Mass General Brigham
Health Plan

Breyanzi
(Lisocabtagene maraleucel)

Policy Number: 011

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X	X	X
No Prior Authorization			

Breyanzi is a chimeric antigen receptor T cell therapy (CAR-T), designed to harness the power of the patient's immune system to recognize and attack their cancer cells. CAR-T is a type of treatment where white blood cells (T cells) are modified in a laboratory to add a gene that helps the patient's own T cells target their cancer.

FDA-Approved Indication
Breyanzi is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy for the treatment of:

- Adult patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy including:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from any indolent lymphoma);
  - Primary mediastinal large B-cell lymphoma;
  - High grade B-cell lymphoma; and
  - DLBCL arising from follicular lymphoma grade 3B
- Brenyazi is not indicated for the therapy of primary central nervous system lymphoma.

Criteria

1. Criteria for Initial Approval

Authorization of a single treatment may be granted to patients 18 years of age or older for treatment of **Large B-cell lymphoma** (including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from any indolent lymphoma, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma) when ALL of the following criteria are met:

A. The disease is relapsed or refractory to treatment after two or more lines of systemic therapy.

OR

B. Refractory to first-line chemo or relapse within 12 months of first-line chemo, or refractory to first-line chemo or relapse after first-line chemo and are not eligible for hematopoietic stem cell transplantation (HSCT)

And all of the following:

C. The member has not received any prior FDA approved CD19-directed therapy[1].
D. The patient does not have primary central nervous system lymphoma.
E. The lymphoma must be CD19-positive by IHC or flow cytometry.
F. The healthcare facility that dispenses and administers Breyanzi must be enrolled and comply with the Breyanzi Risk Evaluation and Mitigation Strategy known as REMS.

[1] Exceptions for non-FDA approved CD19 therapies will be reviewed on an individual case by case basis. A detailed medical review will be required.

G. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

2. Required Documentation
   - Testing or analysis confirming CD19 protein on the surface of the B-cell
   - Documentation of two prior lines of therapy
   - Provider/patient REMS certification/enrollment

3. Duration of Therapy
   - Single treatment course
   - Additional courses of therapy are considered experimental/investigational.

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has an NCD for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Effective
February 2023: Annual Review. Added Medicare Advantage to table. Under Criteria section, added refractory to first-line chemo or relapse language. Medicare variation language added. References updated.
February 2022: Annual Update. Criteria section updated to include indication "DLBCL arising from any indolent lymphoma". Under Criteria section, edit to item B. statement now reads "any prior FDA approved CD19-directed therapy", and footer added. References updated.
October 2021: Code update.
July 2021: Effective Date.

References
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