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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 4, 2020
Subject:	Monjuvi	**Page:**	1 of 5

Last Review Date: December 8, 2023

Monjuvi

Description

Monjuvi (tafasitamab-cxix)

Background
Monjuvi (tafasitamab-cxix) is an Fc-modified monoclonal antibody that 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. Upon binding to CD19, Monjuvi mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis (1).

Regulatory Status
FDA-approved indication: Monjuvi 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 (ASCT) (1).

Monjuvi should be administered with lenalidomide for a maximum of 12 cycles, then Monjuvi should be continued as monotherapy until disease progression or unacceptable toxicity (1).

Monjuvi can cause infusion-related reactions. Patients should be premedicated before starting Monjuvi infusion. Premedications may include acetaminophen, histamine H_1 receptor antagonists, histamine H_2 receptor antagonists, and/or glucocorticosteroids. For patients not experiencing infusion-related reactions during the first 3 infusions, premedication is optional for subsequent infusions (1).

Monjuvi can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. Complete blood counts (CBC) should be monitored prior to administration of each treatment cycle and throughout treatment (1).

Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with Monjuvi and following the last dose. Patients should be monitored for signs and symptoms of infection and managed as appropriate (1).

Monjuvi may cause fetal B-cell depletion when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Monjuvi and for at least 3 months after the last dose. Monjuvi is initially administered with lenalidomide which is contraindicated in pregnant women because lenalidomide can cause birth defects and death of the unborn child (1).

The safety and effectiveness of Monjuvi in pediatric patients have not been established (1).

Related policies
Zynlonta

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Monjuvi may be considered **medically necessary** if the conditions indicated below are met.

Monjuvi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

AND ALL of the following:

a. **NOT** eligible for autologous stem cell transplant (ASCT)
b. Used in combination with lenalidomide, as tolerated
c. Prescriber agrees to monitor the patient for signs and symptoms of infusion-related reactions and administer premedication if needed
d. Prescriber agrees to monitor complete blood counts (CBC) for myelosuppression
e. Prescriber agrees to monitor the patient for infections
f. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Monjuvi and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor the patient for signs and symptoms of infusion-related reactions and administer premedication if needed
c. Prescriber agrees to monitor complete blood counts (CBC) for myelosuppression
d. Prescriber agrees to monitor the patient for infections
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Monjuvi and for 3 months after the last dose

Policy Guidelines

Pre – PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Monjuvi (tafasitamab-cxix) is an Fc-modified monoclonal antibody that 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. Upon binding to CD19, Monjuvi mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis. The safety and effectiveness of Monjuvi in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Monjuvi while maintaining optimal therapeutic outcomes.

References
1. Monjuvi [package insert]. Boston, MA: Morphosys US Inc.; June 2021.
2. NCCN Drugs & Biologics Compendium® Tafasitamab-cxix 2023. National Comprehensive Cancer Network, Inc. Accessed on September 29, 2023.

Policy History

Date	Action
September 2020	Addition to PA
December 2020	Annual review
June 2021	Annual review and reference update
September 2021	Annual review and reference update
June 2022	Annual review and reference update
March 2023	Annual review and reference update

September 2023	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.