Premier Health Plan

# POLICY AND PROCEDURE



**POLICY TITLE:** ***Kymriah (tisagenlecleucel)***
**DEPARTMENT:** **Clinical Pharmacy Services- Utilization Management**
**ORIGINAL DATE:** ***May 2018***

**Last P & T Committee Approval Date:** May 2018

**Product Applicability:** *mark all applicable products below:*

| | |
|---|---|
| **COMMERCIAL** | [ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x ] All |
| **OTHER** | [ x ] Self-funded/ASO |

## PURPOSE

The purpose of this policy is to define the prior authorization process for Kymriah™ (tisagenlecleucel).

Kymriah™ (tisagenlecleucel) is 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.

## DEFINITIONS

N/A

## POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Kymriah™ (tisagenlecleucel), is subject to the prior authorization process.

## PROCEDURE

### Initial Authorization Criteria:

*Must meet all of the criteria listed below:*

- Must have a diagnosis of one of the following:
  - B-cell precursor acute lymphoblastic leukemia (CD19 positive) that is refractory or in second or later relapse
    - Must be age 25 years or younger
- 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.
  - Must have had at least two lines of systemic therapy
  - Must be at least 18 years old
- Must be prescribed by a hematologist or oncologist that practices within a Kymriah Treatment Center under a Risk Evaluation and Mitigation Strategy
- Must be for autologous use only
- Must not have evidence of an active infection
- Must not have evidence of an active inflammatory disorder
- Must provide confirmation that tocilizumab (Actemra) and emergency equipment are available prior to infusion and during the recovery period

### Reauthorization Criteria:

Reauthorization is not allowed for this one-time infusion treatment.

### Limitations:

| Length of Authorization (if above criteria met) | |
|---|---|
| Initial Authorization | Up to 1 month (1 infusion) |
| Reauthorization | N/A |

If the established criteria are not met, the request is referred to a Medical Director for review.

## REFERENCES

1. Kymriah [prescribing information]. East Hanover, New Jersey CSL Novartis Pharmaceuticals Corporation. May 2018.

## RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

## REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| *New Policy* | *05/18* |
| | |