Monjuvi™ (tafasitamab-cxix)
(Intravenous)

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I. Length of Authorization

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 SDV: 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]:

Diffuse Large B-Cell Lymphoma (DLBCL)

- 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 18 years or older; **AND**

Universal Criteria [1,2,3]

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient does not have CNS lymphoma involvement; **AND**

- Patient has not received an allogeneic stem cell transplant OR autologous-SCT within the prior 3 months of therapy; **AND**
- Patient has not received prior therapy with immunomodulatory imide (IMiD-class) agents (e.g., lenalidomide); **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**

Diffuse Large B-Cell Lymphoma (DLBCL) †Φ [1,2,3]

- Therapy will be initiated in combination with lenalidomide (Note: use is for up to 12 cycles only); **AND**
- Patient is ineligible for intensive therapy (i.e., high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT)); **AND**
    - Patient has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified *(excluding primary refractory AND 'double or triple hit'[i.e., translocations of MYC, BCL2, and/or BCL6] disease)*; **AND**
        - Used as subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease; **OR**
    - Patient has a diagnosis of DLBCL arising/transformed from low grade lymphoma such as Follicular or Marginal Zone *(excluding primary refractory AND 'double or triple hit'[i.e., translocations of MYC, BCL2, and/or BCL6] disease)*; **AND**
        - Patient received multiple lines of prior therapies, including two or more prior lines of chemoimmunotherapy for indolent or transformed disease; **OR**
        - Patient received minimal or no chemoimmunotherapy prior to histologic transformation with no response or progressive disease after chemoimmunotherapy which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated

† 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 the following: severe infusion type reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc.; **AND**
- Disease response with treatment defined as 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 (continued tafasitamab single-agent maintenance therapy may be continued until disease progression or unacceptable toxicity)

V. Dosage/Administration

Indication	Dose
Diffuse Large B-cell Lymphoma	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:

- J9999 – Not otherwise classified, antineoplastic drugs *(Discontinue use effective 04/01/2021)*
- C9070 – Injection, tafasitamab-cxix, 2 mg; 1 billable unit = 2 mg *(HOPPS-Hospital Outpatient Prospective Payment System Use Only) ((Discontinue use effective 04/01/2021))*
- J9349 – Injection, tafasitamab-cxix, 2 mg; 1 billable unit = 2 mg *(Effective 04/01/2021)*

NDC:

- Monjuvi 200 mg lyophilized powder in single-dose vial for injection: 73535-0208-xx

VII. References

1. Monjuvi [package insert]. Boston, MA; Morphosys, Inc., July 2020. Accessed September 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tafasitamab. National Comprehensive Cancer Network, 2020. 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 September 2020.
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.

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
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: http://www.cms.gov/medicare-coverage-database/search/advanced-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)

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