Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of: 1) Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy; and 2) Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, 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; and 3) Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (accelerated approval).

Yescarta (axicabtagene ciloleucel) will be considered for coverage when the following criteria are met:

### Large B-Cell Lymphoma

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of large B-cell lymphoma; AND
3. Member’s disease is refractory or relapsed, defined as one of the following:
   a) No response, partial response, disease progression, or relapse after **two or more** lines of systemic therapy, including both:
      i) an anti-CD20 monoclonal antibody (e.g., rituximab) unless tumor is CD20-negative and
      ii) a chemotherapy regimen that contains an anthracycline
   b) Relapsed after autologous hematopoietic stem cell transplantation (HSCT)
   c) Primary refractory disease (incomplete response to first line chemoimmunotherapy, including at least an anti-CD20 monoclonal antibody unless tumor is CD20-negative and a chemotherapy regimen that contains an anthracycline)
   d) Relapsed within 12 months (complete remission following first line chemoimmunotherapy that includes at least an anti-CD20 monoclonal antibody unless tumor is CD20-negative and a chemotherapy regimen that contains an anthracycline, followed by relapse); AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Prior allogeneic HSCT
   b) History or presence of primary central nervous system (CNS) lymphoma
   c) Prior CAR-T therapy; AND
6. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
8. Member’s weight is documented for dose calculation.
9. **Dosage allowed/Quantity limit:** 2 × 10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2 × 10^8 CAR-positive viable T cells.

*If all the above requirements are met, the medication will be approved for 3 months.*

For **reauthorization**:
1. Yescarta will not be reauthorized for continued therapy.

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**Follicular Lymphoma**

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has a diagnosis of relapsed or refractory follicular lymphoma; AND
3. Member has measurable disease after 2 or more lines of systemic therapy, including the combination of an anti-CD20 monoclonal antibody and an alkylating agent; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Prior allogeneic HSCT
   b) History or presence of primary central nervous system (CNS) lymphoma
   c) Prior CAR-T therapy; AND
6. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
8. Member’s weight is documented for dose calculation.
9. **Dosage allowed/Quantity limit:** 2 × 10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2 × 10^8 CAR-positive viable T cells.

*If all the above requirements are met, the medication will be approved for 3 months.*

For **reauthorization**:
1. Yescarta will not be reauthorized for continued therapy.

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CareSource considers Yescarta (axicabtagene ciloleucel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/24/2017</td>
<td>New policy for Yescarta created.</td>
</tr>
<tr>
<td>08/27/2018</td>
<td>Criteria expanded for member’s disease history requirement.</td>
</tr>
<tr>
<td>08/04/2020</td>
<td>Defined age 18 or older for adults. Specified trial requirement for 2 or more lines of chemo or relapsed after autologous stem cell transplant. Removed pre-treatment regimens because they are already addressed in REMS. Required screening results for active infections. Removed hypersensitivity to aminoglycoside requirement, CNS disorders, and other forms of malignancy from exclusion list. Added prior CAR-T treatment, life expectancy to exclusion list. Updated the name of REMS program.</td>
</tr>
<tr>
<td>05/19/2021</td>
<td>Added criteria for new indication of follicular lymphoma. Large B-Cell Lymphoma: Removed life expectancy restriction. Added ECOG score. Added “partial response” to 3a per NCCN slide BCEL-7.</td>
</tr>
</tbody>
</table>
Modified large B cell criteria to accommodate label expansion to include 2nd line use. Removed list of large B cell lymphoma subtypes.

References:


Effective date: 10/01/2022
Revised date: 05/05/2022