



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
- ▶ IncyteCARES for MONJUVI

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 judgment, payer specific guidance, and other requirements.

For Questions Regarding MONJUVI Reimbursement and Access, Please Call IncyteCARES at 1-855-452-5234, Monday through Friday, 8 AM - 8 PM ET

INDICATIONS AND USAGE

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 IncyteCARES for MONJUVI.

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 (NCCN 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 the 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	=	100 Units

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 **1-855-452-5234**, Monday through Friday 8 AM - 8 PM ET

Please see Important Safety Information on pages 2 and 9 and the 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 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	Chemotherapy administration, intravenous infusion technique; each additional hour, 1-8 hours <i>(List separately in addition to code for primary procedure)</i>	96415
Intrathoracic lymph nodes	C83.32	JW Modifier - Modifier for wastage / discarded units <i>Requirements for wastage / discarded units should be confirmed on a payer by payer basis</i>	JW
Intra-abdominal lymph nodes	C83.33	JZ Modifier - Modifier for zero product wastage	JZ
Lymph nodes of axilla and upper limb	C83.34	MONJUVI DRUG CODES	
Lymph nodes of inguinal region and lower limb	C83.35	HCPCS Code	J9349 (Injection, tafasitamab-cxix, 2mg)
Intrapelvic lymph nodes	C83.36	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>
Spleen	C83.37		
Lymph nodes of multiple sites	C83.38		
Extranodal and solid organ sites	C83.39		

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](https://www.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										CARRIER			
PICA										PICA			
1. MEDICARE (Medicare#)	MEDIICAID (Medicaid#)	TRICARE (TRICARE#)	CHAMPVA (Member ID#)	GROUP HEALTH PLAN (ID#)	FECA BLK/LUNG (ID#)	OTHER (ID#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1)						
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)				3. PATIENT'S BIRTH DATE (MM DD YY)		SEX (M F)	4. INSURED'S NAME (Last Name, First Name, Middle Initial)						
5. PATIENT'S ADDRESS (No., Street)				6. PATIENT RELATIONSHIP TO INSURED (Self Spouse Child Other)			7. INSURED'S ADDRESS (No., Street)						
CITY		STATE		8. RESERVED FOR NUCC USE			CITY		STATE				
ZIP CODE		TELEPHONE (Include Area Code)					ZIP CODE		TELEPHONE (Include Area 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		b. RESERVED FOR NUCC USE		c. RESERVED FOR NUCC USE		d. INSURANCE PLAN NAME OR PROGRAM NAME		10a. EMPLOYMENT? (Current or Previous) YES NO		10b. AUTO ACCIDENT? YES NO		10c. OTHER ACCIDENT? YES NO	
10a. EMPLOYMENT? (Current or Previous) YES NO		10b. AUTO ACCIDENT? YES NO		10c. OTHER ACCIDENT? YES NO		10d. CLAIM CODES (Designated by NUCC)		11a. INSURED'S DATE OF BIRTH (MM DD YY)		SEX (M F)		11b. OTHER CLAIM ID (Designated by NUCC)	
11a. INSURED'S DATE OF BIRTH (MM DD YY)		SEX (M F)		11c. INSURANCE PLAN NAME OR PROGRAM NAME		11d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO		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.			
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) (MM DD YY) QUAL.				15. OTHER DATE (MM DD YY) QUAL.			16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM TO) (MM DD YY)						
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE				17a. NPI			18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM TO) (MM DD YY)						
19. ADDITIONAL INFORMATION (Designated by NUCC)				20. OUTSIDE LAB? YES NO			21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.				22. RESUBMISSION CODE ORIGINAL REF. NO.		
A. Diagnosis Code				24A-B		24D	24E				24G		
24. A. DATE(S) OF SERVICE (From To) (MM DD YY MM DD YY)		B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS) MODIFIER		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. ICD-9-CM (Family Rel.)	I. ID. QUAL.	J. RENDERING PROVIDER ID. #		
1 04 01 21 04 01 21 11		11		96413		A	\$\$	1		NPI			
2 04 01 21 04 01 21 11		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? (For gov. claim, see back) YES NO	28. TOTAL CHARGE \$	29. AMOUNT PAID \$	30. Rsvd for NUCC Use						
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

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 DATE	
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 OCCURRENCE DATE	
34		35		36		37	
38		39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPS CODE		45 SERV. DATE	
46		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
0335	Chemo Infusion Intravenous	96413		04012021	1	\$\$	
0636	Injection, tafasitamab-cxix, 2mg	J9349		04012021	XXX	\$\$	
PAGE OF		CREATION DATE		TOTALS			
50 PRAYER NAME		51 HEALTH PLAN ID		52 REL. INFO		53 ARR. BEN.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 P/POL		60 INSURED'S UNIQUE ID		61 GROUP NAME	
62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66		67		68		69	
70 PATIENT REASON DX		71 PPS CODE		72 ECI		73	
74 PRINCIPAL PROCEDURE DATE		75 OTHER PROCEDURE DATE		76 ATTENDING NPI		77 QUAL	
78 LAST		79 FIRST		80 LAST		81 FIRST	
82 OTHER PROCEDURE DATE		83 OTHER PROCEDURE DATE		84 OTHER PROCEDURE DATE		85 OTHER PROCEDURE DATE	
86 OTHER NPI		87 QUAL		88 LAST		89 FIRST	
90 REMARKS		91 B1CC		92 LAST		93 FIRST	
94 OTHER NPI		95 QUAL		96 LAST		97 FIRST	
98 OTHER NPI		99 QUAL		100 LAST		101 FIRST	

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 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** — **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
Cencora
5025 Plano Parkway, Carrollton, TX 75010
Phone: 800-746-6273 | Fax: 800-547-9413
Service@asdhealthcare.com
www.asdhealthcare.com
MONJUVI Item # 58057

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

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
GMB-SPDOncologySalesTeam@cardinalhealth.com
MONJUVI Item # 5653530

Oncology Supply
Cencora
2801 Horace Shepard Drive, Dothan, AL 36303
Phone: 800-633-7555
Service@oncologysupply.com
www.oncologysupply.com
MONJUVI Item # 58057

McKesson Specialty Care Distribution
6535 N State Highway 161, Irving, TX 75039
Phone: 800-482-6700
mscs.mckesson.com
MONJUVI Item # 5010390

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.

- 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

**For More Information, Contact IncyteCARES at 1-855-452-5234 or
Visit HCP.IncyteCARES.com/MONJUVI**

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

INCYTECARES FOR MONJUVI

WE'RE HERE TO SUPPORT YOUR ELIGIBLE PATIENTS DURING TREATMENT

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



Information and resources available through IncyteCARES for MONJUVI include:

- Benefits verification and prior authorization or appeal support
- Information about savings and financial assistance options*
- Practice resources and forms

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.

SAVINGS, FINANCIAL ASSISTANCE, AND SUPPORT OPTIONS FOR MONJUVI



For Eligible Patients With Commercial Health Insurance
IncyteCARES for MONJUVI Savings Program



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



Questions?

Call IncyteCARES for MONJUVI at **1-855-452-5234**
Monday through Friday 8 AM - 8 PM ET

For more information and resources, visit HCP.IncyteCARES.com/MONJUVI

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%).

Please see the Full [Prescribing Information](#).

REFERENCES: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for B-Cell Lymphomas V.2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 30, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.



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

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



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