Carvykti™ (ciltacabtagene autoleucel)

Humana

Pharmacy Coverage Policy

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

Carvykti (ciltacabtagene autoleucel), a chimeric antigen receptor T cell therapy (CART), is BCMA-directed for patients with multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an antiCD38 monoclonal antibody.

Multiple myeloma (MM) is a rare hematologic malignancy. National Cancer Institute's SEER data, in 2020, estimated there would be 32,270 new cases of myeloma and 12,830 people would die of this disease. This accounts for 2.1% of all Cancer deaths in U.S. The 5-year survival is at 54% while the median age is 69 years at diagnosis.

Carvykti (ciltacabtagene autoleucel) is a cell suspension for intravenous infusion. A single dose of Carvykti (ciltacabtagene autoleucel) contains a cell suspension of 0.5 - 1.0 x 10^6 CARpositive T cells per kg body weight 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

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

Multiple Myeloma

- **The member has a diagnosis of multiple myeloma AND**
- **The member has relapsed or refractory disease, defined by International Myeloma Working Group (IMWG) criteria AND**
- **The member has had at least four lines of previous systemic therapies including an immunomodulatory agent (e.g. lenalidomide, pomalidomide), a proteasome**

inhibitor (e.g. bortezomib, carfilzomib), and an anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) AND

- **The member is greater than or equal to 18 years of age AND**
- **The member will be using Carvykti in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m2 daily for 3 days and cyclophosphamide 300 mg/m2 daily for 3 days) AND**

- **The member will be using Carvykti at a treatment center that is certified to administer Carvykti**

Carvykti (ciltacabtagene 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

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

- **The member has active hepatitis B (HBs AG-positive) or hepatitis C infection**
- **The member has received prior allogeneic transplant**
- **The member has received prior treatment with a chimeric antigen receptor T (CAR-T) cell therapy**

- **Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.** **Background** **This is a prior authorization policy about Carvykti (ciltacabtagene autoleucel).**

Refer all requests or questions regarding Carvykti (ciltacabtagene autoleucel) to the Corporate Transplant Department at 1-866-421-5663 . Fax: 502-508-9300 Email: transplant@humana.com Carvykti (ciltacabtagene autoleucel) is only available at certain centers.

Black Box Warnings

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI. Do not administer**

CARVYKTI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

- **Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI. Provide supportive care and/or corticosteroids as needed.**
- **Parkinsonism and Guillain-Barré syndrome and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI.**
- **Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS),**

including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI. HLH/MAS can occur with CRS or neurologic toxicities.

- **Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI.**
- **CARVYKTI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI REMS.**

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 Onc*

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Carvykti; Ciltacabtagene autoleucel; MM; Multiple Myeloma; CAR-T; BCMA; pharmacy

References

Carvykti (ciltacabtagene autoleucel) [prescribing information]. Janssen Biotech. Horsham, PA. March 2022.

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.