Monjuvi® (tafasitamab-cxix)
(Intravenous)

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Last Review Date: 12/01/2022
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Dates Reviewed: 06/2021, 12/2021, 12/2022

I. Length of Authorization [1]

Coverage will be provided for six months and may be renewed.

- Combined use with lenalidomide must not exceed a maximum of 12 cycles; however, continued maintenance tafasitamab monotherapy 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 & 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]:

B-Cell Lymphomas

- 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, 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 histological transformation of indolent lymphomas (follicular lymphoma or marginal zone lymphoma) to diffuse large B-cell lymphoma (DLBCL); **AND**
    - Used in combination with lenalidomide in non-candidates for transplant if previously treated with an anthracycline and anti-CD20 therapy; **AND**
        - Used as second line therapy for partial response, no response or progressive disease following chemoimmunotherapy in patients with histologic transformation to diffuse large B-cell lymphoma after minimal or no prior treatment; **OR**
        - Used for patients who have received multiple lines of chemoimmunotherapy for indolent or transformed disease; **OR**
- Patient has diffuse large B-cell lymphoma (DLBCL); **AND**
    - Used as subsequent therapy in combination with lenalidomide in non-candidates for transplant if previously treated with anti-CD20 therapy; **AND**
        - Used for relapsed or refractory 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 in non-candidates for CAR T-cell therapy; **OR**
        - Used as alternative systemic therapy (if not previously used) for relapsed/refractory disease in non-candidates for CAR T-cell therapy

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

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

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet 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 12 cycles (tafasitamab single-agent maintenance therapy may be continued until disease progression or unacceptable toxicity)

V. Dosage/Administration [1]

Indication	Dose
B-Cell Lymphomas	The recommended dosage of Monjuvi is 12 mg/kg as an intravenous infusion 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 Monjuvi in combination with lenalidomide for a maximum of 12 cycles and then continue Monjuvi as monotherapy 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 (STANDARD)

1. Monjuvi [package insert]. Boston, MA; Morphosys, Inc., June 2021. Accessed October 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tafasitamab. National Comprehensive Cancer Network, 2022. 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 October 2022.
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 5.2022. National Comprehensive

Cancer Network, 2022. 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 October 2022.

VIII. References (ENHANCED)

1e. Morschhauser F, Flinn IW, Advani R, et al. Polatuzumab vedotin or pinatuzumab vedotin plus rituximab in patients with relapsed or refractory non-Hodgkin lymphoma: final results from a phase 2 randomised study (ROMULUS). Lancet Haematol. 2019 May;6(5):e254-e265. doi: 10.1016/S2352-3026(19)30026-2.

2e. Mounier N, El Gnaoui T, Tilly H, et al. Rituximab plus gemcitabine and oxaliplatin in patients with refractory/relapsed diffuse large B-cell lymphoma who are not candidates for high-dose therapy. A phase II Lymphoma Study Association trial. Haematologica. 2013;98(11):1726-1731. doi:10.3324/haematol.2013.090597.

3e. Caimi PF, Ai WZ, Alderuccio JP, et al. Loncastuximab tesirine in relapsed or refractory diffuse large B-cell lymphoma (LOTIS-2): a multicentre, open-label, single-arm, phase 2 trial. Lancet Oncol 2021;22:790-800.

4e. Kalakonda N, Maerevoet M, Cavallo F, et al. Selinexor in patients with relapsed or refractory diffuse large B-cell lymphoma (SADAL): a single-arm, multinational, multicentre, open-label, phase 2 trial. Lancet Haematol. 2020 Jul;7(7):e511-e522. doi: 10.1016/S2352-3026(20)30120-4.

5e. Magellan Health, Magellan Rx Management. Monjuvi Clinical Literature Review Analysis. Last updated October 2022. Accessed October 2022.

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
C83.90	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
C85.20	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

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

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 Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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