Tecartus™ (brexucabtagene autoleucel)

INDEPENDENT CARE HEALTH PLAN

Pharmacy Coverage Policy

Effective Date: January 1, 2024
Revision Date: 11/28/2024
Review Date: --
Line of Business: Medicare
Policy Type: Prior Authorization

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.

Description

Tecartus (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy, which involves reprogramming a patient's own T cells with a retroviral transduction to express a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells.

Tecartus (brexucabtagene autoleucel) is indicated for the treatment of 1) adult patients with relapsed or refractory mantle cell lymphoma (MCL); and 2) Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Brexucabtagene autoleucel is available as Tecartus 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 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

Tecartus (brexucabtagene autoleucel) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Mantle cell lymphoma

- The member has a diagnosis of mantle cell lymphoma **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 Tecartus (brexucabtagene autoleucel) in conjunction with lymphodepleting chemotherapy, unless contraindicated **AND**
- The member will be using Tecartus (brexucabtagene autoleucel) at a treatment center that is certified to administer Tecartus (brexucabtagene autoleucel)

Acute Lymphoblastic Leukemia (ALL)

- The member has a diagnosis of B-cell precursor acute lymphoblastic leukemia **AND**
- The member has relapsed or 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 greater than or equal to 18 years of age **AND**
- The member will be using Tecartus (brexucabtagene autoleucel) in conjunction with

lymphodepleting chemotherapy, unless contraindicated **AND**
- The member will be using Tecartus (brexucabtagene autoleucel) at a treatment center that is certified to administer Tecartus (brexucabtagene autoleucel)

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

Coverage Limitations

Tecartus (brexucabtagene autoleucel) therapy is not considered medically necessary for members with the following concomitant conditions:

- The member has a diagnosis of primary central nervous system lymphoma

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Tecartus (brexucabtagene autoleucel).

Refer all requests or questions regarding Tecartus (brexucabtagene autoleucel) to the Corporate Transplant Department at 1-866-421-5663 .
Fax: 502-508-9300
Email: transplant@humana.com

Tecartus (brexucabtagene autoleucel) is only available at certain centers. For more information, please visit: https://www.tecartus.com.

Black Box Warnings

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Tecartus. Do not administer Tecartus 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 Tecartus, including concurrently with CRS or after CRS resolution. Monitor for neurological events after treatment with Tecartus. Provide supportive care as needed.

- Tescartus is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS 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]

Provider Claims Codes

For medically billed requests, please visit https://www.icarehealthplan.org/Prior-Authorization.htm. Select applicable Prior Authorization Listing for medical and procedural coding information.

Medical Terms

Tecartus; brexucabtagene; mantle cell; MCL; Acute Lymphoblastic Leukemia; ALL; CAR-T; pharmacy

References

Tecartus (brexucabtagene autoleucel) [prescribing information]. Kite Pharma. Santa Monica, CA. October 2021.

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.