Yescarta
(axicabtagene ciloleucel)

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

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

- Adult members (“patients”) with relapsed or refractory large B-cell lymphoma including:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;
  - Primary mediastinal large B-cell lymphoma;
  - High grade B-cell lymphoma; and
  - DLBCL arising from follicular lymphoma

- Yescarta is not indicated for the therapy of primary central nervous system lymphoma.

**Criteria for Initial Approval**

1. **Patient Criteria**

   Authorization of a single treatment may be granted to members 18 years of age or older for treatment of **Large B-cell lymphoma** (including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma) when ALL of the following criteria are met:

   A. The disease is refractory to treatment or relapsed after two or more lines of systemic therapy.
   B. The member has not received any prior FDA approved CD19-directed therapy (e.g. Tecartus, Yescarta, or Kymriah)\(^1\).
   C. The member does not have primary central nervous system lymphoma.
   D. The lymphoma must be CD19-positive by Immunohistochemistry or flow cytometry at the time of the most recent relapse.

2. **Facility Criteria**

   A. The healthcare facility that dispenses and administers Yescarta must be enrolled and comply with the Yescarta Risk Evaluation and Mitigation Strategy known as REMS.
   B. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

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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.
C. Yescarta 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 lymphoma
   - Documentation of two prior lines of therapy

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

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<td>Q2041</td>
<td>Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose</td>
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Effective

February 2020: Annual Review. Policy Criteria clarified; removed “within three months”. References updated.
February 2018: Effective Date.

References


