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.

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\(^1\) 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.

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<tr>
<th>CPT/HCPC Codes</th>
<th>Code Description</th>
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<tr>
<td>Q2053</td>
<td>Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose</td>
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Effective
March 2021: Effective Date.

References


