

# Monjuvi® (tafasitamab-cxix) (Intravenous)

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## I. Length of Authorization <sup>1</sup>

- Initial: Prior authorization validity will be provided for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter, unless otherwise specified.
  - Follicular Lymphoma: Prior authorization validity may be renewed up to a maximum of twelve (12) 28-day cycles
  - All Other B-Cell Lymphoma Sub-Types when used in combination with lenalidomide: Prior authorization validity may be renewed up to a maximum of twelve (12) 28-day cycles (*Note: continued treatment as a single-agent may be renewed until disease progression or unacceptable toxicity*)

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

### Follicular Lymphoma

- Cycles 1 to 3: 700 billable units on days 1, 8, 15 and 22 of each 28-day cycle
- Cycle 4 to 12: 1400 billable units per 28-day cycle

### All Other B-Cell Lymphoma Sub-Types

- Cycle 1: 700 billable units on days 1, 4, 8, 15 and 22 of the 28-day cycle
- Cycles 2 and 3: 700 billable units on days 1, 8, 15 and 22 of each 28-day cycle
- Cycle 4 and beyond: 1400 billable units per 28-day cycle

## III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

### **Universal Criteria** <sup>1-3</sup>

- Patient has not received prior therapy with immunomodulatory imide (IMiD-class) agents (e.g., lenalidomide, etc.); **AND**
- Patient has not received prior therapy with CD19-directed therapy (e.g., axicabtagene, tisagenlecleucel, loncastuximab tesirine, etc.) OR patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**

## B-Cell Lymphomas † ‡ ◊<sup>1-4</sup>

- Patient has follicular lymphoma †; **AND**
  - Used as subsequent therapy for no response, relapsed, refractory, or progressive disease; **AND**
  - Patient does NOT have a relapsed or refractory marginal zone lymphoma; **AND**
  - Patient has received at least one prior systemic therapy including an anti-CD20 monoclonal antibody; **AND**
  - Used in combination with lenalidomide and rituximab; **OR**
- Patient has diffuse large B-cell lymphoma (DLBCL) (*including DLBCL not otherwise specified and DLBCL arising from low grade lymphoma*) †; **AND**
  - Used for relapsed or refractory disease in patients who are not eligible for autologous stem cell transplant (ASCT); **AND**
  - Used in combination with lenalidomide; **OR**
- Patient has histologic transformation of indolent lymphomas (follicular lymphoma or marginal zone lymphoma) to DLBCL ‡; **AND**
  - Used in combination with lenalidomide if previously treated with an anthracycline-based regimen and no intention to proceed to transplant; **AND**
    - Used as additional therapy for partial response, no response, progressive, or relapsed disease following chemoimmunotherapy for histologic transformation after minimal or no prior therapy; **OR**
    - Used for patients who have received multiple lines of prior therapy including ≥2 chemoimmunotherapy regimens for indolent or transformed disease; **OR**
- Patient has HIV-related B-cell lymphomas (i.e., HIV-related DLBCL, primary effusion lymphoma, HHV8-positive DLBCL [not otherwise specified], or plasmablastic lymphoma), high-grade B-cell lymphomas †; **AND**
  - Used as subsequent therapy in combination with lenalidomide and no intention to proceed to transplant; **AND**
    - Used for relapsed disease >12 months after completion of first-line therapy; **OR**
    - Used for primary refractory disease (partial response, no response, or progression) or relapsed disease <12 months after completion of first-line therapy AND patient is a non-candidate for CAR T-cell therapy; **OR**
    - Used as alternative systemic therapy (if not previously used) for relapsed/refractory disease and patient is a non-candidate for CAR T-cell therapy; **OR**
- Patient has monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type) ‡; **AND**
  - Used as subsequent therapy in combination with lenalidomide and no intention to proceed to transplant; **AND**

- Used for relapsed disease >12 months after completion of initial treatment with chemoimmunotherapy; **OR**
- Used for primary refractory disease (partial response, no response, or progression) or relapsed disease <12 months after completion of initial treatment with chemoimmunotherapy AND patient is a non-candidate for CAR T-cell therapy; **OR**
- Used as alternative systemic therapy (if not previously used) for relapsed/refractory disease and patient is a non-candidate for CAR T-cell therapy

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Ⓞ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Coverage may be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe myelosuppression (e.g., thrombocytopenia, neutropenia, anemia, lymphopenia), severe infection, etc.; **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread

