| POLICY NUMBER<br>UM ONC_1324 | SUBJECT<br>Kymriah™ (tisagenlecleucel) | | DEPT/PROGRAM<br>UM Dept | PAGE 1 of 2 |
|---|---|---|---|---|
| DATES COMMITTEE REVIEWED<br>09/13/17, 09/21/18, 08/14/19, 12/11/19, 06/10/20 | APPROVAL DATE<br>June 10, 2020 | EFFECTIVE DATE<br>June 26, 2020 | COMMITTEE APPROVAL DATES (latest version listed last)<br>09/13/17, 09/21/18, 08/14/19, 12/11/19, 06/10/20 | |
| PRIMARY BUSINESS OWNER: UM<br>APPROVED BY: Dr. Andrew Hertler | | COMMITTEE/BOARD APPROVAL<br>Utilization Management Committee | | |
| URAC STANDARDS<br>HUM 1 | | NCQA STANDARDS<br>UM 2 | ADDITIONAL AREAS OF IMPACT | |
| CMS REQUIREMENTS | STATE/FEDERAL REQUIREMENTS | | APPLICABLE LINES OF BUSINESS<br>All | |

## I. PURPOSE

To define and describe the accepted indications for Kymriah (tisagenlecleucel) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**

    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**

    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

    e. When available, generic alternatives are preferred over brand-name drugs.

2. **Acute Lymphoblastic Leukemia (ALL)**

    a. Kymriah (tisagenlecleucel) is being used when the following criteria are met:

        i. Member has Acute Lymphoblastic Leukemia with confirmed documentation of CD19 tumor expression (demonstrated in bone marrow or peripheral blood by flow cytometry) **AND**

        ii. Member has experienced disease relapse after allogeneic stem cell transplantation (SCT) and member is ≥ 6 months from above transplantation at the time of infusion **OR**

iii. Member has relapsed/refractory Philadelphia chromosome-negative B-ALL that has progressed after 2 cycles of a standard chemotherapy regimen for initial diagnosis OR after 1 cycle of standard chemotherapy for relapsed leukemia **OR**

iv. Member has relapsed/refractory Philadelphia chromosome-positive B-ALL that has progressed after failure of 2 TKI- containing regimens.

3. **B-Cell Lymphomas**

   a. The member has grade 1-2 relapsed or refractory follicular lymphoma or relapsed/refractory DLBCL- Diffuse Large B-Cell Lymphoma AND member has experienced disease progression after two or more lines of systemic therapy (if tisagenlecleucel or axicabtagene ciloleucel not previously given).

## III. EXCLUSION CRITERIA

1. Kymriah (tisagenlecleucel) is being used after disease progression on or after CAR-T cell therapy directed towards CD19 antigen ( Kymriah or Yescarta).
2. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

## IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

## V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

None

## VII. REFERENCES

1. Kymriah PI prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.