

# Monjuvi (tafasitamab-cxix)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Monjuvi (tafasitamab-cxix) 200 mg vial for intravenous use

## **APPROVAL CRITERIA**

- I. Individual has a diagnosis of one of the following B-cell lymphomas;
  - A. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (Label, NCCN 2A);  
**OR**
  - B. HIV-related DLBCL (NCCN 2A); **OR**
  - C. High-grade B-cell lymphomas (NCCN 2A); **OR**
  - D. Monomorphic PTLD (B-cell type) (Label, NCCN 2A); **OR**
  - E. Follicular Lymphoma Grade 1-2 (NCCN 2A); **OR**
  - F. Histologic transformation of Indolent Lymphomas to Diffuse Large B-Cell lymphoma (NCCN 2A);

### **AND**

- II. Individual has received one to three prior lines of therapy, and one prior therapy line must have included a CD20-targeted therapy (e.g. rituximab); **AND**
- III. Individual is not eligible for high dose chemotherapy (HDC) with autologous stem-cell transplantation (ASCT); **AND**
- IV. Using in one of the following ways:
  - A. In combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity; **OR**
  - B. As monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity.

Requests for Monjuvi (tafasitamab-cxix) may not be approved for all other indications not included above.

### **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 5, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 5, 2024.

- a. B-Cell Lymphomas. V2.2024. Revised April 30, 2024.
- 6. Salles G, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicenter, prospective, single-arm, phase 2 study. Lancet Oncol 2020. Published online June 5, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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