

## Corporate Medical Policy

### Tafasitamab-cxix (Monjuvi<sup>®</sup>)

<b>File Name:</b>	tafasitamab_monjuvi
<b>Origination:</b>	10/2020
<b>Last CAP Review:</b>	1/2021
<b>Next CAP Review:</b>	1/2022
<b>Last Review:</b>	1/2021

#### Description of Procedure or Service

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Tafasitamab-cxix (Monjuvi<sup>®</sup>) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adults 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).

DLBCL is the most common subtype of non-Hodgkin lymphoma (NHL), representing approximately one-third of NHL patients. It is an aggressive and quickly progressing NHL in which survival without treatment is measured in months. While there have been many advancements in the treatment of DLBCL, a cure is not achieved in most patients using conventional therapy, and roughly 30 to 40% of patients suffer relapse. For patients who are refractory to initial treatment and for patients who relapse after an initial response, only a small percentage will experience prolonged disease-free survival with salvage chemoimmunotherapy treatment alone. The preferred treatment for a first relapse of DLBCL or primary refractory DLBCL is salvage chemoimmunotherapy followed by autologous hematopoietic stem cell transplantation (HSCT). However, the outcome for relapsed/refractory DLBCL patients who are ineligible for transplant remains poor.

Tafasitamab-cxix (Monjuvi) is a humanized CD19-directed cytolytic monoclonal antibody, which was approved by the U.S. Food and Drug Administration (FDA) in July 2020 for the treatment of relapsed or refractory DLBCL. It works by binding to CD19 expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including DLBCL, which induces B-cell lysis via apoptosis and immune effector mechanisms. Use of tafasitamab and lenalidomide combined increases antibody-dependent cellular cytotoxicity compared to use alone.

#### **Related Medical Policies:**

CAR-T Therapy

Hematopoietic Stem-Cell Transplant for Non-Hodgkin Lymphomas

Monoclonal Antibodies for Non-Hodgkin Lymphoma and Acute Myeloid Leukemia in the Non-Hematopoietic Stem Cell Transplant Setting

Polatuzumab vedotin-piiq (Polivy<sup>™</sup>)

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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# Tafasitamab-cxix (Monjuvi<sup>®</sup>)

BCBSNC will provide coverage for tafasitamab-cxix (Monjuvi<sup>®</sup>) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Tafasitamab-cxix (Monjuvi) is covered

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### Initial Therapy

Tafasitamab-cxix (Monjuvi) may be considered medically necessary for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) when the following criteria are met:

1. The patient has a diagnosis of DLBCL, including DLBCL arising from low grade lymphoma; **and**
2. The patient has relapsed or refractory disease; **and**
3. Previous therapy included an anti-CD20 antibody; **and**
4. Tafasitamab is administered in combination with lenalidomide\*; **and**
5. The patient is not a candidate for autologous hematopoietic stem cell transplantation (HSCT); **and**
6. The patient has not previously undergone allogeneic HSCT; **and**
7. The patient does not have active central nervous system lymphoma.

Initial authorization: 12 months

### Continuation Therapy

Continuation of treatment with tafasitamab-cxix (Monjuvi) beyond 12 months after initiation of therapy, and every 12 months thereafter, is considered medically necessary for the treatment of diffuse large B-cell lymphoma (DLBCL) when the following criteria are met:

1. The patient is currently receiving tafasitamab, and continues to meet initial criteria or would have met initial criteria at the time of treatment initiation; **and**
2. Tafasitamab is administered as monotherapy\*; **and**
3. The patient has continued clinical benefit on tafasitamab therapy as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile.

\*Tafasitamab is administered in combination with lenalidomide for a maximum of 12 cycles

Use of tafasitamab-cxix (Monjuvi) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, (see Policy Guidelines); **OR**

# Tafasitamab-cxix (Monjuvi<sup>®</sup>)

- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

## When Tafasitamab-cxix (Monjuvi) is not covered

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Tafasitamab-cxix (Monjuvi) is considered **investigational** and therefore not covered when the above criteria are not met.

Tafasitamab-cxix (Monjuvi) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Tafasitamab-cxix (Monjuvi) is covered.”

