



# BILLING & CODING GUIDE

**This Guide Provides an Overview of Coverage, Coding, and Available Patient Support Services for MONJUVI**

- ▶ Introduction
- ▶ Facilitating Coverage and Coding
- ▶ Coding and Billing Requirements
- ▶ Provider Readiness - Process and Tips
- ▶ 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 their clinical judgement, payer specific guidance, and other requirements.



**For Questions Regarding MONJUVI Reimbursement and Access,  
Please Call My MISSION Support at 855-421-6172**

## 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).



This **Billing & Coding Guide** is intended to provide an overview of MONJUVI coding and coverage information. Please use this guide as a tool to support the reimbursement process and as a source of information on services available through My MISSION Support.

While this guide provides information on navigating the reimbursement process, please note all enclosed coding information is for reference purposes only. This information does not guarantee payment or coverage for any product or service.

**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)\*

\*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.

## 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 9)*

Please see additional Important Safety on page 9 and full [Prescribing Information](#).

# FACILITATING COVERAGE AND CODING

MONJUVI HAS A UNIQUE J-CODE:

**J9349**

Injection, tafasitamab-cxix, 2mg

Payer requirements regarding detailed claim form information may vary. It is important to check with individual payers on their specific requirements, especially as related to units of measurement.

## MONJUVI J-CODE BILLING UNIT CONVERSION

J9349 Billing Unit	=	2mg
1 Single-Dose Vial of MONJUVI	=	200mg
200mg Vial	=	<b>100 Units</b>

The total number of mg administered will vary based on patient weight.

## What can I do to support timely reimbursement of MONJUVI claims?

- ▶ Follow the payer’s policy information regarding MONJUVI coverage requirements:
  - ▶ Prior Authorization
  - ▶ Patient medical history and prior treatments
  - ▶ Other supporting clinical information
- ▶ When completing the 1450 or 1500 Claims Form, use the MONJUVI specific J-Code: J9349 (Injection, tafasitamab-cxix, 2mg)
- ▶ Include correct number of units administered
  - ▶ E.g., One 200 mg vial is equal to 100 units
  - ▶ Separately, use the JW modifier to report discarded units as required
  - ▶ If no product was discarded, include the JZ modifier to attest to no wastage
- ▶ Ensure accuracy of the following information needed to process the claim:
  - ▶ CPT Code
  - ▶ Patient Diagnosis and information
  - ▶ Correct NDC Format (Payers typically require the 11-digit format)
  - ▶ Prior Authorization Number (if applicable)
- ▶ Check your payer agreements to ensure you understand any specific reimbursement needs for MONJUVI
- ▶ Make sure electronic claims are successfully submitted

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 health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.



**For Billing and Coding or Reimbursement Questions, or to Request Support From a Member of the Field Access and Reimbursement Team, Call 855-421-6172, M-F 8 AM to 8 PM ET**

Please see Important Safety Information on pages 2 and 9 and full [Prescribing Information](#).

# CODING AND BILLING REQUIREMENTS

## COVERAGE

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 Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of MONJUVI will vary by payer. Some payers may also apply utilization restrictions for MONJUVI.

## CODING

Please refer to the table below to support appropriate claims processing for MONJUVI.

Effective April 1, 2021, MONJUVI has pass-through status (in effect until December 31, 2023) and a permanent J-code - J9349 (Injection, tafasitamab-cxix, 2mg).

