Tafasitamab-cxix (Monjuvi®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: **J9349** per 2 mg

Condition(s) listed in policy *(see criteria for details)*

- B-cell lymphoma

AHFS therapeutic class: antineoplastic agent
Mechanism of action: CD19-directed cytolytic antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for tafasitamab-cxix (Monjuvi®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

B-cell lymphoma

1. Diagnosis of B-cell lymphoma [e.g., DLBCL, including DLBCL arising from low-grade lymphoma, AIDS-related B-cell lymphomas (e.g., DLBCL, primary effusion lymphoma, HHV8+ DLBCL not otherwise specified, plasmablastic lymphoma), Post-Transplant Lymphoproliferative Disorders, High-Grade B-cell Lymphomas, and Follicular Lymphoma],
2. Disease is relapsed or refractory, **AND**
3. Being used in combination with lenalidomide

Covered Dose
Cycle 1: Up to 12 mg/kg IV on Days 1, 4, 8, 15, and 22 of the 28-day cycle. Each treatment cycle is 4 weeks, total of 5 doses per cycle.
Cycles 2-3: Up to 12 mg/kg IV on Days 1, 8, 15, and 22 of each 28-day cycle. Each treatment cycle is 4 weeks, total of 4 doses per cycle.
Subsequent cycles: Up to 12 mg/kg IV on Days 1 and 15 of each 28-day cycle. Each treatment cycle is 4 weeks, total of 2 doses per cycle.

Coverage period
Indefinite

ICD-10:
C83.30-C83.39, C83.90-C83.99, C85.20-C85.29

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for tafasitamab-cxix (Monjuvi®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 200 mg (lyophilized powder in a single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Monjuvi® (tafasitamab-cxix) [Prescribing Information]. Boston, MA: Morphosys US Inc.; 6/2021.
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Monjuvi (2020). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. B-cell lymphomas (Version 5.2022). Available by subscription at: www.nccn.org.

(7) Policy Update

Date of last review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- New indication in Section (2): Added coverage for additional B-cell lymphoma subtypes: AIDS-related B-cell lymphomas, Post-Transplant Lymphoproliferative Disorders, High-Grade B-cell Lymphomas, Follicular Lymphoma

  ***Rationale**: NCCN category 2A support*

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee