Kymriah is a chimeric antigen receptor cancer therapy (CAR T), designed to harness the power of 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
Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- 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, high grade B cell lymphoma and DLBCL arising from follicular lymphoma.
- Kymriah is not indicated for the treatment of patients with central nervous system lymphoma.

### Criteria
1. Criteria for Initial Approval

#### Acute lymphoblastic leukemia
Authorization of a single treatment may be granted to patients less than 25 years of age for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) 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 as confirmed by testing or analysis.
C. The patient has not received prior treatment with Kymriah or Yescarta.
D. The healthcare facility that dispenses and administers Kymriah must be enrolled and comply with the Risk Revaluation and Mitigation Strategy known as Kymriah REMS.
E. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.
DLBCL
Authorization of a single treatment may be granted to patients 18 years of age or older for treatment of Large B-cell lymphoma (including DLBCL not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma) when all of the following criteria are met:

A. The disease is relapsed or refractory to treatment after two or more lines of systemic therapy.
B. The patient has not received a previous treatment course of Kymriah or Yescarta.
C. The patient does not have primary central nervous system lymphoma.
D. The lymphoma must be CD19-positive by IHC or flow cytometry.
E. The healthcare facility that dispenses and administers Kymriah must be enrolled and comply with the Kymriah Risk Evaluation and Mitigation Strategy known as REMS.
F. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

2. 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 ALL.
   • Documentation of 2 prior lines of therapy for DLBCL.

3. 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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<tbody>
<tr>
<td>Q2042</td>
<td>Tisagenlecleucel, up to 600 million car-positive viable 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 3 months”. References updated.
February 2018: Effective Date.

References


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