Breyanzi
(Lisocabtagene maraleucel)

	Commercial and Qualified Health Plans	MassHealth
Authorization required	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 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, 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.
B. The patient has not received a previous treatment course of Breyanzi, Kymriah, or Yescarta.
C. The patient does not have primary central nervous system lymphoma.
D. The lymphoma must be CD19-positive by IHC or flow cytometry.
E. The healthcare facility that dispenses and administers Breyanzi must be enrolled and comply with the Breyanzi Risk Evaluation and Mitigation Strategy known as REMS.
F. 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.

CPT/HCPC Codes

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

October 2021: Code update.
July 2021: Effective Date.

References

Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. Lancet. 2020 Sep 19;396(10254):839-852. doi: 10.1016/S0140-6736(20)31366-0. Epub 2020 Sep 1. PMID: 32888407.

Breyanzi Prescribing Information. Bristol Myers Squibb; February 2021.