Lisocabtagene Maraleucel (Breyanzi®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

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.

A. FDA-Approved Indication
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:
   i. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
   ii. 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
   iii. Relapsed or refractory disease after two or more lines of systemic therapy

Limitations of use: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.

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

B. 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

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart notes, medical record documentation or claims history supporting previous lines of therapy.

III. EXCLUSIONS

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

A. Primary central nervous system lymphoma
B. Previous treatment course with the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
C. 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)
D. Inadequate and unstable kidney, liver, pulmonary or cardiac function
E. Active hepatitis B, active hepatitis C or any active uncontrolled infection
F. Active graft versus host disease
G. Active inflammatory disorder

IV. CRITERIA FOR INITIAL APPROVAL

A. Adult Large B-cell lymphomas

Authorization of 3 months may be granted for treatment of B-cell lymphomas in members 18 years of age or older when either of the following criteria are 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:
   i. Diffuse large B-cell lymphoma (DLBCL) [including DLBCL NOS, follicular lymphoma grade 3, DLBCL arising from indolent lymphomas]
   ii. 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)
   iii. Primary mediastinal large B-cell lymphoma
   iv. 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)
   v. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
2. The member has received prior treatment with first-line chemoimmunotherapy and has any of the following B-cell lymphoma subtypes:
   i. Diffuse large B-cell lymphoma (DLBCL) [including DLBCL NOS, and follicular lymphoma grade 3]
   ii. 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)
   iii. Primary mediastinal large B-cell lymphoma
   iv. 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)
   v. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

B. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

Authorization of 3 months 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 venetoclax-based regimens.

C. Pediatric Primary Mediastinal Large B-cell Lymphoma

Authorization of 3 months may be granted for treatment of 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 prior chemoimmunotherapy regimens and achieved partial response.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Breyanzi [package insert]. Bothell, WA: Juno Therapeutics Inc.; March 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 8, 2024.
3. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 1.2024). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 8, 2024.
4. 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.

EFFECTIVE DATE 8/30/2024

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