

## Drug Policy:

# Breyanzi™ (lisocabtagene maraleucel)

<b>POLICY NUMBER</b> UM ONC_1421	<b>SUBJECT</b> Breyanzi™ (lisocabtagene maraleucel)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 3</b>
<b>DATES COMMITTEE REVIEWED</b> 03/10/21, 05/12/21	<b>APPROVAL DATE</b> May 12, 2021	<b>EFFECTIVE DATE</b> May 28, 2021	<b>COMMITTEE APPROVAL DATES</b> 03/10/21, 05/12/21	
<b>PRIMARY BUSINESS OWNER: UM</b>		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>URAC STANDARDS</b> HUM 1	<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>	
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> Commercial, Exchange, Medicaid	

### I. PURPOSE

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

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

#### A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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](#)
2. 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](#)

3. 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**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.

#### **B. Diffuse Large B-Cell Lymphoma, confirmed CD-19 positive**

1. Breyanzi (lisocabtagene maraleucel) may be used, as monotherapy, for the treatment of adult members with relapsed or refractory large B-cell lymphoma (CD-19 positive) after disease progression on/after two or more lines of systemic therapy, including chemoimmunotherapy containing anti-CD20 and anthracycline (unless anthracyclines are contraindicated). Lymphoma sub-types include diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

### **III. EXCLUSION CRITERIA**

- A. Disease progression while taking Breyanzi (lisocabtagene maraleucel) or an anti-CD19 CAR-T cell therapy [e.g., Kymriah (tisagenlecleucel) or Yescarta (axicabtagene ciloleucel)].
- B. Dosing exceeds single dose limit of Breyanzi (lisocabtagene maraleucel)  $110 \times 10^6$  CAR-positive viable T-cells.
- C. Does not exceed duration limit as one time administration.
- D. The member does not have adequate bone marrow reserve.
- E. The member does not have adequate renal, hepatic, cardiac and pulmonary function defined as:
  1. Creatinine clearance  $> 30$  mL/min
  2. Serum ALT  $\leq 5$  times the upper limit of normal
  3. Cardiac ejection fraction  $\geq 40\%$ , no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant pleural effusion
  4. Baseline oxygen saturation  $> 91\%$  on room air.
- F. Primary central nervous system lymphoma.
- G. Active serious infection.
- H. Inflammatory disorders.
- I. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

### **IV. MEDICATION MANAGEMENT**

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

### **V. APPROVAL AUTHORITY**

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

### **VI. ATTACHMENTS**

- A. None

## VII. REFERENCES

- A. Breyanzi prescribing information. Juno Therapeutics, Inc. Bothell, WA 2021.
- B. Clinical Pharmacology Elsevier Gold Standard 2021.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.