Lisocabtagene maraleucel (Breyanzi®)	Place of Service Outpatient Facility Administration Hospital Administration HCPCS: Q2054 up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Condition listed in policy (*see criteria for details*)

- B-cell lymphoma

AHFS therapeutic class: Antineoplastic Agents

Mechanism of action: CD19-directed genetically modified autologous T cell immunotherapy

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for lisocabtagene maraleucel (Breyanzi®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

B-cell lymphoma

1. Diagnosis of B-cell lymphoma defined as one of the following: diffuse large BCL not otherwise specified, high-grade BCL, primary mediastinal large BCL, follicular lymphoma grade 3B, B-cell monomorphic post-transplant lymphoproliferative disorders (PTLD), AIDS-related B-cell lymphomas [DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL not otherwise specific (NOS)], or histologic transformation to diffuse large B-cell lymphoma from one of the following: follicular lymphoma or marginal zone lymphoma (gastric MALT lymphoma, nodal marginal zone lymphoma, nongastric MALT lymphoma (noncutaneous), or splenic marginal zone lymphoma), **AND**
2. Patient does not have primary central nervous system lymphoma, **AND**
3. Patient is ≥ 18 years old, **AND**
4. Patient has not received prior treatment with CAR-T therapy, including Breyanzi, **AND**
5. Being used as single-agent therapy, **AND**
6. Meets one of the following:
    A. Refractory disease to first-line chemoimmunotherapy, **OR**
    B. Relapse within 12 months of first-line chemoimmunotherapy, **OR**
    C. Relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age, **OR**
    D. Relapsed or refractory disease after receiving at least two prior lines of systemic therapy

Covered Doses
One-time IV infusion. Per prescribing information, a single dose contains 50 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components)

Coverage Period
Single infusion per lifetime

ICD-10:
B20, C82.4, C83.30-C83.39, C83.80-C83.89, C83.90-C83.99, C85.10-C85.19, C85.20-C85.29, C85.80-C85.89, D47.Z1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for lisocabtagene maraleucel (Breyanzi®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
A single dose of Breyanzi contains 50 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose 5 mL vials. Each mL contains 1.5 × 10^6 to 70 × 10^6 CAR-positive viable T cells

- 73153-900-01: outer carton containing each CD8 component and CD4 component
- 73153-901-08: CD8 component (up to 4 vials)
- 73153-902-04: CD4 component (up to 4 vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Breyanzi® (lisocabtagene maraleucel) [Prescribing information]. Bothell, WA: Juno Therapeutics Inc., a Bristol-Myers Squibb Company; 6/2022.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Breyanzi (2022). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network B-Cell Lymphomas (Version 2.2023). Available by subscription at: www.nccn.org.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 1Q2024
Changes from previous policy version:
- No clinical change to policy following revision.