# **SPECIALTY GUIDELINE MANAGEMENT**

# **BREYANZI** (lisocabtagene maraleucel)

#### **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

BREYANZI is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, 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.

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

#### B. 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 specific)
- 2. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

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. CRITERIA FOR INITIAL APPROVAL

## **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 all of the following criteria are met:

- A. The member has any of the following B-cell lymphoma subtypes:
  - 1. Diffuse large b-cell lymphoma (DLBCL) [including DLBCL NOS, Follicular lymphoma grade 3, DLBCL arising from indolent lymphomas (including follicular lymphoma, nodal marginal zone lymphoma, gastric MALT lymphoma, non-gastric MALT lymphoma, splenic marginal zone lymphoma)]
  - 2. 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)
  - 3. Primary mediastinal large B-cell lymphoma

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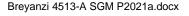


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- 4. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
- 5. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
- B. The member has received prior treatment with two or more lines of systemic therapy.
- C. The member does not have primary central nervous system lymphoma.
- D. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
- E. 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).
- F. The member has adequate and stable kidney, liver, pulmonary and cardiac function.
- G. The member does not have active hepatitis B, active hepatitis C or any active uncontrolled infection.
- H. The member does not have active graft versus host disease.
- I. The member does not have an active inflammatory disorder.

## **IV. REFERENCES**

- 1. Breyanzi [package insert]. Bothell, WA: Juno Therapeutics Inc.; February 2021.
- 2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 05, 2021.
- 3. 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.



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