DLBCL ICD-10-CM DIAGNOSIS CODES		DRUG ADMINISTRATION / CPT CODES	
Unspecified site	C83.30	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial drug	96413
Lymph nodes of head, face, and neck	C83.31		
Intrathoracic lymph nodes	C83.32	Chemotherapy administration, intravenous infusion technique; each additional hour, 1-8 hours <i>(List separately in addition to code for primary procedure)</i>	96415
Intra-abdominal lymph nodes	C83.33		
Lymph nodes of axilla and upper limb	C83.34	JW Modifier - Modifier for wastage / discarded units <i>Requirements for wastage / discarded units should be confirmed on a payer by payer basis</i>	JW
Lymph nodes of inguinal region and lower limb	C83.35		
Intrapelvic lymph nodes	C83.36	JZ Modifier - Modifier for zero product wastage	JZ
Spleen	C83.37		
Lymph nodes of multiple sites	C83.38		
Extranodal and solid organ sites	C83.39		
		MONJUVI DRUG CODES	
		HCPCS Code	J9349 (Injection, tafasitamab-cxix, 2mg)
		NDC Number	10-Digit - 73535-208-01 11-Digit - 73535-0208-01 <i>Payer requirements regarding use of a 10-digit or 11-digit NDC vary</i>

## PAYMENT FOR MONJUVI

PAYER TYPE	PAYMENT METHODOLOGY
Medicare	Average Sales Price (ASP) +6%*
Commercial Payers and Medicaid	Most Non-Medicare payers will pay separately for MONJUVI, however, payment rates will vary by payer and provider contract

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

## PHYSICIAN OFFICE: SAMPLE CMS-1500 CLAIM FORM

MONJUVI and the associated services provided in the physician's office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing MONJUVI is provided below as an example. 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. **Providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.**

### Box 21

Enter appropriate diagnosis code(s)

### Box 24A-B

Enter the date of service and the appropriate place of service code

### Box 24D

Enter the appropriate drug and administration codes, for example:

- Administration - 96413 (chemo infusion for 1st hour, single or initial drug) and 96415 (chemo infusion for each additional hour, 1-8 hours)
- Drug - J9349 (Injection, tafasitamab-cxix, 2mg)

**Note:** Discarded product should be reported on a separate line using the JW modifier

Include the JZ modifier if no amount of drug was discarded

### Box 24E

Specify the diagnosis, from Box 21, that relates to the drug or procedure listed in Box 24D

### Box 24G

Enter the number of MONJUVI service units administered:

- J9349 Billing Unit = 2mg
- 1 Single Dose Vial = 200mg
- 200mg Vial = 100 Units

The total number of mg administered will vary based on patient weight

### HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

HEALTH INSURANCE CLAIM FORM										PICA														
1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK LUNG OTHER										1a. INSURED'S I.D. NUMBER														
(Medicare#) (Medicaid#) (ID#DoD#) (Member ID#) (ID#) (ID#)										(For Program in Item 1)														
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE		SEX		4. INSURED'S NAME (Last Name, First Name, Middle Initial)															
5. PATIENT'S ADDRESS (No., Street)					6. PATIENT RELATIONSHIP TO INSURED		7. INSURED'S ADDRESS (No., Street)																	
CITY					Self Spouse Child Other		CITY																	
STATE					8. RESERVED FOR NUCC USE		STATE																	
ZIP CODE					TELEPHONE (Include Area Code)		ZIP CODE																	
( )					( )		( )																	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO:			11. INSURED'S POLICY GROUP OR FECA NUMBER																
a. OTHER INSURED'S POLICY OR GROUP NUMBER					a. EMPLOYMENT? (Current or Previous)			a. INSURED'S DATE OF BIRTH																
b. RESERVED FOR NUCC USE					YES NO			MM DD YY M F																
c. RESERVED FOR NUCC USE					b. AUTO ACCIDENT? PLACE (State)			b. OTHER CLAIM ID (Designated by NUCC)																
d. INSURANCE PLAN NAME OR PROGRAM NAME					YES NO			c. INSURANCE PLAN NAME OR PROGRAM NAME																
10d. CLAIM CODES (Designated by NUCC)					c. OTHER ACCIDENT?			d. IS THERE ANOTHER HEALTH BENEFIT PLAN?																
					YES NO			YES NO If yes, complete Items 9, 9a, and 9d.																
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.														
SIGNED _____ DATE _____										SIGNED _____														
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)					15. OTHER DATE		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION																	
MM DD YY QUAL					MM DD YY		FROM MM DD YY TO MM DD YY																	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE					17a. ICD-9-CM		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES																	
					17b. NPI		FROM MM DD YY TO MM DD YY																	
19. ADDITIONAL INFORMATION (Designated by NUCC)					20. OUTSIDE LAB?		20. OUTSIDE LAB? \$ CHARGES																	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)					22. RESUBMISSION CODE		23. PRIOR AUTHORIZATION																	
A. Diagnosis Code					ORIGINAL REF. NO.		24G																	
E. I. J. K. L. M. N. O. P. Q. R. S. T. U. V. W. X. Y. Z.					24. A. DATE(S) OF SERVICE		B. PLACE OF SERVICE		C. CPT/HCPCS		D. PROCEDURES, SERVICES, OR SUPPLIES		E. DIAGNOSIS		F. \$ CHARGES		G. DAYS OR UNITS		H. ICD-9-CM		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
1					04   01   21   04   01   21   11		96413		A		\$\$		1		NPI									
2					04   01   21   04   01   21   11		J9349		A		\$\$		XXX		NPI									
3															NPI									
4															NPI									
5															NPI									
6															NPI									
25. FEDERAL TAX I.D. NUMBER					SSN EIN		26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT?		28. TOTAL CHARGE		29. AMOUNT PAID		30. Rsvd for NUCC Use									
									YES NO		\$		\$											
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)					32. SERVICE FACILITY LOCATION INFORMATION					33. BILLING PROVIDER INFO & PH # ( )														
SIGNED _____ DATE _____					a. NPI b.					a. NPI b.														

