Tecartus
(brexucabtagene autoleucel)

Policy Number: 054

<table>
<thead>
<tr>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorization required</td>
<td>X</td>
</tr>
<tr>
<td>No Prior Authorization</td>
<td>X</td>
</tr>
</tbody>
</table>

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 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)
   D. The member has previously received a BTKI:
      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-ALL

---

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.

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org
Authorization of a single treatment may be granted to members 18 years of age or older for treatment of B cell Acute Lymphoblastic Leukemia (B-ALL) when ALL of the following criteria are met:

A. The disease is refractory or relapsed after treatment.
B. If the B-ALL is Philadelphia chromosome positive prior therapy must have included a 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.

### CPT/HCPC Codes

<table>
<thead>
<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

**Effective**
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**


