SmartHealth Ascension

Tafasitamab-cxix

(Monjuvi®) J9349 (2mg)

Covered with prior authorization

Monjuvi® (tafasitamab-cxix) may be authorized when the following criteria are met:

- Individual has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma; **AND**
- 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**
- Individual is not eligible for high dose chemotherapy (HDC) with autologous stem-cell transplantation (ASCT); **AND**
- Individual is using in one of the following ways:
  - In combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity; **OR**
  - As monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria:
Monjuvi® (tafasitamab-cxix) is considered medically necessary for continued use when initial criteria are met **AND** the patient has experienced clinical benefit to therapy **AND** has not experienced an unacceptable toxicity.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Monjuvi® (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Monjuvi® [Prescribing Information]. Boston, MA: MorphoSys AG; 2022.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021
4. Salles G, et al. Tafasitamab plus lenanlidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicenter, prospective, single-arm, phase 2 study. Lancet Oncol 2020.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.