MONJUVI
tafasitamab-cxix

rituximab &
lenalidomide

Billing & Coding Guide

- Coverage, Coding, & Payment for MONJUVI
- Best Practices for Timely Claims Reimbursement
- Example Claims Forms: CMS-1500 & CMS-1450
- Provider Readiness–Process and Tips
- IncyteCARES for MONJUVI–Patient Support Program Overview

This Billing and Coding Guide is intended to provide an overview of coding and coverage information for MONJUVI. Please use this guide to support the reimbursement process and as a source of information on IncyteCARES for MONJUVI.

While this guide provides information on navigating the reimbursement process, please note all enclosed coding information is for reference purposes only 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.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

For questions regarding MONJUVI reimbursement and access, please call IncyteCARES at 1-855-452-5234, M-F, 8 AM to 8 PM ET

Please see Important Safety Information throughout and the full Prescribing Information for more information about MONJUVI.

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

Coverage, Coding, & Payment for MONJUVI

Coverage and payment methodology for MONJUVI will vary by payer type

For Medicare patients, MONJUVI will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.

There are no prior authorization requirements for MONJUVI under traditional fee-for-service Medicare plans.

For patients enrolled in a commercial health plan, Medicare Advantage, or Medicaid, coverage of MONJUVI will vary by payer. Some payers may also apply utilization restrictions for MONJUVI. When seeking coverage, providers should be prepared for the possibility of needing to go through the prior authorization process.

Payment Methodology

MEDICARE

Standard Medicare Part B reimbursement is average sales price (ASP) + 6%.*

COMMERCIAL PAYERS & MEDICAID

Drug reimbursement will vary by payer but is generally the contracted reimbursement rate between the payer and provider.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

*If Medicare sequestration is in effect, a statutory reduction to the payment is applied. Please visit CMS.gov for more information.

FOR FL

INDICATIONS & USAGE

Follicular Lymphoma

MONJUVI (tafasitamab-cxix), in combination with lenalidomide and rituximab, is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Limitations of Use: MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

Contraindications:

None.

Warnings and Precautions:

- **Infusion-Related Reactions (IRRs).** MONJUVI (tafasitamab-cxix) 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.
- **Myelosuppression.** MONJUVI can cause serious or severe myelosuppression, including neutropenia, lymphopenia, thrombocytopenia, and anemia. Monitor complete blood counts (CBCs) before 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. Among 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab in inMIND, Grade 3 or higher infections occurred in 24%. Monitor patients for signs and symptoms of infection and manage infections as appropriate. Consider infection prophylaxis per institutional guidelines. Consider treatment with subcutaneous or intravenous immunoglobulin (IVIG) as appropriate.

Please see additional Important Safety Information throughout and the full Prescribing Information for more information about MONJUVI.

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Coverage, Coding, & Payment for MONJUVI (CONT'D)

Please refer to the coding information below to support appropriate claims processing for MONJUVI for the treatment of follicular lymphoma (FL). Payer requirements for coding may vary. For the most accurate list of codes and billing requirements, please confirm with the individual payer.

NDC		
	10-Digit	11-Digit
200 mg	50881-013-03	50881-**0**013-03

HCPCS Coding	
J9349	Injection, tafasitamab-cxix, 2 mg

HCPCS Modifiers	
JZ	Zero drug amount discarded/not administered to any patient
JW	Drug amount wasted/discarded units

ICD-10-CM Diagnosis Codes	
C82.00 – C82.09	Follicular lymphoma grade I
C82.10 – C82.19	Follicular lymphoma grade II
C82.20 – C82.29	Follicular lymphoma grade III
C82.30 – C82.39	Follicular lymphoma grade IIIa
C82.50 – C82.59	Diffuse follicle center lymphoma
C82.60 – C82.69	Cutaneous follicle center lymphoma
C82.80 – C82.89	Other types of follicular lymphoma
C82.90 – C82.9	Follicular lymphoma, unspecified

Revenue Codes			
Administration		Drug	
0335	Chemotherapy Administration - IV	**0636**	Drugs requiring detailed coding

Drug Administration / CPT® Code	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial drug

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.

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Best Practices for Timely Claims Reimbursement

MONJUVI has a unique J-Code

J9349 Injection, tafasitamab-cxix, 2 mg

One single-dose vial of MONJUVI contains 200 mg of tafasitamab-cxix, equal to 100 billing units when using HCPCS code J9349.

Payer requirements regarding detailed claim form information may vary. It is important to check with individual payers on their specific requirements and ensure accurate documentation of services and units of measure.

