

Medical Policy Manual **Approved Revision: Do Not Implement Until 4/2/21**

Tafasitamab-cxix

NDC CODE(S) 73535-0208-XX MONJUVI 200MG Solution Reconstituted (MORPHOSYS US)

DESCRIPTION

Tafasitamab-cxix is a humanized CD19-directed cytolytic monoclonal antibody that contains an IgG1/2 hybrid Fc-domain with 2 amino acid substitutions to modify the Fc-mediated functions of the antibody. Tafasitamab-cxix binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma (DLBCL).

Upon binding to CD19, tafasitamab-cxix mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

POLICY

- Tafasitamab-cxix for the treatment of diffuse large B-cell lymphoma (DLBCL) is considered **medically necessary** if the medical appropriateness criteria are met. (See **Medical Appropriateness** below.)
- Tafasitamab-cxix for the treatment of other conditions/diseases is considered **investigational**

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Tafasitamab-cxix for the treatment of diffuse large B-cell lymphoma (DLBCL) is considered **medically appropriate** if **ALL** of the following criteria are met:
 - Individual is 18 years of age or older
 - Absence of **ALL** of the following:
 - Active infection, including clinically important localized infections
 - CNS lymphoma involvement
 - Individual has not received an allogeneic stem cell transplant OR autologous-SCT within the prior 3 months of therapy
 - Individual has not received prior therapy with immunomodulatory imide (IMiD-class) agents (e.g., lenalidomide)
 - Individual has not received prior therapy with CD19-directed therapy (e.g., axicabtagene, tisagenlecleucel, etc.) **OR** individual previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
 - Therapy will be initiated in combination with lenalidomide (Note: use is for up to 12 cycles only)
 - Individual is ineligible for intensive therapy (i.e., high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT) **and ANY ONE** of the following:
 - Individual has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, (excluding *primary refractory AND 'double or triple hit' [i.e., translocations of MYC, BCL2, and/or BCL6] disease*) and used as subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease
 - Individual has a diagnosis of DLBCL arising/transformed from low grade lymphoma such as Follicular or Marginal Zone (excluding primary refractory AND 'double or triple hit'[i.e., translocations of MYC, BCL2, and/or BCL6] disease) and **ANY ONE** of the following:
 - Individual received multiple lines of prior therapies, including two or more prior lines of chemoimmunotherapy for indolent or transformed disease



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- Individual received minimal or no chemoimmunotherapy prior to histologic transformation with no response or progressive disease after chemoimmunotherapy which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated

RENEWAL CRITERIA

- Tafasitamab-cxix is considered **medically appropriate** for renewal **ALL** of the following criteria are met:
 - Individual continues to meet initial approval criteria
 - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion type reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc.
 - Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread
 - Combination therapy with lenalidomide may not exceed a maximum of 12 cycles (continued tafasitamab single-agent maintenance therapy may be continued until disease progression or unacceptable toxicity)

INDICATION(S)	DOSAGE & ADMINISTRATION
Diffuse Large B-Cell Lymphoma (DLBCL)	<p>The recommended dosage of Monjuvi is 12 mg/kg as an intravenous infusion according to the following dosing schedule:</p> <ul style="list-style-type: none"> • Cycle 1: Days 1, 4, 8, 15 and 22 of a 28-day cycle. • Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle. • Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle. <p>Administer Monjuvi in combination with lenalidomide for a maximum of 12 cycles and then continue Monjuvi as monotherapy until disease progression or unacceptable toxicity.</p>

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed

- Combined use with lenalidomide must not exceed a maximum of 12 cycles; however, continued maintenance tafasitamab monotherapy may be renewed until disease progression or unacceptable toxicity.

Refer to **DOSAGE LIMITS** below

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee’s Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member’s health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.



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ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

Lexi-comp Online. (2020, September). AHFS DI. Tafasitamab-cxix. Retrieved December 3, 2020 from Lexi-comp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, September). *Tafasitamab-cxix*. Retrieved December 3, 2020 from MICROMEDEX Healthcare Series.

National Comprehensive Cancer Network. (2020). NCCN Drugs & Biologics Compendium® Tafasitamab-cxix Retrieved, December 3, 2020 from the National Comprehensive Cancer Network.

Salles, G., Duell, J., González Barca, E., Tournilhac, O., Jurczak, W., et al. (2020) Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *The Lancet Oncology*. 21(7):978-988. doi: 10.1016/S1470-2045(20)30225-4. Epub 2020 Jun 5

U. S. Food and Drug Administration. (2020, July). Center for Drug Evaluation and Research. *Monjuvi™ (Tafasitamab-cxix) for injection*. Retrieved December 3, 2020 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761163s000lbl.pdf

EFFECTIVE DATE 4/2/2021

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