Monjuvi® (tafasitamab-cxix)
(Intravenous)

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I. Length of Authorization [1]

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Combination therapy with lenalidomide may not exceed a maximum of twelve (12) 28-day cycles (continued treatment as a single-agent may be renewed until disease progression or unacceptable toxicity).

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Monjuvi 200 mg single-dose vial: 7 vials per dose
  - Cycle 1: 35 vials per 28-day cycle
  - Cycle 2 and 3: 28 vials per 28-day cycle
  - Cycle 4 and beyond: 14 vials per each 28-day cycle

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

- 700 billable units (1400 mg) per dose on the following schedule:
  - Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle
  - Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle
  - Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

Universal Criteria [1-3]

- 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 † ‡ Φ [1-4]

- 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); Φ Orphan Drug

IV. Renewal Criteria [1]

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**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe myelosuppression (e.g., thrombocytopenia, neutropenia, anemia), severe infection, etc.; **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Combination therapy with lenalidomide may not exceed a maximum of twelve (12) 28-day cycles (continued treatment as a single-agent may be renewed until disease progression or unacceptable toxicity)

V. Dosage/Administration [1]

Indication	Dose
B-Cell Lymphomas	Administer 12 mg/kg intravenously according to the following dosing schedule: ○ Cycle 1: Days 1, 4, 8, 15 and 22 of a 28-day cycle. ○ Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle. ○ Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle. 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.

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: 73535-0208-xx

VII. References

1. Monjuvi [package insert]. Boston, MA; Morphosys US, Inc., June 2021. Accessed February 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tafasitamab-cxix. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE

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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 1.2024. National Comprehensive Cancer Network, 2024. 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 February 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
C83.39	Diffuse large B-cell lymphoma 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)
Z85.72	Personal history of non-Hodgkin lymphoma

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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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