09-J3000-81

Original Effective Date: 11/15/20

Reviewed: 06/11/25

Revised: 06/01/26

Subject: Tafasitamab-cxix (Monjuvi®) IV Infusion

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Tafasitamab (Monjuvi) is a CD19-directed cytolytic monoclonal antibody approved by the Food and Drug Administration (FDA) in July 2020, and, in combination with lenalidomide, is indicated 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). This indication was approved under accelerated approval based on overall response rate, and continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). In June 2025, the FDA approved an additional indication of, in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL). Tafasitamab, as sponsored by the innovator drug company, previously received an orphan drug designation for the treatment of DLBCL in December 2014 and follicular lymphoma in January 2021. Tafasitamab also received orphan designations for the treatment of extranodal/nodal/splenic/marginal zone lymphomas in December 2024. Tafasitamab works by binding to the CD19 antigen expressed on the surface of pre-B and mature B lymphocytes causing B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis. In vitro, the combination of tafasitamab and lenalidomide increased ADCC activity in DLBCL tumor cells compared with tafasitamab or lenalidomide alone. Other DLBCL treatments that target CD19 include loncastuximab tesirine (Zynlonta) and the anti-CD19 CAR T-cell therapies such as axicabtagene ciloleucel (Yescarta), lisocabtagene maraleucel (Breyanzi), and tisagenlecleucel (Kymriah).

Diffuse large B-cell lymphomas are the most common lymphoid neoplasms in adults, and account for approximately 32% of non-Hodgkin lymphoma (NHLs) cases diagnosed annually. The DLBCLs exhibits large heterogeneity in morphologic, genetic, and clinical aspects. Multiple clinicopathologic entities are defined by the 2017 World Health Organization (WHO) classification, which are sufficiently distinct to be considered separate diagnostic categories. Combination chemoimmunotherapy in the first-line setting (e.g., rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone [R-CHOP]) is associated with a 5-year survival rate ranging from 60% to 70%. Interim restaging should be performed to identify patients who disease has not responded to or has progressed on induction therapy. Based on a number of prognostic factors, 20% to 50% of DLBCL cases are refractory or relapse after first-line chemotherapy and the response rates to subsequent salvage chemotherapy and consolidation with autologous hematopoietic stem cell transplantation (HSCT) is suboptimal.

The National Comprehensive Cancer Network (NCCN) B-cell Lymphoma Guidelines (Version 2.2025 - February 10, 2025) list tafasitamab + lenalidomide as a category 2A recommendation for DLBCL as second-line therapy under "Preferred regimens" for both (1) relapsed disease <12 months after completion of first-line therapy (excluding primary refractory disease) in non-candidates for CAR T-cell therapy, and (2) relapsed disease >12 months after completion of first-line therapy in patients with no intention to proceed to transplant. There is a footnote stating, "It is unclear if tafasitamab-cxix or loncastuximab tesirine-lpyl or if any other CD19-directed therapy would have a negative impact on the efficacy of subsequent anti-CD19 CAR T-cell therapy". The guidelines also list tafasitamab + lenalidomide under "Preferred regimens" (under the subsection of no intention to proceed to transplant) as a category 2A treatment option for histological transformation of indolent lymphoma to DLBCL in patients previously treated with an anthracycline-based regimen. This regimen includes the same footnote as above. In addition, the guidelines include recommendations for classic follicular lymphoma. For second-line therapy, the regimen of tafasitamab + lenalidomide + rituximab (≥1 prior systemic therapy including an anti-CD20 mAb) is listed as category 2A recommendation under "Preferred regimens". This regimen also includes the same footnote as above.

The safety and efficacy of tafasitamab leading to FDA approval was assessed in the single-arm, phase 2 L-MIND study in 80 adult patients with relapsed or refractory DLBCL who were not candidates for high-dose chemotherapy or ASCT. Patients received tafasitamab and lenalidomide for up to twelve 28-day cycles followed by tafasitamab monotherapy in patients with stable disease or better, until disease progression. Tafasitamab dosage was 12 mg/kg IV on days 1, 8, 15, and 22 for cycles 1 to 3, and an additional loading dose on day 4 of cycle 1. Starting with cycle 4, tafasitamab was given on days 1 and 15 of each cycle. Lenalidomide dosage was 25 mg orally daily on days 1 to 21 of each 28-day cycle. The median age was 72 years and subjects had a median of two prior therapies (range, 1 to 4); 11% of patients had received a prior ASCT. After a minimum of 12 months of follow-up (median, 13.2 months), the objective response rate (assessed by an independent review committee) was 60% (95% CI, 48% to 71%). The complete response (CR) rate was 43%. The median duration of response was 21.7 months. At a median follow-up time of 17.3 months, the progression-free survival time was 12.1 months. The median overall survival (OS) time was not reached at a median follow-up time of 19.6 months; the 12-month and 18-month OS rates were 74% and 64%, respectively. Serious adverse events included febrile neutropenia (6%), bronchitis (2%), pneumonia (6%), pulmonary embolism (4%), atrial fibrillation (2%), and congestive cardiac failure (2%).

