



Kymriah
Kymriah (tisagenlecleucel) Q2042
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Relapsed or Refractory B-Cell Acute Lymphoblastic Leukemia (ALL) – Pediatric and Young Adult

- Patient is up to 25 years of age AND
- Confirmed diagnosis of B-cell precursor ALL AND
- Patient is refractory to first-line therapy OR
- Patient has relapsed after first-line therapy OR
- Patient has relapsed after allogeneic stem cell transplant (at least 6 months post-transplant) AND
- ECOG performance status 0-2 or Lansky performance status ≥50 AND
- No active CNS involvement (CNS-1 or CNS-2 permitted) AND

Relapsed or Refractory Large B-Cell Lymphoma (LBCL)

- Patient is 18 years or older AND
- Histologically confirmed diagnosis of DLBCL, high-grade B-cell lymphoma, DLBCL arising from follicular lymphoma, or primary mediastinal large B-cell lymphoma AND
- Patient has received two or more prior lines of systemic therapy AND
- Patient has relapsed or refractory disease following most recent therapy AND

- ECOG performance status 0-2 AND
- No primary CNS lymphoma AND

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

- Patient had an **adequate response** or **significant improvement** while on this medication.
- Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Kymriah Prior Authorization

Drug Name(s):

KYMRIAH

TISAGENLECLEUCEL

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Kymriah

- Diffuse large B-cell lymphoma, Relapsed or refractory, following 2 or more lines of systemic therapy
- Follicular lymphoma, Relapsed or refractory, following 2 or more lines of systemic therapy
- Precursor B-cell acute lymphoblastic leukemia, Refractory or in second or later relapse

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Consideration:

- **Cytokine Release Syndrome (CRS):** CRS, including fatal or life-threatening reactions, occurred in patients receiving tisagenlecleucel. Do not administer tisagenlecleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- **Neurological Toxicities:** Neurological toxicities, which may be severe or life-threatening, can occur following treatment with tisagenlecleucel, including concurrently with CRS. Monitor for neurological events after treatment with tisagenlecleucel. Provide supportive care as needed.
- **Secondary Hematological Malignancies:** T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including tisagenlecleucel

Resources:

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=kymriah&SearchFilter=filterNone#>