

tisagenlecleucel (Kymriah)

HCPCS: Q2042 Tisagenlecleucel, up to 600 million CAR-positive viable T cells

LOB:	MCAL
Duration of Approval:	One single dose per lifetime
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)Kymriah (tisagenlecleucel) 2.5 x 10⁸ CAR-positive injection****All requests must be approved by a Medical Director******PA CRITERIA FOR APPROVAL:**

- The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a National Comprehensive Cancer Network (NCCN)-supported indication **AND**
- The medication is prescribed by an oncologist or hematologist **AND**
- The member does **NOT** have any of the following **(a–b)**:
 - An active infection (including tuberculous, HIV, hepatitis B virus [HBV] and hepatitis C virus [HCV]) or inflammatory disorders
 - Primary central nervous system lymphoma**AND**
- For acute lymphoblastic leukemia (ALL),** the member meets **ONE** of the following **(a or b)**:
 - The member is 18 to 25 years old and meets **ONE** of the following **(1, 2 or 3)**:
 - Member has relapsed disease following hematopoietic stem cell transplant (HSCT)
 - Philadelphia chromosome negative (Ph-) and has refractory disease or two or more relapses
 - Philadelphia chromosome positive (Ph+) and has refractory disease or two or more relapses following therapy that included two tyrosine kinase inhibitors (TKIs) (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) **OR** has documented intolerance to TKI therapy (**Note:** Bosutinib and nilotinib have NCCN-supported off-label use for acute lymphoblastic leukemia [ALL])
 - The member is more than 18 years old and meets **ONE** of the following:
 - Refractory disease or two or more relapses
 - Minimal residual disease (MRD) positive after consolidation therapy
 - BCR-ABL1 positive or Ph+ **AND** one of the following **(a, b or c)**:
 - Less than complete response after induction therapy
 - Relapsed disease and has documented intolerance to TKI therapy (e.g., imatinib, dasatinib ponatinib)
 - Relapsed disease following HSCT**AND**
- The member has not been previously treated with Kymriah or any other chimeric antigen receptor T-cell (CAR-T) therapy (such as Abecma, Aucatyzi, Breyanzi, Carvykti, Tecartus or Yescarta) **AND**
- The medication will be provided by an authorized treatment center (such as City of Hope, Cedar Sinai, UCLA, UCSD) (**NOTE:** Other authorized treatment centers can be found here: www.us.kymriah.com/treatment-center-locator/)

OTHER INFORMATION:

HCPCS	Description	Brand name
Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Kymriah

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****Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for [Kymriah](#) for billing information and follow allowable number of units to approve. ****

REFERENCES:

1. Kymriah Prescribing Information. www.novartis.com/us-en/sites/novartis_us/files/kymriah.pdf. 12/2025.
2. National Comprehensive Cancer Network (NCCN) Acute Lymphoblastic Leukemia. www.nccn.org/professionals/physician_gls/pdf/all.pdf. Version 1.2026. 04/2026.
3. National Comprehensive Cancer Network (NCCN) Pediatric Acute Lymphoblastic Leukemia. Version 1.2026. 08/2025. www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf
4. National Comprehensive Cancer Network (NCCN) B-Cell Lymphomas. Version 4.2026. 05/2026. www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.
5. Novartis Pharmaceuticals. A Phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in pediatric patients with relapsed and refractory B-cell acute lymphoblastic leukemia. Study Protocol. cdn.clinicaltrials.gov/large-docs/49/NCT02435849/Prot_002.pdf. NLM Identifier: NCT02435849.
6. DHCS Cell and Gene Therapy Overview. mcweb.apps.prddcmis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYyIPyP5ULO. 09/2025.