For an efficient claims and reimbursement process, employ the following strategies:

- **Verify accuracy** of patient information
- **Use the MONJUVI specific J-code:** J9349 (Injection, tafasitamab-cxix, 2 mg) when completing a claim
- **Ensure accurate coding:** Refer to the MONJUVI Billing & Coding Guide for appropriate codes and modifiers
  - Reference the included example claims forms for guidance on accurately recording appropriate codes and supplemental information
- **Include correct number** of units administered. Note: One 200 mg single-dose vial is equal to 100 billing units
- **Include correct modifier**
  - To report no product discarded - record the JZ Modifier on the same line as the HCPCS code
  - To report product wastage - record the JW Modifier on a second claim line
- **Ensure accuracy of information** needed to process the claim
  - Correct NDC format – use 10- or 11-digit format based on payer requirements
  - Prior authorization number, if applicable
- **Check your payer agreements** to ensure you understand any specific reimbursement needs for MONJUVI and follow the payer's recommendations for providing additional information (eg, medical records)
- **Make sure** electronic claims are successfully submitted
- **Stay up to date** with payer coverage policies

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.

For questions regarding billing, coding, or reimbursement for MONJUVI, call IncyteCARES to be connected with a Field Access Manager
1-855-452-5234, M-F, 8 AM to 8 PM ET

The information herein is provided for educational purposes only. Insurance coverage and reimbursement are not guaranteed. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see Important Safety Information throughout and the full Prescribing Information for more information about MONJUVI.

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Using the JW & JZ Modifiers for Accurate Claims

It is important to use the correct modifier to reflect any wastage

The JW and JZ modifiers are HCPCS Level II modifiers used for claims that bill for single-dose container drugs. Improper use or omission of the JW and JZ modifiers may result in returned claims, requiring resubmission.

While MONJUVI is distributed in a single-dose vial, its dosage is based on the patient's weight, which may result in leftover medication that must be discarded but is eligible for payment under the discarded drug policy. In these cases, the JW modifier is used to report wastage. When using the JW modifier to bill for discarded drugs, the amount administered should be rounded up to the next billing unit.

In the event there is no wastage, the JZ modifier is used to indicate that no amount of drug was discarded or eligible for payment.

JW Modifier: Reporting Wastage

Two claim lines will be used:

1	**J9349**	No Modifier	Units Administered
2	**J9349**	JW Modifier	Units Wasted

JZ Modifier: Documenting No Wastage

Use a single claim line:

1	**J9349**	JZ Modifier	Units Administered

Example 1: 40 kg patient

Administered 12 mg/kg of MONJUVI, equal to 480 mg of MONJUVI, drawn from **three** 200 mg single-use vials.
In this example, the JW modifier is used to report 120 mg (3 mL) of wastage on the CMS-1500 Claim Form.

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N47353520801 ML 12.0															
MM	DD	YY	MM	DD	YY	11		J9349			$$	240		NPI	
N47353520801 ML 3.0															
MM	DD	YY	MM	DD	YY	11		J9349	JW		$$	60		NPI	

Example 2: 70 kg patient

Administered 12 mg/kg of MONJUVI, equal to 840 mg of MONJUVI, drawn from **five** 200 mg single-use vials.
In this example, the JW modifier is used to report 160 mg (4 mL) of wastage on the CMS-1450 Claim Form.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	N47353520801 ML21.0	J9349	MM-DD-YY	420	$$			1
2									2
3	0636	N47353520801 ML4.0	J9349 - JW	MM-DD-YY	80	$$			3

Example 3: 50 kg patient

Administered 12 mg/kg of MONJUVI, equal to 600 mg of MONJUVI, drawn from **three** 200 mg single-use vials.
In this example, the JZ modifier is reported to denote no drug was discarded on the CMS-1450 Claim Form.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	N47353520801 ML15.0	J9349 - JZ	MM-DD-YY	300	$$			1

Inclusion of the JZ or JW modifier is required for timely reimbursement and approval of claims.

Questions? Contact your Field Access Manager or call IncyteCARES for MONJUVI at **1-855-452-5234,** M-F, 8 AM to 8 PM ET

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

Please see Important Safety Information throughout and the full Prescribing Information for more information about MONJUVI.

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MONJUVI Example CMS-1500 Claim Form
Physician Office Setting

This example form is provided for guidance and reference only.

