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 covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Breyanzi (lisocabtagene maraleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of 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:

1. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
2. 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
3. Relapsed or refractory disease after two or more lines of systemic therapy including the following:
   a. Anti-CD20 (e.g. rituximab or obinutuzumab); AND
   b. Anthracycline (e.g. doxorubicin); OR
   c. For members with transformed follicular lymphoma arising from DLBCL, prior chemotherapy for follicular lymphoma and subsequently have refractory disease after transformation to diffuse large B-cell lymphoma (DLBCL)

Limitations of Use: *Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma.*

Compendial Uses

1. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-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)

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, medical record documentation or claims history supporting lines of therapy including lab work and diagnostic testing within 7 to 14 days of the approval request to determine the member has adequate organ and bone marrow function and meets the medical necessity criteria.

Criteria for Initial Approval

Adult Large B-cell Lymphomas

Authroization of 3 months may be granted for a one-time treatment of B-cell lymphomas with Breyanzi in members 18 years of age or older at the time of the infusion when ALL of the following criteria are met:

1. The member has received prior treatment with either of the following:
    a. 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 3B, 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. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse 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. 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, follicular lymphoma grade 3B, DLBCL arising from indolent lymphomas)
        ii. High-grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL 2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
        iii. Primary mediastinal large B-cell lymphoma
2. The member does not have primary central nervous system lymphoma.
3. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
4. The member has an ECOG performance status of 0 to 2. (Member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.)
5. The member has adequate and stable kidney, liver, pulmonary and cardiac function as demonstrated by all of the following:
    a. Creatinine clearance >30mL/minute
    b. Ejection fraction ≥40%; no clinically significant cardiac disease

c. Alanine aminotransferase (ALT) under 5 times the upper limit of normal

6. The member does not have clinically significant active infection, including confirmation member does not have active hepatitis B (HBsAG negative) or hepatitis C virus (anti-HCV negative); (a history of hepatitis B or hepatitis C virus is permitted if the viral load is undetectable per quantitative PCR and/or nucleic acid testing).
7. The member has adequate bone marrow reserve/function to receive lymphodepleting chemotherapy as determined by the treating hematologist/oncologist.
8. The member does not have active graft versus host disease.
9. The member does not have an active inflammatory disorder.
10. The member will receive Breyanzi at a treatment center that is certified to administer Breyanzi per Breyanzi REMS requirements.

Continuation of Therapy

Repeat treatment of Breyanzi for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

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

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- Bachier CR, Palomba ML, Abramson JS, et al. Outpatient Treatment with Lisocabtagene Maraleucel (liso-cel) in Three Ongoing Clinical Studies in Relapsed/Refractory (R/R) B Cell Non-Hodgkin Lymphoma (NHL), Including Second-Line Transplant Ineligible Patients: Transcend NHL 001, Outreach, and PILOT. Blood (2019) 134 (Supplement_1): 2868

- Bristol-Myers Squibb Announces Liso-Cel Met Primary and Secondary Endpoints in TRANSCEND NHL 001 Study. Press Release 12/7/2019
- NCT02631044. Clinical.Trials.gov
- The National Comprehensive Cancer Network (NCCN) B-Cell Lymphomas 5.2021. Also available at https://www.nccn.org
- American Cancer Society Key Statistics for Non-Hodgkin Lymphoma. Last revised January 12, 2021
- Patrick DL, Powers A, Jun MP, et al. Effect of lisocabtagene maraleucel on HRQoL and symptom severity in relapsed/refractory large B-cell lymphoma. Blood Adv. Apr 27, 2021; 5(8): 2245-2255. PMID 33904895
- Cancer Facts and Figures 2022 American Cancer Society

POLICY HISTORY

Policy #: 05.04.75
Original Effective Date: January 1, 2023
Reviewed: October 2022
Revised:
Current Effective Date: January 1, 2023