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

PRODUCT INFORMATION

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).

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.

(continued on page 6)

Please see additional Important Safety Information on page 6 and the Full Prescribing Information for more information about MONJUVI.

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Manufactured by	*Incyte Corporation* 855-463-3463
Marketed by	*Incyte Corporation* www.Incyte.com
Product Name	MONJUVI
Established Name	tafasitamab-cxix
Product Website	www.MONJUVIHCP.com

Not actual size

NCCN PREFERRED

National Comprehensive Cancer Network® (NCCN®) recommends as an NCCN Category 2A, Preferred Treatment Option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend tafasitamab-cxix (MONJUVI) + lenalidomide as an NCCN Category 2A preferred second-line or subsequent treatment option (if not previously used) for certain* patients living with DLBCL.[1†]

*Category 2A treatment option for patients who relapsed in less than 12 months and are non-candidates for CAR T-cell therapy (excluding primary refractory disease); Category 2A treatment option for patients who relapsed after more than 12 months with no intention to proceed with transplant.[1]

†It is unclear if tafasitamab or loncastuximab tesirine or if any other CD19-directed therapy will 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.

PRODUCT INFORMATION	
Description	200 mg single-dose vial as lyophilized powder for reconstitution
Sales Unit	One single-dose vial
Units Per Case	One vial per carton
NDC	*10-Digit* - 50881-013-03 | 11-Digit - 50881-**0**013-03
Global Trade Identification Numbers	00373535208013 | 30373535208014 (case)

HCPCS CODING	PRICING
J9349 (Injection, tafasitamab-cxix, 2 mg) Effective April 1, 2021	Wholesale Acquisition Cost (WAC) $1,368.50 / Vial Established January 2025

Please see additional Important Safety Information on page 6 and the Full Prescribing Information for more information about MONJUVI.

PRODUCT AVAILABILITY

- MONJUVI is available through a network of Specialty Distributors authorized to distribute and/or dispense the medication. 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 below

DISTRIBUTION

- All orders must be placed with one of the Specialty Distributors listed below:

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

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

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

DISPENSING PACK DIMENSIONS (APPROXIMATE)

Depth: 33.5 mm	Height: 76 mm	Width: 37.5 mm

STORAGE INFORMATION

- MONJUVI for injection is a sterile, preservative-free, white to slightly yellowish lyophilized powder for reconstitution supplied as a 200 mg single-dose vial. Each 200 mg vial is individually packaged in a carton
- Store refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do not shake. Do not freeze
- Use the reconstituted MONJUVI solution immediately. If needed, store the reconstituted solution in the vial for a maximum of 12 hours either refrigerated at 36°F to 46°F (2°C to 8°C) or room temperature at 68°F to 77°F (20°C to 25°C) before dilution. Protect from light during storage. Do not freeze or shake
- If not used immediately, store the diluted MONJUVI infusion solution refrigerated for up to 18 hours at 36°F to 46°F (2°C to 8°C) and/or at room temperature for up to 12 hours at 68°F to 77°F (20°C to 25°C). The room temperature storage includes time for infusion. Protect from light during storage. Do not freeze or shake

PRODUCT EXPIRATION

- Expiration date printed on both single-dose vial and carton

Please see additional Important Safety Information on page 6 and the Full Prescribing Information for more information about MONJUVI.

DOSAGE AND ADMINISTRATION HIGHLIGHTS

- The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion according to the dosing schedule shown below
- Administer MONJUVI in combination with lenalidomide 25 mg orally on Days 1 to 21 of each 28-day cycle for a maximum of 12 cycles, then continue MONJUVI as monotherapy until disease progression or unacceptable toxicity. Refer to the lenalidomide prescribing information for lenalidomide dosage recommendations
- MONJUVI Dosing Schedule:
  - Cycle 1 – Days 1, 4, 8, 15 and 22
  - Cycles 2 and 3 – Days 1, 8, 15 and 22
  - Cycle 4 and beyond – Days 1 and 15
- MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions (IRRs)

See Full Prescribing Information for additional details on dosing and administration including preparing the infusion, prophylaxis for infusion-related reactions, and dose modifications for adverse reactions.