MONJUVI and the associated services delivered by non-institutional providers in a physician office setting are billed on the CMS-1500 Claim Form. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. **Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.**

Box 19
Some payers may require additional information for proper processing. This may include*:
drug name, strength, route of administration, dosage administered, and NDC

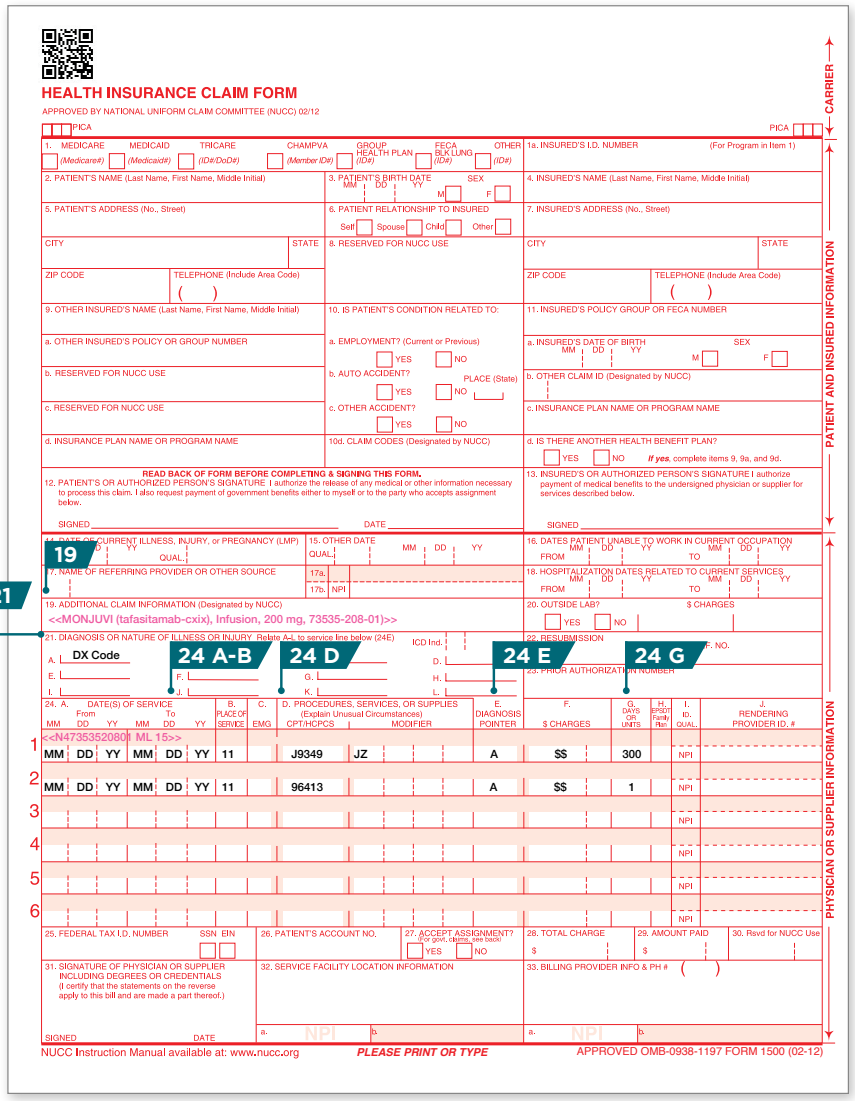
Box 21
Enter the ICD-10-CM diagnosis code

Box 24 A-B
Enter the date of service and appropriate place of service code. If NDC reporting is required, include the following in the shaded portion of Box 24A*:
N4+11-Digit NDC+ML+Unit quantity administered

Box 24 D
Enter the appropriate HCPCS, modifier, and CPT® codes. For example:
- Drug - J9349 (Injection, tafasitamab-cxix, 2 mg)
- Modifier
  - JZ (include the JZ modifier on the same line as the HCPCS code to indicate no amount of drug was discarded)
  - JW (include the JW modifier on a separate line as the HCPCS code to indicate amount of drug discarded)
- Administration - 96413 (Chemo infusion for first hour, single or initial drug)

Box 24 E
Refer to the diagnosis (Box 21), relating to the drug or procedure listed in Box 24D

Box 24 G
Enter number of units for each line item
- J9349 billing unit = 2 mg
- Single-dose vial = 200 mg
- 200 mg vial = 100 units



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.

*Always refer to specific payer policies as billing requirements may vary by payer, including use of the 10- or 11-digit NDC.

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MONJUVI Example CMS-1450 Claim Form
Physician Office Setting

This example form is provided for guidance and reference only.

