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 CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- adult patients with large B-cell lymphoma (LBCL), including 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, who have:
    - refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
    - refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
    - relapsed or refractory disease after 2 or more lines of systemic therapy.
    - Limitations of Use: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.
- adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

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 one of the conditions listed above when ALL of the following criteria are met:

A. The member has not received any prior FDA approved CD19-directed therapy[1].
B. The member does not have primary central nervous system lymphoma.
C. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
D. The healthcare facility that dispenses and administers Breyanzi must be enrolled and comply with the Breyanzi Risk Evaluation and Mitigation Strategy known as REMS.
E. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.
F. The member has one of the following:
    - Large B-cell lymphoma (including diffuse large B-cell lymphoma (DLBCL) not other specified, DLBCL arising from indolent lymphoma, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, DLBCL arising from follicular lymphoma, and follicular lymphoma) when one of the following is met:
        - The disease is relapsed or refractory to treatment after two or more lines of systemic therapy, or
        - 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 not eligible for hematopoietic stem cell transplantation (HSCT); or
    - Mantle cell lymphoma
        - The disease is relapsed or refractory to treatment after two or more lines of systemic therapy including a Burton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor
    - Chronic lymphocytic leukemia/small lymphocytic lymphoma
        - The disease is relapsed or refractory to treatment after two ore more lines of systemic therapy including a BTK inhibitor and a BCL-2 inhibitor.

2. Required Documentation
    - Documentation of prior lines of therapy
    - Provider/patient REMS certification/enrollment

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

MassHealth Variation
Mass General Brigham Health Plan uses the MassHealth Drug List for coverage determinations for members of the MGB ACO. Criteria for Breyanzi are found in Table 75: T-Cell Immunotherapies.

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

[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.

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
38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous
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

April 2025: Annual review. Codes updated. Added criteria for chronic lymphocytic leukemia/small lymphocytic lymphoma, follicular lymphoma, and mantle cell lymphoma. Added ECOG requirement. References updated.
September 2024: Ad hoc update. Added MassHealth Variation.
February 2024: Annual review. Removed requirement for CD19 testing.
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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