



Monjuvi
Monjuvi (Tafasitamab-cxix) J9349
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Diffuse Large B-Cell Lymphoma (DLBCL) – Relapsed or Refractory (FDA-Approved)

- Patient is 18 years or older
- Histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low-grade lymphoma
- Patient is not eligible for autologous stem cell transplant (ASCT)
- Patient has received at least one prior systemic therapy (including anti-CD20 therapy)
- ECOG performance status 0-2
- Prescribed by or in consultation with hematologist/oncologist

Follicular Lymphoma (FL) – Relapsed or Refractory (FDA-Approved)

- Patient is 18 years or older
- Histologically confirmed diagnosis of follicular lymphoma
- Patient has received at least one prior systemic therapy
- Therapy is in combination with lenalidomide and rituximab
- ECOG performance status 0-2
- Prescribed by or in consultation with hematologist/oncologist

HIV-Related B-Cell Lymphomas (NCCN 2A)

- Patient has confirmed diagnosis of HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HHV8-positive DLBCL, or HIV-related plasmablastic lymphoma
- Therapy is in combination with lenalidomide
- Patient has received at least one prior systemic therapy
- ECOG performance status 0-2
- Prescribed by or in consultation with hematologist/oncologist

High-Grade B-Cell Lymphoma (HGBL) – Relapsed or Refractory (NCCN 2A)

- Patient has histologically confirmed diagnosis of high-grade B-cell lymphoma (including double/triple hit)
- Therapy is in combination with lenalidomide
- Patient has received at least one prior systemic therapy
- Patient is not a candidate for or has failed CAR-T therapy OR transplant is not intended
- ECOG performance status 0-2
- Prescribed by or in consultation with hematologist/oncologist

Histologic Transformation of Indolent Lymphomas to DLBCL (NCCN 2A)

- Patient has documented histologic transformation from indolent lymphoma (e.g., follicular lymphoma, marginal zone lymphoma) to DLBCL
- Therapy is in combination with lenalidomide
- Patient has received prior anthracycline-based regimen OR has had multiple prior lines of therapy for indolent disease
- Transplant is not intended
- ECOG performance status 0-2
- Prescribed by or in consultation with hematologist/oncologist

Post-Transplant Lymphoproliferative Disorder (PTLD) – Monomorphic B-Cell Type (NCCN 2A)

- Patient has confirmed diagnosis of monomorphic PTLD (B-cell type)**
- Therapy is in combination with lenalidomide**
- Patient has relapsed or refractory disease following initial chemoimmunotherapy**
- Patient is not a candidate for CAR-T therapy OR transplant is not intended**
- ECOG performance status 0-2**
- Prescribed by or in consultation with hematologist/oncologist**

Continuation of Therapy Criteria (All Indications)

- Patient continues to meet initial approval criteria
- Documentation indicates disease response or stabilization (e.g., no disease progression, stable or decreasing tumor size)
- No unacceptable toxicity requiring discontinuation
- For patients who have completed up to 12 cycles of combination therapy with lenalidomide, Monjuvi may continue as monotherapy until disease progression or unacceptable toxicity

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

- Patient had an **adequate response** or **significant improvement** while on this medication.
- Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Monjuvi Prior Authorization

Drug Name(s):

MONJUVI

TAFASITAMAB-CXIX

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per NCCN, CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Hematologist, Oncologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Monjuvi

- Diffuse large B-cell lymphoma, Relapsed or refractory, including disease arising from low-grade lymphoma, and not eligible for autologous stem cell transplant, in combination with lenalidomide,
- Follicular lymphoma, Relapsed or refractory, in combination with lenalidomide and rituximab

Off-Label Uses:

N/A

Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/0CE27B/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8D27D9/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933028&contentSetId=100&title=Tafasitamab-cxix&servicesTitle=Tafasitamab-cxix&brandName=Monjuvi&UserMdxSearchTerm=Monjuvi#