MONJUVI and the associated services delivered by institutional providers in a physician office setting are billed on the CMS-1450 Claim Form. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. **Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.**

Box 42
List the appropriate revenue code for each service provided. Drugs billed with HCPCS codes usually require revenue code 0636 (drugs requiring detailed coding)

Box 43
Enter a description for each revenue code

If NDC reporting is required, include the following*:
N4+11-Digit NDC+ML+Unit quantity administered

Box 44
Enter the appropriate HCPCS, modifier, and CPT® codes. For example:

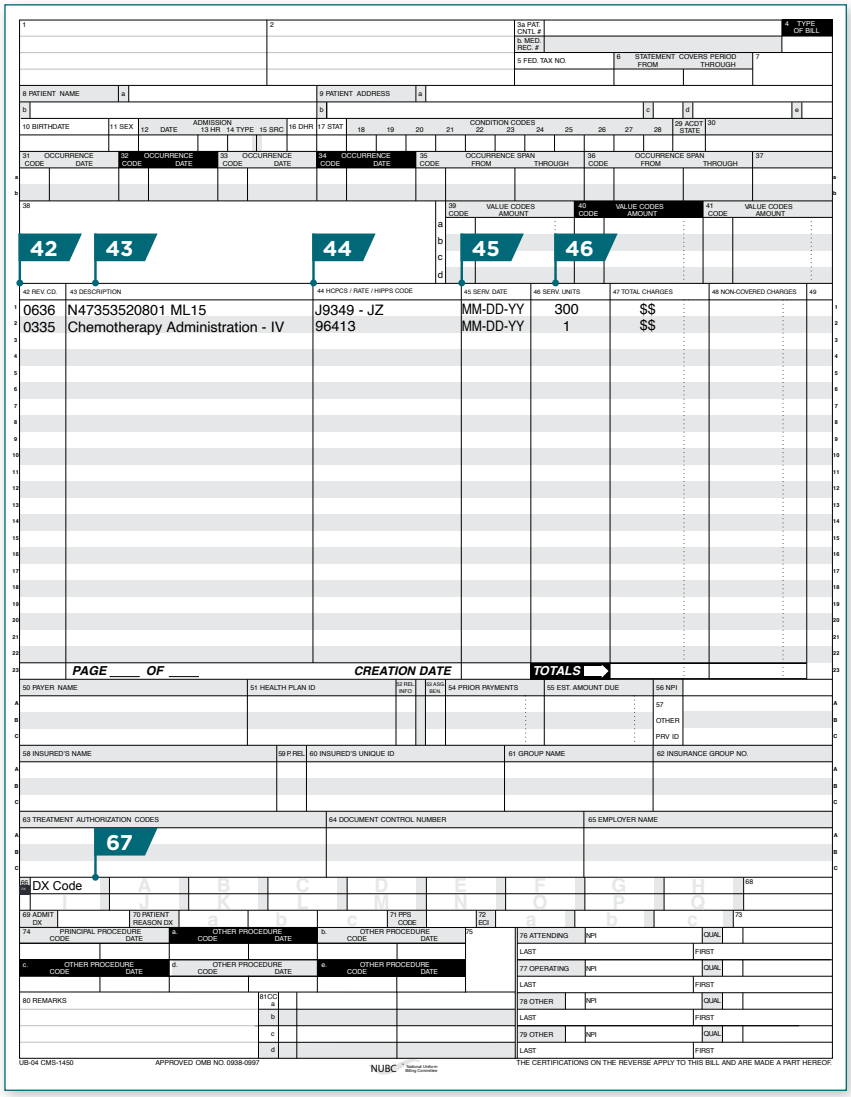
- Drug - J9349 (Injection, tafasitamab-cxix, 2 mg)
- Modifier
  - JZ (Include the JZ modifier on the same line as the HCPCS code to indicate no amount of drug was discarded)
  - JW (Include the JW modifier on a separate line as the HCPCS code to indicate amount of drug discarded)
- Administration - 96413 (Chemo infusion for 1st hour, single or initial drug)

Box 45
Enter the date of service

Box 46
Enter number of units for each line item

- J9349 billing unit = 2 mg
- Single-dose vial = 200 mg
- 200 mg vial = 100 Units

Box 67
Enter the ICD-10-CM diagnosis code



*Always refer to specific payer policies as billing requirements may vary by payer, including use of the 10- or 11-digit NDC.

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.

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Provider Readiness – Process & Tips

When preparing to treat a patient with MONJUVI for follicular lymphoma (FL), consider the steps below to facilitate patient access, proper claims submission, and appropriate reimbursement. For questions or support on any of these steps, please reach out to IncyteCARES for MONJUVI at **1-855-452-5234** or visit **HCP.IncyteCARES.com/MONJUVI** to complete an enrollment form.