RECONSTITUTION

- Calculate the dose (mg) and determine the number of vials needed
- Reconstitute each 200 mg MONJUVI vial with 5 mL Sterile Water for Injection, USP with the stream directed toward the wall of each vial to obtain a final concentration of 40 mg/mL tafasitamab-cxix
- Gently swirl the vial(s) until completely dissolved. Do not shake or swirl vigorously. Complete dissolution may take up to 5 minutes
- Visually inspect the reconstituted solution for particulate matter or discoloration. The reconstituted solution should appear as a colorless to slightly yellow solution. Discard the vial(s) if the solution is cloudy, discolored, or contains visible particles
- Use the reconstituted MONJUVI solution immediately. If needed, store the reconstituted solution in the vial for a maximum of 12 hours either refrigerated at 36°F to 46°F (2°C to 8°C) or room temperature at 68°F to 77°F (20°C to 25°C) before dilution. Protect from light during storage

DILUTION

- Determine the volume (mL) of the 40 mg/mL reconstituted MONJUVI solution needed based on the required dose
- Remove a volume equal to the required MONJUVI solution from a 250 mL 0.9% Sodium Chloride Injection, USP infusion bag and discard it
- Withdraw the necessary amount of MONJUVI and slowly dilute in the infusion bag that contains the 0.9% Sodium Chloride Injection, USP to a final concentration of 2 mg/mL to 8 mg/mL. Discard any unused portion of MONJUVI remaining in the vial
- Gently mix the intravenous bag by slowly inverting the bag. *Do not shake*. Visually inspect the infusion bag with the diluted MONJUVI infusion solution for particulate matter and discoloration prior to administration
- If not used immediately, store the diluted MONJUVI infusion solution refrigerated for up to 18 hours at 36°F to 46°F (2°C to 8°C) and/or at room temperature for up to 12 hours at 68°F to 77°F (20°C to 25°C). The room temperature storage includes time for infusion. Protect from light during storage

Do not shake or freeze the reconstituted or diluted infusion solutions

Please see additional Important Safety Information on page 6 and the Full Prescribing Information for more information about MONJUVI.

PRODUCT ORDER AND RETURN INFORMATION

- For information on ordering, please call:
  Phone: 833-958-2078
- Credit for returns is subject to Incyte's current Return Goods Policy
  For more information, please call:
  Phone: 866-765-0919
- For returns of expired product or product damaged in shipment, please contact your distributor

ADVERSE EVENT REPORTING

- Contact Incyte Corporation or the FDA to report an adverse event:

Incyte Corporation	**FDA**
Phone: 855-463-3463	Phone: 1-800-FDA-1088
Email: medinfo@incyte.com	Web: www.fda.gov/medwatch

PRODUCT COMPLAINTS

- For product complaints other than adverse event reporting, please contact Incyte Corporation at:
  Phone: 855-463-3463 Email: medinfo@incyte.com

US MEDICAL INFORMATION INQUIRIES

- For all medical information questions, please contact Incyte Corporation at:
  Phone: 855-463-3463 Email: medinfo@incyte.com

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

For more information and resources for Healthcare Professionals:

- Visit **HCP.IncyteCARES.com/MONJUVI**
- Call IncyteCARES for MONJUVI at **1-855-452-5234**, Monday through Friday, 8 AM–8 PM ET

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

Please see additional Important Safety Information on page 6 and the Full Prescribing Information for more information about MONJUVI.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions *(continued)*

- **Infections.** Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose. In L-MIND, 73% of the 81 patients with DLBCL who received MONJUVI developed an infection. Grade 3 or higher infection occurred in 30%. The most frequent infections of any grade were respiratory tract infections (51%, including pneumonias) and urinary tract infection (17%). 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.
- **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 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 DLBCL were neutropenia (51%), respiratory tract infection (51%), fatigue (38%), anemia (36%), diarrhea (36%), thrombocytopenia (31%), cough (26%), pyrexia (24%), peripheral edema (24%), and decreased appetite (22%).

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

REFERENCE: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell lymphomas V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 18, 2025. To view the most recent and complete version of the guideline, go to NCCN.org.

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Incyte

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