

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.



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)^{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.

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.



10-digit or 11-digit NDC vary

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 adm technique; up to 1 h | 96413 | | | | | |
| Lymph nodes of head, face, and neck | C83.31 | | | | | | | |
| Intrathoracic lymph nodes | C83.32 | infusion technique; | Chemotherapy administration, intravenous infusion technique; each additional hour, 1-8 hours | | | | | |
| Intra-abdominal lymph nodes | C83.33 | (List separately in a procedure) | iddition to code for primary | | | | | |
| Lymph nodes of axilla and upper limb | C83.34 | JW Modifier - Modif | JW | | | | | |
| Lymph nodes of inguinal region and lower limb | C83.35 | , | Requirements for wastage / discarded units should be confirmed on a payer by payer basis | | | | | |
| Intrapelvic lymph nodes | C83.36 | JZ Modifier - Modifi | JZ | | | | | |
| Spleen | C83.37 | MONJUVI DRUG CODES | | | | | | |
| Lymph nodes of multiple sites | C83.38 | HCPCS Code J9349 (Injection, tafasitamab-cxi) | | | | | | |
| Extranodal and solid organ sites | C83.39 | NDC Number | 10-Digit - 73535-208- 11-Digit - 73535- 0 208 Payer requirements regardin | -01 | | | | |

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.

Please see Important Safety Information on pages 2 and 9 and the Full Prescribing 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 2 | 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

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 NUCC Instruction Manual available at: www.nucc.org
 Instruction Manual available at: www.nucc.org
 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 | 1 | | | 2 | | | 3a CN b.1 RE | PAT. TL # MED. C. # | | | FYPE F BILL |
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| List the appropriate revenue code | | | | | | | | ED. TAX NO. | 6 STATEMENT COVE FROM | THROUGH 7 | |
| for each service provided. Drugs | 8 PATIENT 1 | AME | 2 | | 9 PATIENT ADDRESS | а | | | | | _ |
| that are billed with HCPCS codes usually require revenue code | b 10 BIRTHDA | TE 11 | SEX 12 DATE 13 HR | 0N 14 TYPE 15 SRC 16 | DHR 17 STAT 18 1 | 9 20 21 | CONDITION COD | ES 24 25 | c d 26 27 28 STAT | e DT 30 | |
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| Box 43 | | | | | | a | DDE AMOUNT | | DE AMOUNT | CODE AMOUNT | |
| For each item, enter the description | 42 | 4 | 3 | | 44 | c | 45 | 46 | | | |
| of the revenue code used | 42 REV. CD. | 43 DESCRIPTIC | <u> </u> | | 44 HCPCS / RATE / HIPPS | d | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES | |
| | 1 0335 | | nfusion Intraven | ous | 96413 | SCODE | 04012021 | | \$\$ | 48 NUN-COVERED CHARGES | 49 |
| Box 44 | ² 0636 | Injectior | ı, tafasitamab-cxi | x, 2mg | J9349 | | 04012021 | XXX | \$\$ | | |
| Enter the appropriate HCPCS | 4 | | | | | | | | | | |
| codes, for example: | 6 | | | | | | | | | | |
| • Administration - 96413 (chemo | 7 | | | | | | | | | | |
| infusion for 1st hour, single or | 9 | | | | | | | | | | |
| initial drug) and 96415 (chemo infusion for each additional | 10 | | | | | | | | | | |
| hour, 1-8 hours) | 12 | | | | | | | | | | 1 |
| Drug - J9349 (Injection, | 13 | | | | | | | | | | 1 |
| tafasitamab-cxix, 2mg) | 15 | | | | | | | | | | 1 |
| Note: Discarded product should | 17 | | | | | | | | | | 1 |
| be reported on a separate line | 18 | | | | | | | | | | |
| using the JW modifier | 20 | | | | | | | | | | |
| Include the JZ modifier if no | 22 | | | | | | | | | | |
| amount of drug was discarded | 23 50 PAYER N | PAGE | OF | 51 HEALTH PL | | S2 REL S3 ASG. 54 | PRIOR PAYMENTS | 55 EST. AMOL | INT DUE 56 NPI | | <u> </u> |
| | ^ | | | | | INFO BEN. | | | 57 OTHER | | |
| Box 45 | с | | | | | | | | PRV ID | | |
| Enter the service date | 58 INSURED | 'S NAME | | 59 P.R | EL 60 INSURED'S UNIQUE I | D | 61 GF | NOUP NAME | 62 INSURAM | ICE GROUP NO. | |
| | в | | | | | | | | | | E |
| Box 46 | 63 TREATME | ENT AUTHORIZA | TION CODES | | 64 DOCUMENT CO | NTROL NUMBER | | 6 | 5 EMPLOYER NAME | | |
| Enter the number of service units administered: | Ê | 57 | | | | | | | | | |
| | c | | | | | | _ | _ | | 68 | |
| • J9349 Billing Unit = 2mg | DX C | Code | J | | Ľ M | | N. | 0 | P (| 2 | |
| • 1 Single Dose Vial = 200mg | 69 ADMIT DX 74 | PRINCIPAL PROC | 70 PATIENT REASON DX | | b. OTHER P | 71 PPS CODE ROCEDURE | 72 ECI 75 76 | ATTENDING N | b C | 73 QUAL | |
| 200mg Vial = 100 Units | | | | | | | v | ST | | FIRST | |
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| administered will vary based on patient weight | 80 REMARK | s | | 81CC a b | | | | OTHER N | | QUAL | |
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| D. 67 | UB-04 CMS-1 | 450 | APPROVED OMB NO | d 0938-0997 | NUR | C National Unitorm Billing Committee | | IST E CERTIFICATIONS (| | FIRST IIS BILL AND ARE MADE A PART | HEREOF. |
| Box 67 | | | | | NOD | Alling Committee | | | | | |

Please see Important Safety Information on pages 2 and 9 and the Full Prescribing Information.

Enter the primary diagnosis code

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.

- 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
- **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

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

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

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

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.

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.

IncyteCARES



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-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%).

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.



Please see Important Safety Information on pages 2 and 9 and the Full Prescribing Information.



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