

Medical Policy:

Carvykti™ (ciltacabtagene autoleucel) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.351	March 4, 2025	May 12, 2022

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This 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. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions:

Carvykti, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of adults with relapsed or refractory multiple myeloma, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Length of Authorization

Coverage will be provided for 1 dose and may not be renewed.

Dosing Limits [Medical Benefit]

Approve up to 1 x 10⁸ CAR-T cells administered intravenous as a single dose.

Max Units (per dose and over time) [HCPCS Unit]:

1 billable unit (1 dose of up to 100 million autologous CAR-positive viable T-cells)

Guideline

****For Medicare members: Carvykti- please refer to our separate LCD/NCD Medicare criteria**

I. Initial Criteria

1. **Multiple Myeloma.** Approve a single dose if the patient meets the following criteria (A, B, C, D, E, F, G, H, I, J, K, L, M, N, and O):
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has relapsed or refractory disease; **AND**
 - i. Patient has received at least one (1) prior line of therapy, including a proteasome inhibitor (e.g., bortezomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.); **AND**
 - a) Patient is refractory to lenalidomide; **OR**
 - ii. Patient has received at least three (3) prior lines of therapy
 - C. Patient has received, or plans to receive, lymphodepleting chemotherapy prior to infusion of Carvykti; **AND**
 - D. Patient has not been previously treated with chimeric antigen receptor (CAR-T) therapy; **AND**
Note: Examples of CAR-T therapy includes Carvykti, Abecma (idecabtagene vicleucel intravenous infusion), Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene intravenous infusion), and Yescarta (axicabtagene intravenous infusion).
 - E. The medication is prescribed by, or in consultation with, an Oncologist; **AND**
 - F. Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy; **AND**
 - G. Patient does not have an active infection or inflammatory disorder; **AND**
 - H. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during ciltacabtagene autoleucel treatment, and until immune recovery following treatment; **AND**
 - I. Patient has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
 - J. Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
 - K. Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
 - L. Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant, active, CNS pathology; **AND**
 - M. Patient does not have active or a history of plasma cell leukemia; **AND**
 - N. Patient has an ECOG performance status of 0-1; **AND**
 - O. Healthcare facility has enrolled in the CARVYKTI REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities.

Dosing/Administration:

Carvykti is provided as a single dose intravenous infusion. The recommended dose range is $0.5\text{--}1.0 \times 10^6$ CAR positive viable T cells per kg of body weight, with a maximum dose of 1×10^8 CAR-positive viable T cells per single infusion.

Applicable Procedure Codes

Code	Description
C9098	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Applicable NDCs

Code	Description
57894-0111-01	Carvykti Intravenous Suspension 70mL
57894-0111-02	Carvykti Intravenous Suspension 30mL

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/4/2025	<p>Addition of Q2056 Ciltacabtagene autoleucl, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.</p> <p>Addition of "or Patient has received at least three (3) prior lines of therapy" to relapsed/refractory option.</p>
EmblemHealth & ConnectiCare	5/29/2024	<p>Revision: Initial Criteria- Multiple Myeloma: Removed :Patient has received "four or more lines" and Updated with "at least one prior line of therapy," including Removed: "one from each of the following (i, ii, and iii):" Removed: "Patient has received an anti-CD38 monoclonal antibody; AND Note: <i>Anti-CD38 monoclonal antibodies include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), and Sarclisa (isatuximab-irfc intravenous infusion).</i>"</p> <p>Added: "Patient is refractory to lenalidomide"</p>
EmblemHealth & ConnectiCare	4/8/2024	<p>Added Statement: **For Medicare members: Carvykti- please refer to our separate LCD/NCD Medicare criteria</p>
EmblemHealth & ConnectiCare	3/25/2024	<p>Annual Review: Updated dosing limits, removed J9999 and C9399, removed C90.1, C90.12, C90.2, C90.22, C90.3, C90.32, and Z85.79</p> <p>Initial Criteria: Multiple Myeloma: added: "Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy; AND Patient does not have an active infection or inflammatory disorder; AND Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during ciltacabtagene autoleucl treatment, and until immune recovery following treatment; AND Patient has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); AND Prophylaxis for infection will be followed according to standard institutional guidelines; AND Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); AND Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant, active, CNS pathology; AND Patient does not have active or a history of plasma cell leukemia; AND Patient has an ECOG performance status of 0-1; AND Healthcare facility has enrolled in the CARVYKTI REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities"</p>

EmblemHealth & ConnectiCare	07/21/2023	Annual Review: Removed code C9098, added code Q2056. Added ICD-10 Codes: C90.10, C90.12, C90.2, C90.22, C90.30, C90.32, Z85.79
EmblemHealth & ConnectiCare	5/12/2022	New Policy

References

1. Carvykti™ intravenous infusion [prescribing information]. Horsham, PA: Janssen Biotech; February 2022.