

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: **Commercial (Traditional)** **Commercial (Individual/Optimized)**

Medicaid

This request is: **Urgent** (life threatening) **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Kymriah[®] (tisagenlecleucel)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Physician: _____ Phys. Phone: _____ Phys. Fax: _____

Physician Address: _____

Physician NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

New request Continuation request

Drug product: Kymriah intravenous suspension **Start date** (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Place of administration: Physician's office

Outpatient infusion

Facility: _____ NPI: _____ Fax: _____

Home infusion

Facility: _____ NPI: _____ Fax: _____

Billing: Physician to buy and bill

Facility to buy and bill

Specialty Pharmacy

Pharmacy: _____ NPI: _____ Fax: _____

ICD-10 Diagnosis code(s): _____

Drug cost information

The wholesale acquisition cost for one dose of Kymriah[®] is \$475,000.

Precertification Requirements

Before this drug is covered, documentation must be submitted to support that the patient meets all of the following requirements:

1. Diagnosis of refractory or relapsed B-cell precursor acute lymphoblastic leukemia (ALL)
 - a. **Refractory:** Patient did not achieve a complete response after at least 2 cycles of standard chemotherapy
 - b. **Relapsed:** Patient achieved complete response and experienced relapses at least 2 times following standard chemotherapy (minimum of 2 cycles)
 - i. If Philadelphia chromosome *positive* (Ph+), patient must also have tried and failed, be intolerant to, or have a contraindication to at least 2 tyrosine kinase inhibitors (TKI)
 - ii. If Philadelphia chromosome *negative* (Ph-), patient must have tried and failed on Blincyto or Besponsa (dependent on patient age)
 - c. Age 25 or younger
 - d. Patient has or will receive lymphodepleting chemotherapy (fludarabine and cyclophosphamide intravenously) within 2 weeks of Kymriah administration date

OR

2. Diagnosis of large B-cell lymphoma (including diffuse large B-cell lymphoma (DLBCL), NOS and high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma)
 - a. Relapsed or refractory disease after ≥2 lines of chemotherapy including rituximab and anthracycline and having failed or ineligible for autologous hematopoietic stem cell transplantation (HSCT)
 - b. Age 18 years or older
 - c. Patient has or will receive lymphodepleting chemotherapy (fludarabine and cyclophosphamide intravenously) within 2 weeks of Kymriah administration date

Kymriah is not covered for patients who have had treatment with any prior gene therapy product.

NOTE: Coverage of Kymriah is limited to the dosing listed in the FDA-approved label. Patients greater than 50 kg will be allowed no more than 2.5×10^8 CAR-positive viable T cells. Patients weighting 50 kg or less will be authorized for weight-based dosing of $0.2 - 5 \times 10^6$ CAR-positive viable T cells.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- Refractory* B-cell precursor acute lymphoblastic ALL (please submit documentation of previous chemotherapies)
- Relapsed* B-cell precursor acute lymphoblastic ALL
- Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)* (please submit documentation of previous chemotherapies)
- Other – the patient’s condition is:* _____
Rationale for use: _____

B. If relapsed B-cell precursor ALL, is the patient Philadelphia chromosome positive?

Yes

1. Has the patient tried and failed, is intolerant to, or has a contraindication to at least 2 tyrosine kinase inhibitors (TKI)?

a) No; rationale for use: _____

b) Yes (please list previous drug therapies)

Drug	Dose	Dates	Outcome
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

No

1. Has the patient tried and failed, is intolerant to, or has a contraindication to Blincyto or Besponsa?

a) No; rationale for use: _____

b) Yes:

Drug	Dose	Dates	Outcome
_____	_____	_____	_____
_____	_____	_____	_____

C. For diffuse large B-cell lymphoma (DLBCL):

a. What is the patient's ECOG score? _____

b. Has the patient had a prior ales allogeneic HSCT?

- Yes
 No

D. Will the patient receive lymphodepleting chemotherapy with IV fludarabine and cyclophosphamide?

Yes (please submit documentation if already completed or treatment plan(s) if not)

No; Rationale for use: _____

Additional information

Note: Prior to approving coverage of Kymriah[®], a member's plan documents must include coverage for gene therapies with the applicable rider.