## Policy Guidelines

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### Dosing and Administration

The recommended dose of Monjuvi is 12 mg/kg given as an intravenous infusion according to the following dosing schedule:

<b>Cycle (28-days)</b>	<b>Dosing Schedule</b>
Cycle 1	Days 1, 4, 8, 15, and 22
Cycles 2 and 3	Days 1, 8, 15, and 22
Cycle 4 and beyond	Days 1 and 15

Monjuvi is administered in combination with lenalidomide 25 mg for a maximum of 12 cycles, and then continued as monotherapy until disease progression or unacceptable toxicity.

Monjuvi should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage possible occurrence of infusion-related reactions. To reduce the risk and severity of infusion-related reactions, patients should be premedicated with acetaminophen, H1 or H2 antagonists, and/or glucocorticoids prior to administration of Monjuvi and lenalidomide. In patients with no infusion-related reactions after the first 3 infusions, premedication may be optional for subsequent infusions.

According to the manufacturer’s safety information for Monjuvi, the most common adverse reactions (≥20% incidence) include neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, fever, peripheral edema, respiratory tract infection, and decreased appetite.

### Evidence Summary

The efficacy of tafasitamab-cxix (Monjuvi) in combination with lenalidomide followed by tafasitamab as monotherapy was evaluated in an open-label, multicenter, single-arm, phase 2 clinical trial (L-MIND; NCT02399085) that included 81 patients with relapsed or refractory DLBCL after 1 to 3 prior systemic regimens, including a CD20-directed cytolytic antibody.

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Patients included in the trial were not candidates for high dose chemotherapy (HDC) followed by autologous stem cell transplantation (ASCT). Study participants received tafasitamab in combination with lenalidomide for up to twelve 28-day cycles followed by tafasitamab monotherapy in patients with stable disease or better, until disease progression or unacceptable toxicity. Tafasitamab dosage was 12 mg/kg intravenously on days 1, 8, 15, and 22 for cycles 1 to 3 with an additional loading dose given on day 4 of cycle 1. Beginning with cycle 4, tafasitamab was administered on days 1 and 15 of each cycle. Lenalidomide dosage was 25 mg orally given daily on days 1 to 21 of each 28-day cycle (maximum of 12 cycles). The primary efficacy endpoint was the proportion of patients with an objective response (complete or partial response), which was 55% (95% CI, 43-67) including a complete response in 37% of patients and partial response in 18% of patients. The median duration of response was 21.7 months (range, 0-24). Tafasitamab in combination with lenalidomide resulted in a high objective response rate and was well tolerated in patients with relapsed or refractory DLBCL who were ineligible for autologous stem cell transplantation.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), “Investigational (Experimental) Services.”

Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: J9349, S0353, S0354*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Morphosys US Inc. Monjuvi (tafasitamab-cxix) for injection for intravenous use. Highlights of prescribing information. July 2020. Available at: <https://www.monjuvi.com/pi/monjuvi-pi.pdf>. Last accessed September 2020.

U.S. Food and Drug Administration. FDA grants accelerated approval to tafasitamab-cxix for diffuse large B-cell lymphoma. July 31, 2020. Available at: <https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-tafasitamab-cxix-diffuse-large-b-cell-lymphoma>. Last accessed September 2020.

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National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas, version 4.2020. Revised August 13, 2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/b-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf). Last accessed September 2020.

Medical Director review 9/2020

Blue Cross NC Pharmacy and Therapeutics Committee 1/2021

## Policy Implementation/Update Information

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- 10/1/20 New policy developed. Monjuvi is considered medically necessary for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) when specified medical criteria and guidelines are met. Added HCPCS codes C9399, J3490, J3590, J9999, S0353, and S0354 to Billing/Coding section. References added. Medical Director review 9/2020. **Policy notification given 10/1/2020 for effective date 1/1/2021.** (krc)
- 12/31/20 Added HCPCS code C9070 to Billing/Coding section effective 1/1/2021. (krc)
- 3/31/21 Added HCPCS code J9349 to Billing/Coding section effective 4/1/2021 and deleted codes C9070, C9399, J3490, J3590, J9999 termed 3/31/2021. Blue Cross NC Pharmacy and Therapeutics Committee 1/5/2021. (krc)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.