My MISSION Support's Program Specialists can help research patient-specific benefits and answer questions related to coding and coverage for MONJUVI. If a prior authorization is required, the My MISSION Support team can help research and communicate payer requirements. In the event of a claim denial, My MISSION Support can research the reason for denial and provide support throughout the appeal process.

Please visit our website at **www.MyMISSIONSupport.com** for helpful materials and additional information.

MONJUVI COMMERCIAL COPAY ASSISTANCE*

My MISSION Support may be able to provide financial support for patient's out-of-pocket costs for MONJUVI.

Upon program enrollment, commercially insured patients will be assessed for copay assistance eligibility. If they qualify, patients may be responsible for a drug copay of as little as $0. My MISSION Support will pay any remaining copay, up to $25,000 per calendar year.

MONJUVI PATIENT ASSISTANCE

For patients who meet financial and insurance requirements, My MISSION Support is pleased to offer MONJUVI free of charge.

Once a patient's eligibility is confirmed and the patient is enrolled in the program, My MISSION Support will coordinate product shipment to the physician's office.

PERSONALIZED PATIENT SUPPORT AND EDUCATION

When a patient enrolls in My MISSION Support, they may opt into receiving additional support and education from an oncology professional. These professionals are specially trained to support a patient's ongoing journey with MONJUVI treatment by providing general disease and treatment information, routine phone-based check-ins, and referrals to additional resources. A patient's doctor should always be their first point of contact for any questions about their condition or treatment.

* Other terms and conditions apply. Visit www.MyMISSIONSupport.com for full eligibility criteria. The program is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]).

Please see Important Safety Information on pages 2 and 10 and full Prescribing Information.

IMPORTANT SAFETY INFORMATION *(continued)*

Warnings and Precautions *(continued)*:

- **Myelosuppression.** MONJUVI can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. Monitor complete blood counts (CBC) prior to administration of each treatment cycle and throughout treatment. Monitor patients with neutropenia for signs of infection. Consider granulocyte colony-stimulating factor administration. Withhold MONJUVI based on the severity of the adverse reaction. Refer to the lenalidomide prescribing information for dosage modifications.
- **Infections.** Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose. 73% of the 81 patients developed an infection. The most frequent infections were respiratory tract infection, urinary tract infection, bronchitis, nasopharyngitis and pneumonia. Grade 3 or higher infection occurred (30% of 81 patients). The most frequent grade 3 or higher infection was pneumonia. Infection-related deaths were reported (2.5% of 81 patients). Monitor patients for signs and symptoms of infection and manage infections as appropriate.
- **Embryo-Fetal Toxicity.** Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus and women of reproductive potential to use effective contraception during treatment with MONJUVI and for at least 3 months after the last dose. The combination of MONJUVI with lenalidomide is contraindicated in pregnant women. Refer to the lenalidomide prescribing information on use during pregnancy.

Adverse Reactions:

The most common adverse reactions (≥20%) were neutropenia (51%), fatigue (38%), anemia (36%), diarrhea (36%), thrombocytopenia (31%), cough (26%), pyrexia (24%), peripheral edema (24%), respiratory tract infection (24%), and decreased appetite (22%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to MORPHOSYS US INC. at (844) 667-1992.

Please see the full Prescribing Information for additional Important Safety Information.

REFERENCES: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.5.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed July 7, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.

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