Medical Drug Clinical Criteria

Subject:	Monjuvi (tafasitamab-cxix)		
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Overview

This document addresses the use of Monjuvi (tafasitamab-cxix). Monjuvi is a CD19-directed cytolytic antibody FDA 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 (ASCT)

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Monjuvi. It is recommended in combination with lenalidomide for treatment of histologic transformation to diffuse large B-cell lymphoma (DLBCL) without translocations of MYC and BCL2 and/or BCL6 in patients who are not candidates for transplant and have received

- minimal or no chemoimmunotherapy prior to histologic transformation to DLBCL and have no response or progressive disease after chemoimmunotherapy (anthracycline- or anthracenedione-based regimens preferred unless contraindicated)
- multiple prior therapies including ≥2 lines of chemoimmunotherapy for indolent or transformed disease

Monjuvi also has a NCCN 2A recommendation as second-line and subsequent therapy in combination with lenalidomide for partial response, no response, relapsed, progressive, or refractory disease in non-candidates for transplant.

Additionally, NCCN 2A recommendation also allows use as second-line and subsequent therapy in combination with lenalidomide for AIDS-related diffuse large B-cell lymphoma, who are not candidates for transplant, high-grade B-cell lymphomas, and monomorphic PTLD (B-cell type).

Monjuvi has an NCCN 2A recommendation for use in combination with lenalidomide as second-line and subsequent therapy for no response, relapsed or progressive disease in those with follicular lymphoma (grade 1-2) that transforms into DLBCL and are not candidates for transplant. This recommendation has no evidence to support its use and is not recommended for early follicular lymphoma due to current available treatment options. NCCN also recommends Monjuvi for transformation of indolent lymphomas to diffuse large B-cell ymphoma.

Definitions and Measures

Diffuse Large B-Cell Lymphoma: or DLBCL is a cancer that starts in white blood cells. It usually grows in lymph nodes- pea sized glands in the neck, groin, armpits, and elsewhere that are part of the immune system.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Monjuvi (tafasitamab-cxix)

Requests for Monjuvi (tafasitamab-cxix) may be approved if the following criteria are met:

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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9349	injection, tafasitamab-cxix, 2 mg [Monjuvi]

ICD-10 Diagnosis

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
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

Document History

Revised: 08/16/2024
Document History:

- 08/16/2024 – Annual Review: Clarify existing NCCN nomenclature for HIV-related B-cell lymphomas. Coding Reviewed: Added ICD-10-CM D47.Z1 for PTLD (B-cell type) to align with NCCN 2A criteria addition 8/19/2022.
- 08/18/2023 – Annual Review: Update criteria with NCCN 2A recommendations for use in additional types of B-Cell lymphomas, follicular and indolent transformation to diffuse LBCL. Coding Reviewed. No changes.
- 08/19/2022 – Annual Review – Update existing criteria with NCCN 2A recommendation for use in additional types of DLBCL—AIDS-related, high-grade B-cell lymphomas, and monomorphic PTLD (B-cell type). Coding reviewed: Removed ICD-10-CM C83.30-C83.39. Added ICD-10-CM C83.30, C83.31, C83.32, C83.33, C83.34, C83.35, C83.36, C83.37, C83.38, C83.39.
- 08/20/2021 – Annual Review: Added NCCN 2A reference to clinical criteria. Coding reviewed: No changes.
- 09/14/2020 – Annual Review: New clinical criteria document for Monjuvi. Coding Reviewed: Added HCPCS J3490, J3590, J9999. Added ICD-10-CM C83.80-C83.39. Effective 1/1/21 Added HCPCS C9070. Added All diagnosis pend for NOC codes only. Effective 4/1/2021 Added HCPCS J9349. Removed J3490, J3590, J9999, C9070. Removed all dx pend.

References

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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 lenanlidomide 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 polices may take precedence over the application of this clinical criteria.