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org)

## HOSPITAL OUTPATIENT: SAMPLE CMS-1450 CLAIM FORM

MONJUVI and the associated services provided in a hospital outpatient setting are billed on the CMS-1450 claim form or its electronic equivalent. A sample CMS-1450 claim form for billing MONJUVI is provided below as an example. 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. **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 that are billed with HCPCS codes usually require revenue code 0636 (drugs requiring detailed coding)

### Box 43

For each item, enter the description of the revenue code used

### Box 44

Enter the appropriate HCPCS codes, for example:

- Administration - 96413 (chemo infusion for 1st hour, single or initial drug) and 96415 (chemo infusion for each additional hour, 1-8 hours)
- Drug - J9349 (Injection, tafasitamab-cxix, 2mg)

**Note:** Discarded product should be reported on a separate line using the JW modifier

Include the JZ modifier if no amount of drug was discarded

### Box 45

Enter the service date

### Box 46

Enter the number of service units administered:

- J9349 Billing Unit = 2mg
- 1 Single Dose Vial = 200mg
- 200mg Vial = 100 Units

The total number of mg administered will vary based on patient weight

### Box 67

Enter the primary diagnosis code

1		2		3a PAT. CNTRL. # 3b MED. REC. #		4 TYPE OF BILL	
8 PATIENT NAME		9 PATIENT ADDRESS		5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR	
17 STAT		18		19		20	
21		22		23		24	
25		26		27		28	
29 ACCT STATE		30		31 OCCURRENCE DATE		32 OCCURRENCE DATE	
33		34		35		36	
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41		42		43		44	
45		46		47		48	
49		50		51		52	
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## PROVIDER READINESS - PROCESS AND TIPS

When preparing to treat a patient with MONJUVI as prescribed, 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 My MISSION Support at 855-421-6172 or visit [www.MyMISSIONSupport.com](http://www.MyMISSIONSupport.com) 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 My MISSION Support to understand potential financial assistance options that may be available for eligible patients
- 3** — **Confirm the patient has access** to lenalidomide so the combination regimen can start as indicated in the FDA-approved product labeling
- 4** — **Schedule the patient** for his or her first MONJUVI infusion
- 5** — **Purchase MONJUVI** (if not already in inventory) through one of the following Specialty Distributors:

