

Tecartus (brexucabtagene autoleucel)

Policy Number: 054

| | Commercial and Qualified Health Plans | MassHealth | Medicare Advantage |
|------------------------|---------------------------------------|------------|--------------------|
| Authorization Required | X | X | X |
| No Prior Authorization | | | |

Tecartus is a chimeric antigen receptor T cell therapy (CAR-T), designed to redirect 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

Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of members (“patients”) 18 years of age or older with relapsed or refractory mantle cell lymphoma (MCL) and relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Criteria for Initial Approval

1. Patient Criteria for initial accelerated approval

Authorization of a single treatment may be granted to members 18 years of age or older for treatment of mantle cell lymphoma (MCL) when **ALL** of the following criteria are met:

- A. The disease is in second or later relapse after a Bruton’s tyrosine kinase inhibitor (BTKI) and chemoimmunotherapy.
- B. The B-cells must be CD19-positive in the latest relapse as confirmed by immunohistochemistry or flow cytometry.
- C. The member has not received any prior FDA approved CD19-directed therapy (e.g. Tecartus, Kymriah or Yescarta)¹
- D. The member has previously received a BTKI and has had an inadequate response, adverse reaction, or contraindication to any of the following BTKIs:
 - i. Ibrutinib
 - ii. Acalabrutinib
 - iii. Zanubrutinib.
- E. The member has previously received Anti-CD20 monoclonal antibody therapy (e.g. rituximab, obinutuzumab) as well as either anthracycline- or benamustine-containing chemotherapy.
- F. The member has adequate organ and bone marrow function as determined by the treating oncologist or hematologist.

2. Patient Criteria for B-cell precursor acute lymphoblastic leukemia (ALL).

Authorization of a single treatment may be granted to members 18 years of age or older for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) when **ALL** of the following criteria are met:

- A. ONE of the following:
 - i. The member has primary refractory ALL; OR

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.

- ii. The member has experienced a first relapse following a remission lasting less than or equal to 12 months; OR
 - iii. The member has relapsed or refractory ALL after second line or higher therapy; OR
 - iv. The member has relapsed or refractory ALL at least 100 days after allogenic stem cell transplant.
- B. The B-cell precursor acute lymphoblastic leukemia is Philadelphia chromosome positive, and the member has had an inadequate response, adverse reaction, or contraindication to ONE tyrosine kinase inhibitor (TKI).
 - C. The B-cells must be CD19-positive in the latest relapse as confirmed by immunohistochemistry or flow cytometry.
3. Facility Criteria
- A. The healthcare facility that dispenses and administers Tecartus must be enrolled and comply with the Risk Revaluation and Mitigation Strategy known as Tecartus REMS.
 - B. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome
 - C. Tecartus is prescribed by a hematologist or oncologist with demonstrated expertise in CAR-T Therapy
4. Required Documentation
- Testing or analysis confirming CD19 protein on the surface of the B-cell.
 - Documentation of refractory disease or prior lines of therapy for MCL.
5. Duration of Therapy
- Single intravenous 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 |
|----------------------------|--|
| Q2053 | Brexucabtagene autoleucel, up to 200 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 for Initial Approval, the following changes were made to align with revised MassHealth guidelines: added “inadequate response,



adverse reaction, or contraindication”, added refractory or relapsed language, added inadequate response to tyrosine kinase inhibitor criteria. Medicare variation language added. References updated.

February 2022: Annual Review. Under section FDA-Approved Indication, added “relapsed or refractory B cell ALL”. Under section Criteria for Initial Approval, added #2 “Patient Criteria for B-ALL”. In addition, formatting changes made for clarity purposes. References updated.

March 2021: Effective Date.

References

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD): Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Implementation Date: 09/20/2021. Updated November 2020. Available: <https://www.cms.gov/medicare-coverage-database/search.aspx>

Tecartus [package insert]. Los Angeles, CA: Kite Pharma; July 2020.

MassHealth Drug List. Medication Class/Individual Agents. Table 75: Chimeric Antigen Receptor (CAR)-T Immunotherapies. Prior-Authorization Requirements. Tecartus ([brexucabtagene autoleucel](#)). Executive Office of Health and Human Services (EOHHS). 2020 December. Accessed at: <https://masshealthdruglist.ehs.state.ma.us/MHDL/pubtheradetail.do?id=1347&drugId=7495>

National Comprehensive Cancer Network (NCCN). B-cell lymphomas. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Plymouth Meeting, PA: NCCN, January 25, 2023. Accessed January 17, 2023.

Reagan PM, Friedberg JW. Axicabtagene ciloleucel and brexucabtagene autoleucel in relapsed and refractory diffuse large B-cell and mantle cell lymphomas. *Future Oncol*. 2021;17(11):1269-1283

Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021 Aug 7;398(10299):491-502. doi: 10.1016/S0140-6736(21)01222-8. Epub 2021 Jun 4. PMID: 34097852.

Simons CL, Malone D, Wang M, et al. Cost-effectiveness for KTE-X19 CAR T therapy for adult patients with relapsed/refractory mantle cell lymphoma in the United States. *J Med Econ*. 2021 Jan-Dec;24(1):421-431. doi: 10.1080/13696998.2021.1894158. PMID: 33634729.

Wang M, Munoz J, Goy A, et al. KTE-X19 CAR T-Cell therapy in relapsed or refractory mantle-cell lymphoma. *N Engl J Med*. 2020;382:1331-42.

Wang M, Munoz J, Goy A, et al. Supplementary Appendix to KTE-X19 CAR T-cell therapy in relapsed or refractory mantle-cell lymphoma. *N Engl J Med* 2020;382:1331-42.

