Tecartus
(brexucabtagene autoleucel)

	Commercial and Qualified Health Plans	MassHealth
Authorization required	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).

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 refractory to treatment or in second or later relapse.
   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 Bruton's tyrosine kinase inhibitor (BTKI) such as:
      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. 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.

[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.

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

3. 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.

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

CPT/HCPC Codes

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

March 2021: Effective Date.

References

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. Clinical Practice Guidelines in Oncology (NCCN Guidelines®), Version 4.2020. Fort Washington, PA: NCCN; 2020.

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

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