



Breyanzi
Breyanzi (lisocabtagene maraleucel) Q2054
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Large B-Cell Lymphoma (LBCL) – After Two or More Lines of Systemic Therapy

- Patient is 18 years or older AND
- Histologically confirmed diagnosis of one of the following B-cell lymphoma subtypes:
 - Diffuse large B-cell lymphoma (DLBCL), not otherwise specified OR
 - DLBCL arising from indolent lymphoma OR
 - High-grade B-cell lymphoma (including double/triple hit) OR
 - Primary mediastinal large B-cell lymphoma OR
 - Follicular lymphoma grade 3B AND
- Patient has received two or more prior lines of systemic therapy AND
- Patient has relapsed or refractory disease following most recent therapy AND
- ECOG performance status 0-2 AND
- No primary central nervous system lymphoma AND
- No active hepatitis B, hepatitis C, or uncontrolled infection AND
- No active graft versus host disease

- Large B-Cell Lymphoma (LBCL) – Second-Line (Transplant Ineligible or Refractory to First-Line)**
 - Patient is 18 years or older AND
 - Histologically confirmed diagnosis of LBCL as above AND
 - Patient has received first-line chemoimmunotherapy AND
 - Patient meets either:
 - Refractory to first-line therapy (no response or progression within 12 months) OR
 - Not eligible for high-dose therapy and stem cell transplant due to age or comorbidities AND
 - ECOG performance status 0-2
- Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) – Relapsed or Refractory**
 - Patient is 18 years or older AND
 - Confirmed diagnosis of CLL or SLL AND
 - Patient has received prior therapy with both:
 - Bruton tyrosine kinase inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib) AND
 - BCL-2 inhibitor (e.g., venetoclax) AND
 - Patient has relapsed or refractory disease following these therapies
- Follicular Lymphoma (FL) – Relapsed or Refractory**
 - Patient is 18 years or older AND
 - Histologically confirmed diagnosis of follicular lymphoma AND
 - Patient has received two or more prior lines of systemic therapy AND
 - ECOG performance status 0-2
- Mantle Cell Lymphoma (MCL) – Relapsed or Refractory**
 - Patient is 18 years or older AND
 - Confirmed diagnosis of mantle cell lymphoma AND
 - Patient has received prior therapy with covalent Bruton tyrosine kinase inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib) AND
 - Patient has relapsed or refractory disease following BTK inhibitor therapy

If not, please provide **clinical rationale** for formulary exception: _____

- Continuation Requests: (Clinical documentation required for all requests)**
 - Patient had an **adequate response** or **significant improvement** while on this medication.
 - Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Breyanzi Prior Authorization

Drug Name(s):

BREYANZI

LISOCABTAGENE MARALEUCEL

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per NCCN, CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Breyanzi

- B-cell lymphoma, Large, relapsed or refractory, after 2 or more lines of systemic therapyView additional information.
- B-cell lymphoma, Refractory to or relapsed after first-line chemoimmunotherapy, not eligible for hematopoietic stem cell transplantation due to comorbidities or ageView additional information.
- B-cell lymphoma, Refractory to or relapsed within 12 months of first-line chemoimmunotherapyView additional information.
- Chronic lymphoid leukemia, Relapsed or refractory, previously treated with at least 2 prior lines of therapy including a BTK inhibitor and a BCL-2 inhibitorView additional information.
- Follicular lymphoma, Relapsed or refractory after 2 or more lines of systemic therapyView additional information.
- Mantle cell lymphoma, Relapsed or refractory after at least 2 prior lines of systemic therapy, including a BTK inhibitorView additional information.
- Marginal zone lymphoma, Relapsed or refractory after at least 2 prior lines of systemic therapyView additional information.
- Small lymphocytic lymphoma, Relapsed or refractory, previously treated with at least 2 prior lines of therapy including a BTK inhibitor and a BCL-2 inhibitor

Off-Label Uses:

N/A

Age Restrictions:

Safety and efficacy have not been established in pediatric patients.

Other Clinical Consideration:

Intravenous (Suspension)

- Cytokine Release Syndrome (CRS): CRS, including fatal or life-threatening reactions, occurred in patients receiving lisocabtagene maraleucel. Do not administer lisocabtagene maraleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.
- Neurologic Toxicities: Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving lisocabtagene maraleucel, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurological events after treatment with lisocabtagene maraleucel. Provide supportive care and/or corticosteroids as needed.
- Secondary Hematological Malignancies: T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including lisocabtagene maraleucel

Resources:

<https://www.micromedexolutions.com/micromedex2/librarian/PFDefaultActionId/evidenceexpert.DoIntegratedSearch?SearchTerm=breyanzi&SearchFilter=filterNone#>

CLINICAL / CMS ONLY