POSITION STATEMENT:

Drug Waste Reduction: Additional medical necessity criteria for dose optimization may apply depending on the requested dose and member's benefit. Refer to Medical Coverage Guideline Drug Waste Reduction, 09-J5000-54.

Initiation of tafasitamab (Monjuvi) **meets the definition of medical necessity** when **EITHER** of the following criteria are met ("1" or "2'):

1. **BOTH** of the following ("a" and "b"):
    a. Member has a confirmed diagnosis of **ANY** of the following ("i" to "iv"):
        i. Classic follicular lymphoma
        ii. Diffuse large B-cell lymphoma (DLBCL) [including DLBCL transformed from an indolent lymphoma such as follicular or marginal zone lymphomas]
        iii. High-grade B-cell lymphomas (HBCL) [including HGBL with MYC and BCL2 and/or BCL6 translocations (a.k.a., double-hit or triple-hit lymphomas) and HGBL, NOS)
        iv. HIV-related B-cell lymphoma that includes one of the following subtypes:
            - HIV-related DLBCL
            - HIV-related plasmablastic lymphoma

- HHV8 (human herpesvirus 8)-positive diffuse large B-cell lymphoma, not otherwise specified (NOS)
- Primary effusion lymphoma

v. Monomorphic post-transplant lymphoproliferative disorders (PTLD) (B-cell type)

b. **ALL** of the following are met ("i" to "iv"):

i. Tafasitamab is being used as second-line or later therapy for relapsed or refractory disease

ii. **EITHER** of the following depending on the member's diagnosis:

- Classic follicular lymphoma - tafasitamab will be used in combination with **BOTH** lenalidomide (Revlimid) **AND** a rituximab product
- Other diagnosis - tafasitamab will be used **EITHER** in combination with lenalidomide **OR** as monotherapy if the member has an FDA-labeled contraindication, had an adverse reaction, or is otherwise not a candidate for lenalidomide – the specific contraindication, adverse reaction, or reason for non-candidacy must be provided

iii. **ANY** of the following depending on the member's diagnosis:

- Classic follicular lymphoma – member has received prior systemic therapy with an anti-CD20 monoclonal antibody [such as a rituximab product or obinutuzumab (Gazyva)]
- DLBCL transformed from an indolent lymphoma – member has received prior systemic therapy with an anthracycline-based regimen (such as doxorubicin), **AND** the member has no intention to proceed to a hematopoietic cell transplant
- Other diagnosis – **EITHER** of the following depending on the time of disease relapse after completion of first-line therapy
  - Less than 12 months – member is **NOT** a candidate for CAR T-cell therapy, **AND** the member does **NOT** have primary refractory disease
  - 12 months of more - member has no intention to proceed to a hematopoietic cell transplant

iv. Dosage of tafasitamab does not exceed 12 mg/kg (based on actual body weight) according to the following dosing schedule (each cycle is 28 days) depending on the indication for use:

- Classic follicular lymphoma
  - Cycles 1 to 3 - Days 1, 8, 15 and 22
  - Cycle 4 and beyond - Days 1 and 15
- DLBCL and other indications:
  - 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

2. Member has another FDA-approved or NCCN-supported diagnosis, and **ALL** of the following are met ("a", "b", and "c"):

a. **EITHER** of the following ("i" or "ii"):

i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

ii. Indication **AND** usage are recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

b. Tafasitamab is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis

c. Dosage of tafasitamab does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

Approval duration: 6 months

Continuation of tafasitamab (Monjuvi) **meets the definition of medical necessity** when **BOTH** of the following criteria are met ("1" and "2"):

1. An authorization or reauthorization for tafasitamab has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of classic follicular lymphoma, DLBCL, HBCL, HIV-related B-cell lymphoma, monomorphic PTLD (B-cell type), or other FDA-approved or NCCN-supported diagnosis; **OR** the member previously met **ALL** indication-specific initiation criteria
2. **EITHER** of the following based on the member's diagnosis ("a" or "b"):
   a. Classic follicular lymphoma, DLBCL, HBCL, HIV-related B-cell lymphoma, or monomorphic PTLD (B-cell type) ("i", "ii", and "iii"):
      i. **EITHER** of the following depending on the member's diagnosis and current duration of treatment:
         - Classic follicular lymphoma - tafasitamab will be used in combination with **BOTH** lenalidomide (Revlimid) **AND** a rituximab product
         - Other diagnosis – **EITHER** of the following:
            - If treatment has been less than 1 year - tafasitamab is being used in combination with lenalidomide, **OR**, if the member has an FDA-labeled contraindication, required permanent discontinuation of lenalidomide due to adverse reactions, or is otherwise not a candidate for lenalidomide, tafasitamab is being used as monotherapy
            - If treatment has been 1 year or greater – tafasitamab is being used as monotherapy

