VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – CAR-T) – Breyanzi Utilization Management Medical Policy
- Breyanzi® (lisocabtagene maraleucel intravenous infusion – Juno Therapeutics)

REVIEW DATE: 01/12/2022

OVERVIEW

Breyanzi, a CD19-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of adults with **relapsed or refractory large B-cell lymphoma** after two or more lines of systemic therapy.[1] This includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Limitations of use: Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma.[1]

Dosing Information

Breyanzi is supplied in separate frozen vials containing the CD8 component and the CD4 component.[1] Each component is supplied in cartons containing one to four vials depending on the concentration of the cryopreserved chimeric antigen receptor (CAR)-positive T-cells. The vials are stored in the vapor phase of liquid nitrogen ≤ -130°C). The dose of Breyanzi is 50 to 110 x 10^6 CAR-positive viable T cells (consisting of a 1:1 mixture of the CD8 and CD4 components), with each component supplied separately in single-dose vials.

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for **B-cell lymphomas** (version 5.2021 – September 22, 2021) recommend Breyanzi for the treatment of a variety of lymphomas after at least two prior chemoimmunotherapy regimens.[2,3] This includes relapsed or refractory DLBCL, high-grade B-cell lymphoma, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, post-transplant lymphoproliferative disorders, transformed nodal marginal zone lymphoma and follicular lymphoma, gastric and non-gastric mucosa-associated lymphoid tissue (MALT) lymphoma, and splenic marginal zone lymphoma.[2,3]

Safety

Breyanzi has a Boxed Warning regarding cytokine release syndrome (CRS) and neurologic toxicities.[1] Breyanzi is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Breyanzi REMS.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Breyanzi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Because of the specialized skills required for evaluation and diagnosis of patients treated with Breyanzi as well as the monitoring required for adverse events and long-term efficacy, approval requires Breyanzi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Breyanzi is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **B-Cell Lymphoma.** Approve a single dose if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** Patient meets one of the following diagnoses (i, ii, iii, iv, v, vi, vii, viii, ix, x, xi, or xii):
     - **i.** Large B-cell lymphoma; OR
     - **ii.** Diffuse large B-cell lymphoma; OR
     - **iii.** High-grade B-cell lymphoma; OR
     - **iv.** Primary mediastinal large B-cell lymphoma; OR
     - **v.** Follicular lymphoma; OR
     - **vi.** Gastric mucosa-associated lymphoid tissue (MALT) lymphoma; OR
     - **vii.** Non-gastric mucosa-associated lymphoid tissue (MALT) lymphoma; OR
     - **viii.** Splenic marginal zone lymphoma; OR
     - **ix.** Transformed nodal marginal zone lymphoma to diffuse large B-cell lymphoma; OR
     - **x.** Transformed follicular lymphoma to diffuse large B-cell lymphoma; OR
     - **xi.** Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma; OR
     - **xii.** Post-transplant lymphoproliferative disorders; AND
   - **B)** Patient is ≥ 18 years of age; AND
   - **C)** Patient has received two or more lines of systemic therapy; AND
   - **D)** Patient has received or plan to receive lymphodepleting chemotherapy prior to infusion of Breyanzi; AND
   - **E)** Patient has not been previously treated with CAR-T therapy; AND
     Note: Examples of CAR-T therapy includes Breyanzi, Kymriah (tisagenlecleucel suspension for intravenous infusion), Tecartus (brexucabtagene suspension for intravenous infusion), and Yescarta (axicabtagene suspension for intravenous infusion).
   - **F)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. The dose is 50 to 110 x 10^6 CAR-positive viable T-cells administered intravenously as a single dose.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Breyanzi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Breyanzi® intravenous infusion [prescribing information]. Bothell, WA: Juno Therapeutics; February 2021.
2. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 5.2021 – September 22, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 29, 2021.
3. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 29, 2021. Search term: lisocabtagene.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/17/2021
Selected Revision	**B-Cell Lymphoma:** The following indications were added to the approval criteria: gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, splenic marginal zone lymphoma, transformed nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma to DLBCL, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, and post-transplant lymphoproliferative disorders.	03/10/2021
Early Annual Revision	**B-Cell Lymphoma:** Added "or plan to receive" to the requirement that the patient has received lymphodepleting chemotherapy prior to infusion of Breyanzi.	01/12/2022