**AmerisourceBergen Specialty Distribution**  
 AmerisourceBergen  
 5025 Plano Parkway, Carrollton, TX 75010  
 Phone: 800-746-6273 | Fax: 800-547-9413  
[Service@asdhealthcare.com](mailto:Service@asdhealthcare.com)  
[www.asdhealthcare.com](http://www.asdhealthcare.com)  
 MONJUVI Item # 58057

**Oncology Supply**  
 AmerisourceBergen  
 2801 Horace Shepard Drive, Dothan, AL 36303  
 Phone: 800-633-7555  
[Service@oncologysupply.com](mailto:Service@oncologysupply.com)  
[www.oncologysupply.com](http://www.oncologysupply.com)  
 MONJUVI Item # 58057

**Cardinal Health Specialty Pharmaceutical Distribution**  
 233 Mason Road, LaVergne, TN 37086  
 Phone: 855-855-0708 | Phone: 877-453-3972  
 Fax: 877-274-9897  
[GMB-SPD-Specialty@cardinalhealth.com](mailto:GMB-SPD-Specialty@cardinalhealth.com)  
[GMB-SPDOncologySalesTeam@cardinalhealth.com](mailto:GMB-SPDOncologySalesTeam@cardinalhealth.com)  
 MONJUVI Item # 5653530

**CuraScript SD**  
 255 Technology Park, Lake Mary, FL 32746  
 Phone: 877-599-7748 | Fax: 800-862-6208  
[Customer.Service@curascript.com](mailto:Customer.Service@curascript.com)  
[www.curascriptsd.com](http://www.curascriptsd.com)  
 MONJUVI Item # 413402

**McKesson Plasma & Biologics**  
 6535 N State Highway 161, Irving, TX 75039  
 Phone: 877-625-2566 | Fax: 888-752-7276  
[MPBOrders@mckesson.com](mailto:MPBOrders@mckesson.com)  
[connect.mckesson.com](http://connect.mckesson.com)  
 MONJUVI Item # 1559434

**McKesson Specialty Care Distribution**  
 6535 N State Highway 161, Irving, TX 75039  
 Phone: 800-482-6700  
[mcs.mckesson.com](http://mcs.mckesson.com)  
 MONJUVI Item # 5010390

For Specialty Pharmacy services, customers can contact:

**Biologics by McKesson**  
 13000 Weston Parkway, Suite 105, Cary, NC 27513  
 Phone: 800-850-4306 | Fax: 800-823-4506 | Email: [MyCareTeam@mckesson.com](mailto:MyCareTeam@mckesson.com)  
[biologics.mckesson.com](http://biologics.mckesson.com)

- 6** — After treatment, **complete and submit a claim** to the payer, including all necessary information and accounting for any unused portion of the product (wastage), if required by the payer



Contact My MISSION Support at 855-421-6172 or  
 Visit [www.MyMISSIONSupport.com](http://www.MyMISSIONSupport.com)

# MY MISSION SUPPORT - PROGRAM OVERVIEW

## A ROBUST SUPPORT PROGRAM FOR ELIGIBLE PATIENTS AND CAREGIVERS

### Personalized Support to Assist in Accessing MONJUVI:

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



### 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<sup>†</sup> 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](http://www.MyMISSIONSupport.com) for full eligibility criteria.

<sup>†</sup> 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"]).

## GETTING STARTED WITH MY MISSION SUPPORT

**1** –  Visit [www.MyMISSIONSupport.com](http://www.MyMISSIONSupport.com) and Click on Enroll

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



Call **855-421-6172**, Monday – Friday 8 AM to 8 PM ET, for Personalized Support From a My MISSION Support Program Specialist, or Visit [www.MyMISSIONSupport.com](http://www.MyMISSIONSupport.com) to Learn More



## 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 ( $\geq 20\%$ ) 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](http://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<sup>®</sup>) 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.



**MONJUVI**<sup>®</sup>  
tafasitamab-cxix | 200mg  
for injection, for intravenous use

Please see Important Safety Information on pages 2 and 9 and full [Prescribing Information](#).



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