

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. AIDS-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.: 2023. 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 6, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 6, 2023.

- a. B-Cell Lymphomas. V4.2023. Revised June 2, 2023.
- 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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