Breyanzi (lisocabtagene maraleucel)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Adult patients with large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS) (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have:
   a. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
   b. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
   c. Relapsed or refractory disease after two or more lines of systemic therapy
2. Adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor
3. Adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy.
4. Adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.
5. Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy.

Limitations of Use

Breyanzi is not indicated for the treatment of:

1. Patients with primary central nervous system lymphoma.

Compendial Uses

1. Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified)
2. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
3. Pediatric primary mediastinal large B-cell lymphoma
4. Mantle cell lymphoma
5. CLL/SLL
6. Histologic (Richter) transformation to DLBCL

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes or medical record documentation demonstrating failure of previous lines of therapy.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

1. Primary central nervous system lymphoma.
2. Previous treatment course with the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy
3. ECOG performance status greater than or equal to 3 (member is not ambulatory and not capable of all self-care, confined to bed or chair more than 50% of waking hours)
4. Inadequate and unstable kidney, liver, pulmonary or cardiac function
5. Active hepatitis B, active hepatitis C or any active uncontrolled infection
6. Active graft versus host disease
7. Active inflammatory disorder

Criteria for Initial Approval

A. Adult Large B-cell Lymphomas

Authorization of 3 months (one dose) may be granted for treatment of B-cell lymphomas in members 18 years of age or older when any of the following criteria is met:

1. The member has received prior treatment with two or more lines of systemic therapy and has any of the following B-cell lymphoma subtypes:
    a. Diffuse large B-cell lymphoma (DLBCL) [including DLBCL NOS, follicular lymphoma grade 3, DLBCL arising from indolent lymphomas]
    b. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
    c. Primary mediastinal large B-cell lymphoma
    d. Follicular lymphoma
    e. Marginal zone lymphoma
    f. HIV-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified)
    g. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

2. The member has received prior treatment with first-line chemoimmunotherapy and has relapsed/refractory disease with any of the following B-cell lymphoma subtypes:
    a. Diffuse large B-cell lymphoma (DLBCL) [including DLBCL NOS, follicular lymphoma grade 3, DLBCL arising from indolent lymphomas]
    b. High-grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
    c. Primary mediastinal large B-cell lymphoma
    d. HIV-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified and plasmablastic lymphoma)
    e. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
3. The member has received prior treatment with a covalent Bruton tyrosine kinase inhibitor (e.g., acalabrutinib [Calquence], ibrutinib [Imbruvica], zanubrutinib [Brukinsa]) and has relapsed/refractory Mantle cell lymphoma.

B. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
Authorization of 3 months (one dose) may be granted for treatment of relapsed or refractory CLL/SLL in members 18 years of age or older when the member has received prior therapy with Bruton tyrosine kinase inhibitor (e.g., acalabrutinib [Calquence], ibrutinib [Imbruvica], zanubrutinib [Brukinsa])- and BCL-2 inhibitor (e.g., venetoclax) -containing regimens.

C. Histologic (Richter) Transformation to DLBCL
Authorization of 3 months (one dose) may be granted for treatment of histologic (Richter) transformation to DLBCL when either of the following criteria is met:
1. Disease is clonally related to unknown clonal status in members with del(17p)/TP53 mutation or who are chemotherapy refractory or unable to receive chemoimmunotherapy
2. Disease is clonally unrelated or member has previously untreated CLL and partial response, refractory disease, or progression on chemoimmunotherapy

D. Pediatric Primary Mediastinal Large B-cell Lymphoma
Authorization of 3 months (one dose) may be granted for treatment of relapsed/refractory primary mediastinal large B-cell lymphoma in members less than 18 years of age when the member has received prior therapy with at least two chemoimmunotherapy regimens and achieved partial response.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits
Breyanzi approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2054 – Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose

REFERENCES

- Breyanzi [package insert]. Bothell, WA: Juno Therapeutics Inc.; December 2025.
- The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 9, 2025.

- The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 2.2025). © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 9, 2025.
- Abramson J, Palomba ML, Gordon L, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicenter seamless design study. Lancet. 2020;396 (10254):839-852.
- Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. September 2021.

POLICY HISTORY

Policy #: 05.04.75
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