#### V. Dosage/Administration <sup>1</sup>

Indication	Dose
Follicular Lymphoma	Administer 12 mg/kg intravenously according to the following dosing schedule: <ul style="list-style-type: none"> <li>○ Cycles 1 to 3: Days 1, 8, 15 and 22 of a 28-day cycle.</li> <li>○ Cycles 4 to 12: Days 1 and 15 of each 28-day cycle.</li> </ul>
All Other B-Cell Lymphoma Sub-Types	Administer 12 mg/kg intravenously according to the following dosing schedule: <ul style="list-style-type: none"> <li>○ Cycle 1: Days 1, 4, 8, 15 and 22 of a 28-day cycle.</li> <li>○ Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle.</li> <li>○ Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.</li> </ul> <p>Administer tafasitamab in combination with lenalidomide for a maximum of twelve (12) 28-day cycles and then continue tafasitamab as a single-agent until disease progression or unacceptable toxicity.</p>

#### VI. Billing Code/Availability Information

HCPCS Code:

- J9349 – Injection, tafasitamab-cxix, 2 mg; 1 billable unit = 2 mg

NDC:

- Monjuvi 200 mg lyophilized powder in single-dose vial for injection: 50881-0013-xx

## VII. References

1. Monjuvi [package insert]. Wilmington, DE; Incyte Corporation, June 2025. Accessed July 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tafasitamab-cxix. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2025.
3. Salles G, Duell J, González Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *Lancet Oncol.* 2020 Jul;21(7):978-988. doi: 10.1016/S1470-2045(20)30225-4. Epub 2020 Jun 5.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
5. Sehn LH, Luminari S, Scholz CW, et al; Tafasitamab Plus Lenalidomide and Rituximab for Relapsed or Refractory Follicular Lymphoma: Results from a Phase 3 Study (inMIND). *Blood* 2024; 144 (Supplement 2): LBA-1. doi: <https://doi.org/10.1182/blood-2024-212970>

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C82.00	Follicular lymphoma grade I unspecified site
C82.01	Follicular lymphoma grade I lymph nodes of head, face, and neck
C82.02	Follicular lymphoma grade I intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I lymph nodes of inguinal region and lower limb
C82.06	Follicular lymphoma grade I intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I spleen
C82.08	Follicular lymphoma grade I lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I extranodal and solid organ sites
C82.10	Follicular lymphoma grade II unspecified site
C82.11	Follicular lymphoma grade II lymph nodes of head, face, and neck
C82.12	Follicular lymphoma grade II intrathoracic lymph nodes

C82.13	Follicular lymphoma grade II intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II spleen
C82.18	Follicular lymphoma grade II lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II extranodal and solid organ sites
C82.20	Follicular lymphoma grade III unspecified site
C82.21	Follicular lymphoma grade III lymph nodes of head, face, and neck
C82.22	Follicular lymphoma grade III intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III spleen
C82.28	Follicular lymphoma grade III lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa unspecified site
C82.31	Follicular lymphoma grade IIIa lymph nodes of head, face, and neck
C82.32	Follicular lymphoma grade IIIa intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa spleen
C82.38	Follicular lymphoma grade IIIa lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb unspecified site
C82.41	Follicular lymphoma grade IIIb lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb spleen

C82.48	Follicular lymphoma grade IIIb lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma unspecified site
C82.51	Diffuse follicle center lymphoma lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma spleen
C82.58	Diffuse follicle center lymphoma lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma extranodal and solid organ sites
C82.60	Cutaneous follicle center lymphoma unspecified site
C82.61	Cutaneous follicle center lymphoma lymph nodes of head, face, and neck
C82.62	Cutaneous follicle center lymphoma intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma spleen
C82.68	Cutaneous follicle center lymphoma lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma extranodal and solid organ sites
C82.80	Other types of follicular lymphoma unspecified site
C82.81	Other types of follicular lymphoma lymph nodes of head, face, and neck
C82.82	Other types of follicular lymphoma intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma spleen lymph nodes of multiple sites
C82.88	Other types of follicular lymphoma lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma extranodal and solid organ sites
C82.90	Follicular lymphoma, unspecified site
C82.91	Follicular lymphoma, unspecified lymph nodes of head, face, and neck
C82.92	Follicular lymphoma, unspecified intrathoracic lymph nodes

C82.93	Follicular lymphoma, unspecified intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified spleen
C82.98	Follicular lymphoma, unspecified lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites
C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ sites
C83.80	Other types of follicular lymphoma, unspecified site
C83.81	Other types of follicular lymphoma, lymph nodes of head, face, and neck
C83.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C83.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C83.87	Other types of follicular lymphoma, spleen
C83.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C83.89	Other types of follicular lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen

C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma extranodal and solid organ sites
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC