CareSource

MEDICAL POLICY STATEMENT
West Virginia Marketplace

Policy Name & Number	Date Effective
CAR-T Medications - Tecartus - WV MP - MM-1094	06/01/2022-11/30/2022
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject
CAR-T medications – Tecartus (brexucabtagene autoleucel)

B. Background
Chimeric antigen receptor T cell therapy (CAR-T) is an autologous T-cell immunotherapy. The member's own T lymphocytes are genetically modified with a gene to produce chimeric antigen receptors (CARs) on the cell surface, making the lymphocytes a CAR-T cell, allowing recognition of an antigen on targeted tumor cells. Once the member's T cells are modified and multiplied, they are infused back into the member to attack cells with the targeted antigen on their surface, eradicating cancer cells and, possibly, resulting in long-term remission for patients.

CAR-T therapy is associated with severe complications and may be life-threatening. These complications include, but are not limited to, cytokine release syndrome, macrophage activation syndrome, anaphylaxis and neurological toxicities and other toxicities, and other medical conditions. Therefore, CAR-T therapy administration should be based on clinical benefits, potential long-term disease control, and toxicity.

C. Definitions
- **Antigen** – A toxin or other foreign substance that induces an immune response in the body, especially the production of antibodies.
- **Chimeric Antigen Receptors** – Proteins that allow T cells to recognize an antigen on a targeted tumor cell.
- **Immunotherapy** – A type of treatment that utilizes the body's own immune system to fight cancer, improves the body's ability to detect and kill cancer cells, and is based on the concept that immune cells or antibodies can recognize and kill cancer cells.
- **Relapsed or Refractory** – Disease progression after last regimen or failure to achieve a partial response or complete response to the last regimen.
- **Risk Evaluation and Mitigation Strategy (REMS)** – A drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.
- **T Lymphocyte (T-cell)** – A subtype of white blood cells comprising a major portion of the immune system and functioning to make antibodies that fight infection by directly killing infected cells in the body.

D. Policy
I. Tecartus
1. Tecartus may be approved for 3 months.
2. Tecartus will not be reauthorized for continued therapy.
3. Tecartus is limited to one infusion per lifetime.

II. Tecartus is a non-preferred product and will only be considered for coverage under the medical benefit when the following medically necessary criteria are met:
1. Member is 18 years old or older.

2. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program.
3. Member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1.
4. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
5. Member has **one** of the following:

A. **Mantle Cell Lymphoma (MCL)**

1. Member has a diagnosis of relapsed or refractory MCL, defined as disease progression after last regimen or failure to achieve a partial response or complete response to the last regimen; and
2. Member has at least one measurable lesion; and
3. Member has had prior treatment with **ALL** of the following:
   - Anthracycline or bendamustine-containing chemotherapy,
   - Anti-CD20 monoclonal antibody (Rituximab),
   - Bruton tyrosine kinase inhibitor (BTKi) (i.e. ibrutinib, acalabrutinib, or zanubrutinib); and
4. Member does NOT have **ANY** of the following:
   - Active or uncontrolled infection,
   - Central nervous system (CNS) lymphoma,
   - History of allogeneic stem cell transplantation,
   - Prior chimeric antigen receptor (CAR) therapy or other genetically modified T-cell therapy.

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

1. Member has a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) defined as **one** of the following:
   a. Primary refractory disease,
   b. First relapse if remission lasted ≤ 12 months,
   c. Relapsed or refractory after two (2) or more lines of therapy,
   d. Relapsed or refractory at least 100 days after allogeneic stem cell transplantation (HSCT); and
2. Documentation of CD19 tumor expression; and
3. Bone marrow with ≥ 5% lymphoblasts by morphologic assessment; and
4. If member has Philadelphia chromosome positive (Ph+) disease, he/she must have relapsed/refractory disease despite treatment with at least two (2) different tyrosine kinase inhibitors (TKIs); and
5. Member does NOT have any of the following:
   - Active or serious infection,
   - Active graft-versus-host disease (GVHD),
   - Prior CAR-T therapy.

III. CareSource considers Tecartus not medically necessary for the treatment of disease states not in this document.

E. Conditions of Coverage
NA

F. Related Policies/Rules
Evidence of Coverage and Health Insurance Contract

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

Pharmacy Policy Statement – Tecartus (brexucabtagene autoleucel)

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2021	
Date Revised	02/07/2022	Updated definitions. Added criteria for acute lymphoblastic leukemia to section D.II. Added references for additional criteria in Section H.
Date Effective	06/01/2022	
Date Archived	11/30/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Arnold F, Friedburg J. Diffuse large B cell lymphoma (DLBCL): Second or later relapse or patients who are medically-unfit. (2021, September 22). Retrieved February 10, 2022 from www.uptodate.com.
2. Dreyling M, Campo E, Hermine O, et al. Newly diagnosed and relapsed mantle cell lymphoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology*. 2017;28:iv62-iv71. doi:10.1093/annonc/mdx223.
3. Larson, R. Treatment of relapsed or refractory acute lymphoblastic leukemia in adults (2021, November 01). Retrieved February 10, 2022 from www.uptodate.com.
4. Mckay P, Leach M, Jackson B, Robinson S, Rule S. Guideline for the management of mantle cell lymphoma. *British Journal of Haematology*. 2018;182(1):46-62. doi:10.1111/bjh.15283.
5. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 3.2021). Retrieved February 11, 2022 from www.nccn.org.
6. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc; 2021.
7. U.S. Food and Drug Administration. FDA approves brexucabtagene autoleucel for relapsed or refractory B-cell precursor acute lymphoblastic leukemia (2021, October 1). Retrieved on February 7, 2022 from www.fda.gov.
8. Wang M, Munoz J, Goy A, et al. KTE-X19 CAR-T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma. *N Engl J Med*. 2020;382(14):1331-1342. doi:10.1056/NEJMoa1914347.

Independent medical review – 03/2022