1. **Research and understand** patient-specific benefits and coverage for MONJUVI
2. If there are access concerns, be sure to **enroll your patient** in IncyteCARES to understand potential financial assistance options that may be available for eligible patients
3. **Schedule the patient** for their first MONJUVI infusion
4. **Purchase MONJUVI** (if not already in inventory) through one of the following specialty distributors:

Specialty Distributors

CardinalHealth | cencora | McKESSON

Prescribers who do not wish to use buy-and-bill should check with their preferred specialty pharmacy for availability. Specialty pharmacies may obtain access to MONJUVI through the specialty distributors listed above.

5. After treatment, **complete and submit a claim** to the payer, including all necessary information. If no product was discarded, include the JZ modifier to attest to no wastage. If product was discarded, include the JW modifier to provide the amount discarded.

If you have questions about this process,
IncyteCARES and your Field Access Manager may be able to help.

Access more information online at
HCP.IncyteCARES.com/MONJUVI

Call 1-855-452-5234,
M–F, 8 AM to 8 PM ET

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IncyteCARES for MONJUVI

Patient Support Program Overview

When You Enroll a Patient, an IncyteCARES for MONJUVI Representative Will:

- Call your patient to welcome them and explain their insurance coverage for MONJUVI
- Assess your patient's eligibility for savings or financial assistance programs,* and help them enroll
- Explain the additional support and resources available to them during treatment

*Terms and conditions apply. Program terms may change at any time.

IncyteCARES

IncyteCARES Supports Your Eligible Patients With Follicular Lymphoma During Treatment With MONJUVI

Our mission is to help patients start and stay on therapy by assisting with access and as-needed support.

For Eligible Patients With Commercial Health Insurance

IncyteCARES for MONJUVI Savings Program

Eligible patients can receive MONJUVI for as little as

$0

subject to certain limits†

To qualify, patients must:

- Have commercial healthcare coverage. Patients insured under federal or state government healthcare programs—including Medicare Part B, Medicare Advantage, Medicaid, TRICARE, or any state medical or pharmaceutical assistance program—are not eligible. Patients without healthcare coverage are also not eligible
- Be a resident of the United States or Puerto Rico
- Have a valid prescription for MONJUVI for an FDA-approved use

†Uninsured, cash-paying, or Alternate Funding Program (AFP) patients are not eligible. Not valid for patients insured through Medicare Part B, Medicare Advantage, Medicaid, TRICARE, or any state medical or pharmaceutical assistance program. Patient enrollment in a copay adjustment program, such as a maximizer or accumulator program, may impact the value of this offer. Annual benefit maximum applies, as may other restrictions. Program benefit applies to medication cost only and does not cover any costs to administer the medication. Valid prescription for MONJUVI® (tafasitamab-cxix) for an FDA-approved indication or compendia-recognized use is required. Please see the full **Patient Terms and Conditions** or call IncyteCARES for MONJUVI at 1-855-452-5234. Update effective as of May 1, 2024.

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IncyteCARES for MONJUVI

Patient Support Program Overview (CONT'D)

Enroll Your Eligible Patients in IncyteCARES for MONJUVI

Completing the enrollment form takes about 15 minutes.

Simply download and complete the form, then fax it to 1-866-870-6341.

Visit **HCP.IncyteCARES.com/MONJUVI** for more information

Enrolled IncyteCARES patients have other financial assistance and support options

When you enroll your patient in IncyteCARES for MONJUVI, we will also review their eligibility for the following programs:

For Eligible Patients Who Are Uninsured or Underinsured for MONJUVI

IncyteCARES for MONJUVI Patient Assistance Program

For All Patients

Information About Nonprofit or Other Support Organizations

The IncyteCARES Team Is Available by Phone Every Weekday

IncyteCARES

Call 1-855-452-5234, M–F, 8 AM to 8 PM ET

Visit HCP.IncyteCARES.com/MONJUVI to learn more

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: (cont'd)

- **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 3 months after the last dose. The combination of MONJUVI with lenalidomide and rituximab is contraindicated in pregnant women. Refer to the lenalidomide prescribing information on use during pregnancy.

Adverse Reactions:

The most common adverse reactions (≥ 20%) in patients with FL receiving MONJUVI were respiratory tract infections (56%) (including COVID-19 infection and pneumonia), diarrhea (38%), rash (37%), fatigue (34%), constipation (29%), musculoskeletal pain (24%), and cough (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 20%) were decreased neutrophils (48%) and decreased lymphocytes (22%).

Please see the full Prescribing Information for more information about MONJUVI.

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