Drug Policy:

Tecartus™ (brexucabtagene autoleucel)

I. PURPOSE

To define and describe the accepted indications for Tecartus (brexucabtagene autoleucel) 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 applicable, generic alternatives are preferred over brand-name drugs.

B. Mantle Cell Lymphoma, CD-19 positive

1. Tecartus (brexucabtagene autoleucel) may be used as monotherapy in members 18 years or older and have Mantle Cell Lymphoma that was either relapsed or refractory to up to 5 prior regimens; prior therapy should have included a chemo-immunotherapy regimen (e.g., R-CHOP, BR, R-Hyper CVAD) and a BTK (Bruton Tyrosine Kinase) inhibitor (e.g., ibrutinib, acalabrutinib, or zanubrutinib) AND

2. Member should have a confirmed diagnosis of Mantle Cell Lymphoma, either with cyclinD1 overexpression or a positive t(11;14) translocation in the lymphoma cells AND

3. Member’s Mantle Cell Lymphoma should be confirmed to be CD-19 positive.

III. EXCLUSION CRITERIA

A. Does not exceed duration limit as one time administration.

B. CD-19 positivity not confirmed.

C. Diagnosis of Mantle Cell Lymphoma not confirmed by either a positive cyclin D1 expression or a positive t(11;14) translocation in lymphoma cells.

D. The member does not have adequate bone marrow reserve defined by ALL the following:
   1. Absolute neutrophil count (ANC) ≥ 1000 cells/uL
   2. Absolute lymphocyte count (ALC) ≥ 100 cells/uL
   3. Platelet Count ≥ 75,000/uL

E. The member does not have adequate renal, cardiac, and pulmonary function defined as:
   1. Creatinine clearance ≥ 60 mL/min
   2. Cardiac ejection fraction ≥ 50% and there is no evidence of pericardial effusion as determined by an echocardiogram (ECHO)
   3. EKG has no clinically significant findings
   4. Baseline oxygen saturation > 92% on room air.

F. Prior Allogeneic hematopoietic stem cell transplant (HSCT).

G. History of CNS lymphoma (including lymphomatous meningitis), history of brain metastases, or any CNS disorder.

H. Active serious infection.

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
VI. ATTACHMENTS
A. None

VII. REFERENCES
B. Tecartus PI prescribing information. Kite Pharma, Inc Santa Monica, CA 2020.