

# Kymriah™ (tisagenlecleucel)



## Pharmacy Coverage Policy

Effective Date: January 01, 2023

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Review Date: October 19, 2022

Line of Business: Medicaid - Louisiana

Policy Type: Prior Authorization

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**Disclaimer  
Description  
Coverage Determination**

**Background  
Medical Terms  
References**

### Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at <http://www.cms.hhs.gov/>. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

### Description

Kymriah (tisagenlecleucel) is a CD19-directed genetically modified autologous T cell immunotherapy, which involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells.

Kymriah (tisagenlecleucel) is indicated for the treatment of (1) patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse and (2) adult patients with relapsed or refractory (r/r) large Bcell 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 (3) Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Tisagenlecleucel is available as Kymriah as a frozen suspension of genetically modified autologous T cells in one infusion bag labeled for the specific recipient.

**Coverage**  
**Determination**

**Please note the following regarding medically accepted indications:**

**All reasonable efforts have been made to ensure consideration of medically accepted**

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**indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:**

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- **National Comprehensive Cancer Network (NCCN) Drugs and Biologics**
- **Compendium**
- **Truven Health Analytics Micromedex DrugDEX**
- **Elsevier/Gold Standard Clinical Pharmacology**
- **Wolters Kluwer Lexi-Drugs**

**Kymriah (tisagenlecleucel) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:**

**Diffuse Large B-Cell Lymphoma (DLBCL)**

- **The member has a diagnosis of large B-cell lymphoma (i.e. diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma) AND**
- **The member has received two or more prior lines of systemic therapy AND**
- **The member has relapsed or refractory disease AND :**
- **The member is greater than or equal to 18 years of age AND**
- **The member will be using Kymriah in conjunction with appropriate lymphodepleting chemotherapy regimen, unless contraindicated AND**

See the **DISCLAIMER**. All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject

may not be included. This document is for informational purposes only.

**The member will be using Kymriah (tisagenlecleucel) at a treatment center that is certified to administer Kymriah (tisagenlecleucel)**

**Acute Lymphoblastic Leukemia**

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- **The member has a diagnosis of B- cell precursor acute lymphoblastic leukemia (ALL)**
- **AND**
- **The member has refractory disease or is in second or subsequent relapse AND**
- **The member has documented CD19 expression in bone marrow or peripheral blood**
- **AND**

**The member is up to 25 years of age AND**

**The member will be using Kymriah in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m<sup>2</sup> daily for 4 days and cyclophosphamide 500 mg/m<sup>2</sup> daily for 2 days) AND**

- **The member will be using Kymriah (tisagenlecleucel) at a treatment center that is certified to administer Kymriah (tisagenlecleucel)**

**Follicular Lymphoma**

- **The member has a diagnosis of follicular lymphoma AND**
- **The member has had two or more lines of previous systemic therapy AND**
- **The member has relapsed or refractory disease AND**
- **The member is greater than or equal to 18 years of age AND**
- **The member will be using Kymriah in conjunction with appropriate lymphodepleting chemotherapy regimen, unless contraindicated AND**
- **The member will be using Kymriah (tisagenlecleucel) at a treatment center that is certified to administer Kymriah (tisagenlecleucel)**

**Kymriah (tisagenlecleucel) will be approved for 60 days duration or as determined through clinical review. A maximum of one dose per lifetime will apply.**

**Coverage**  
**Limitations**

**Kymriah (tisagenlecleucel) therapy is not considered medically necessary for members with the following concomitant conditions:**

- **Any prior gene therapy product**
- **Any prior anti-CD19/anti-CD3 therapy (e.g. blinatumomab), or any other anti-CD19 therapy (e.g. axicabtagene ciloleucel)**

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- **Member has active hepatitis B (HBs AG-positive) or hepatitis C infection**
- **Member has HIV/AIDs**
- **For pediatric ALL diagnosis: Active Grade 2-4 GVHD from a prior allogeneic transplant**
- **For B-cell lymphoma diagnoses: The member has a diagnosis of primary central nervous system lymphoma**
- **For B-cell lymphoma diagnoses: Prior allogeneic transplant**
- **Experimental/Investigational Use – Indications not supported by CMS**

**recognized compendia or acceptable peer reviewed literature. Background This is a prior authorization policy about Kymriah (tisagenlecleucel).**

**Refer all requests or questions regarding Kymriah (tisagenlecleucel) to the Corporate Transplant Department at 1-866-421-5663.**



**Fax: 502-508-9300**



**Email: [transplant@humana.com](mailto:transplant@humana.com)**

**Kymriah (tisagenlecleucel) is only available at certain centers. For more information, please visit:**

**<https://www.us.kymriah.com/treatment-center-locator/>**

**:**

### **Black Box Warnings**

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Kymriah. Do not administer Kymriah to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab.**
- **Neurological toxicities, which may be severe or life-threatening, can occur following treatment with Kymriah, including concurrently with CRS. Monitor for neurological**

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**events after treatment with Kymriah. Provide supportive care as needed.**

- **Kymriah is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS**

### **Warnings and Precautions**

- **Serious infections**
- **Prolonged cytopenias**
- **Hypogammaglobulinemia**
- **Secondary malignancies**

**The American Society of Clinical Oncology HBV screening and management provisional clinical opinion (ASCO [Hwang 2020]) recommends HBV screening with hepatitis B surface antigen, hepatitis B core antibody, total Ig or IgG, and antibody to hepatitis B surface antigen prior to beginning (or at the beginning of) systemic anticancer therapy; do not delay treatment for screening/results. Detection of chronic or past HBV infection requires a risk assessment to determine antiviral prophylaxis requirements, monitoring, and follow-up.**

Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. *J Clin Oncol*. 2020;38(31):3698-3715. doi:10.1200/JCO.20.01757[[PubMed 32716741](#)]

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<b><u>Provider</u></b>	<b><u>For medically billed requests, please visit <a href="http://www.humana.com/PAL">www.humana.com/PAL</a>. Select applicable</u></b>
<b><u>Claims Codes</u></b>	<b><u>Preauthorization and Notification List(s) for medical and procedural coding</u></b>
	<b><u>information.</u></b>
<b><u>Medical Terms</u></b>	<b><u>Kymriah; tisagenlecleucel; acute lymphoid leukemia; Follicular Lymphoma; FL; ALL;</u></b>
	<b><u>CART; pharmacy</u></b>
<b><u>References</u></b>	<b><u>Kymriah (tisagenlecleucel) [prescribing information]. Novartis Pharmaceuticals. East</u></b>
	<b><u>Hanover NJ. May 2022.</u></b>

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**Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL: <http://www.clinicalpharmacology.com>. Updated periodically.**

**Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.**

**Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.**

**NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.**