      ii. Dosage of tafasitamab does not exceed 12 mg/kg (based on actual body weight) according to the following dosing schedule (each cycle is 28 days) depending on the indication for use:
         - Classic follicular lymphoma:
            - Cycles 1 to 3 - Days 1, 8, 15 and 22
            - Cycle 4 and beyond - Days 1 and 15
         - DLBCL and other indications:
            - 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

      iii. Member has not had disease progression during tafasitamab treatment

   b. Other FDA-approved or NCCN-supported diagnosis, and **ALL** of the following ("i", "ii", and "iii"):
      i. Dosage of tafasitamab does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guideline for the specific diagnosis

ii. Tafasitamab is used in a treatment regimen in accordance with the FDA-approved prescribing information or applicable NCCN guideline recommendation for the diagnosis

iii. Member has had a beneficial response to treatment with tafasitamab

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Tafasitamab, in combination with lenalidomide, is indicated 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). This indication is approved under accelerated approval based on overall response rate, and continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Tafasitamab, in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL). Limitations of Use (per product labeling): Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.
- For DLBCL, the recommended dose is 12 mg/kg based on actual body weight administered as an IV infusion according to the following dosing schedule (each cycle is 28 days):
  - 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
  - Administer tafasitamab in combination with lenalidomide 25 mg for a maximum of 12 cycles, then continue tafasitamab as monotherapy until disease progression or unacceptable toxicity.
- For FL, the recommended dose is 12 mg/kg based on actual body weight administered as an IV infusion according to the following dosing schedule (each cycle is 28 days):
  - Cycle 1 to 3 - Days 1, 8, 15 and 22
  - Cycles 4 to 12: Days 1 and 15 of each 28-day cycle.
  - Administer tafasitamab in combination with lenalidomide (Cycles 1 to 12) and rituximab (Cycles 1 to 5).
- Administer premedications 30 minutes to 2 hours prior to starting tafasitamab infusion to minimize infusion-related reactions. Premedications may include acetaminophen, histamine H1 receptor antagonists, histamine H2 receptor antagonists, and/or glucocorticosteroids. For patients not experiencing infusion-related reactions during the first 3 infusions, premedication is optional for subsequent infusions. If a patient experiences an infusion-related reaction, administer premedications before each subsequent infusion.

Dose Adjustments

- Adverse Drug Reactions – Dosage reductions of tafasitamab are not recommended; however, withholding the next dose, reducing the infusion rate, or permanent discontinuation may be needed. Refer to the product labeling for specific recommendations.
- Hepatic Impairment - Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.
- Renal Impairment - Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed.

Drug Availability

- 200-mg single-dose vial as a sterile, preservative-free, white to slightly yellowish lyophilized powder for reconstitution.
- Store refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do not shake. Do not freeze.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- **Infusion-Related Reactions** - Tafasitamab can cause infusion-related reactions. In L-MIND, infusion-related reactions occurred in 6% of the 81 patients. Eighty percent of infusion-related reactions occurred during cycle 1 or 2. In inMIND, infusion-related reactions occurred in 16% of the 274 patients with FL. Signs and symptoms included chills, flushing, dyspnea, and hypertension. These reactions were managed with temporary interruption of the infusion and/or with supportive medication. Premedicate patients prior to starting tafasitamab infusion. Monitor patients frequently during infusion. Based on the severity of the infusion-related reaction, interrupt or discontinue treatment.
- **Myelosuppression** - Tafasitamab can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. In L-MIND, Grade 3 neutropenia occurred in 25% of patients, thrombocytopenia in 12%, and anemia in 7%. Grade 4 neutropenia occurred in 25% and thrombocytopenia in 6%. Neutropenia led to treatment discontinuation in 3.7% of patients. Febrile neutropenia occurred in 12%. In inMIND, new or worsening Grade 3 or 4 cytopenias included decreased neutrophils in 48% (Grade 4, 19%), decreased lymphocytes in 22% (Grade 4, 1.8%), decreased hemoglobin in 9%, and decreased platelets in 8% (Grade 4, 4%). Febrile neutropenia occurred in 4.4%. Monitor CBC prior to administration of each treatment cycle and throughout treatment. Monitor patients with neutropenia for signs of infection. Consider granulocyte colony-stimulating factor administration. Withhold tafasitamab based on the severity of the adverse reaction. Refer to the lenalidomide prescribing information for dosage modifications.
- **Infections** - Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with tafasitamab and following the last dose. In L-MIND, 73% of the 81 patients developed an infection. Grade 3 or higher infection occurred in 30%. Infection-related deaths occurred in 2.5% of patients, including a case of progressive multifocal leukoencephalopathy (PML). The most frequent Grade 3 or higher infection was pneumonia (7%). The most frequent infections of any grade were respiratory tract infections (51%, including pneumonias) and urinary tract infection

(17%). In inMIND, among 274 patients with FL, Grade 3 or higher infections occurred in 24%, including fatal infections in 1.1% of patients. The most frequent Grade ≥ 3 infections were respiratory tract infections (19%), including Grade 3 or higher pneumonia (14%) and COVID-19 infection (11%). Opportunistic infections of any grade occurred in 6% of patients, including herpes simplex or zoster infection (5%), fungal pneumonia (1.1%, including Pneumocytis jirovecii pneumonia in 0.4%), and cytomegalovirus (CMV) reactivation (0.4%). Infection-related deaths were reported in 2.5% of the 81 patients. Monitor patients for signs and symptoms of infection and manage infections as appropriate.

- **Embryo-Fetal Toxicity** - Based on its mechanism of action, tafasitamab may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose. Tafasitamab is initially administered in combination with lenalidomide. The combination of tafasitamab with lenalidomide is contraindicated in pregnant women because lenalidomide can cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J9349	Injection, tafasitamab-cxix, 2 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

B20	Human immunodeficiency virus [HIV] disease (must be billed in combination with C83.30 - C83.39, C83.80 - C83.89, or C85.80 - C85.89)
C82.00 – C82.99	Follicular lymphoma
C83.30 – C83.398	Diffuse large B-cell lymphoma
C83.80 – C83.89	Other non-follicular lymphoma (must be billed in combination with B20)
C83.90 – C83.99	Non-follicular (diffuse) lymphoma, unspecified
C85.10 – C85.19	Unspecified B-cell lymphoma
C85.20 – C85.29	Mediastinal (thymic) large B-cell lymphoma
C85.80 – C85.89	Other specified types of non-Hodgkin lymphoma (must be billed in combination with B20)
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if

based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

CD19: Cluster of Differentiation 19 is a protein found on the surface of B-cells in humans. Fully differentiated plasma cells no longer express CD19.

Diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS): The 2008 WHO classification of mature B-cell lymphomas included DLBCL, NOS as a new category to include germinal center B-cell (GCB) subtype, activated B-cell (ABC) subtype as well as other DLBCL cases that do not belong to any of the four specific subtypes (T-cell/histiocyte rich large B-cell lymphoma, primary CNS DLBCL, primary cutaneous DLBCL ("leg type"), or EBV+ DLBCL of the elderly). The updated 2017 WHO classification system created additional categories that fall outside of the definition of DLBCL, NOS.

RELATED GUIDELINES:

Chimeric Antigen Receptor (CAR) T-Cell Therapies, 09-J3000-94
Loncastuximab Tesirine-lpyl (Zynlonta), 09-J4000-05

OTHER:

None

REFERENCES:

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7. Salles G, Duell J, Gonzalez Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. Lancet Oncol 2020;21(7):978-988.
8. Tafasitamab Plus Lenalidomide and Rituximab for Relapsed or Refractory Follicular Lymphoma: Results from a Phase 3 Study (inMIND) [abstract]. Blood 2024: Abstract LBA-1.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 06/11/25.

GUIDELINE UPDATE INFORMATION:

11/15/20	New Medical Coverage Guideline.
01/01/21	Revision: Added HCPCS code C9070.
04/01/21	Revision: Added HCPCS code J9349 and deleted codes C9070 and J9999.
07/15/22	Review and revision to guideline consisting of updating the description, position statement, billing/coding, related guidelines, and references based on updated NCCN guidelines.
07/15/23	Review and revision to guideline consisting of updating the description, position statement, billing/coding, related guidelines, and references based on updated NCCN guidelines.
07/15/24	Review and revision to guideline consisting of updating the description, position statement, billing/coding, and references based on updated NCCN B-Cell Lymphoma guidelines. Follicular lymphoma removed as a covered indication.
10/01/24	Revision: ICD-10 code updates.
07/15/25	Review and revision to guideline consisting of updating the description, position statement, billing/coding, and references based on updated NCCN B-Cell Lymphoma guidelines. Added classic follicular lymphoma as a new indication which includes a new combination regimen of tafasitamab + lenalidomide + a rituximab product. Removed global requirement that the member does not intend to proceed to transplant. This requirement is now diagnosis specific and, for some diagnoses, based on the time of relapse.
08/15/25	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, and references based on new FDA-approved indication for relapsed or refractory follicular lymphoma.
06/01/26	Revision: Added Drug Waste Reduction statement to the Position Statement.