

Drug Policy:

Tecartus™ (brexucabtagene autoleucl)

POLICY NUMBER UM ONC_1413	SUBJECT Tecartus™ (brexucabtagene autoleucl)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/09/20	APPROVAL DATE September 9, 2020	EFFECTIVE DATE September 25, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/09/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Tecartus (brexucabtagene autoleucl) 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. Mantle Cell Lymphoma

1. The member has relapsed or refractory mantle cell lymphoma and Tecartus (brexucabtagene autoleucl) will be used as a single agent **AND**
2. The member is refractory to at least 5 prior therapies including an anthracycline- based regimen (e.g. R-CHOP), bendamustine- based chemoimmunotherapy, an anti-CD20 antibody (e.g. rituximab, obinutuzumab, or ofatumumab), and a Bruton tyrosine kinase inhibitor (e.g. ibrutinib, acalabrutinib, or zanubrutinib).

III. EXCLUSION CRITERIA

- A. Tecartus (brexucabtagene autoleucl) is being used after disease progression with the same regimen or prior CAR therapy or other genetically modified T cell therapy.
- B. Concurrent use with other systemic immunosuppressive therapy or live virus vaccines.
- C. Dosing exceeds single dose limit of Tecartus (brexucabtagene autoleucl) 2×10^8 chimeric antigen receptor (CAR)-positive viable T cells (approximately 68 mL).
- D. Does not exceed duration limit as one time administration.
- E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Grade 3 or 4 febrile neutropenia is 6% (low risk level).^B
- B. The frequency of emesis is 13% (low risk level).^B
- C. 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. Tecartus PI prescribing information. Kite Pharma, Inc Santa Monica, CA 2020.
- B. Clinical Pharmacology Elsevier Gold Standard 2020.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2020.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2020.