Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 221.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Monjuvi (tafasitamab-cxix)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Monjuvi (tafasitamab-cxix)

II. Purpose/Objective:
To provide a policy of coverage regarding Monjuvi (tafasitamab-cxix)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Monjuvi (tafasitamab-cxix) is a humanized CD19-directed, Fc-modified monoclonal antibody that binds to CD19 antigen, which is expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma. After binding to CD19, tafasitamab mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity and phagocytosis. Administering in combination with lenalidomide results in increased antibody-dependent cellular cytotoxicity activity compared to either agent alone.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Monjuvi (tafasitamab-cxix) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

1. **Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)**
   - Medical record documentation of age greater than or equal to 18 years **AND**
   - Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
   - Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma **AND**
   - Medical record documentation that the member is not eligible for autologous stem cell transplant (ASCT) **AND**
   - Medical record documentation that Monjuvi will be used in combination with Revlimid (lenalidomide)

2. **Relapsed or Refractory Follicular Lymphoma (FL)**
   - Medical record documentation of age greater than or equal to 18 years **AND**
   - Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
   - Medical record documentation of relapsed or refractory follicular lymphoma (FL) **AND**
   - Medical record documentation that Monjuvi will be used in combination with lenalidomide (Revlimid) and rituximab

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Limitation of use: 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.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Monjuvi [prescribing information]. Boston, MA: Morphosys US Inc; June 2025.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/15/20

Revised: 9/15/22 (Medicaid PARP statement), 9/11/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 8/29/24 (LOB table, taglines), 8/19/25 (FL added)

Reviewed: 9/15/21

MA UM Committee approval: 12/31/23, 12/31/24, 10/27/25

DHS PARP approval: 9/16/24, 9/12/25