

Medical Policy:

CARVYKTI™ (ciltacabtagene autoleucel) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.351	July 21, 2023	May 12, 2022

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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 1×10^8 CAR-T cells administered intravenous as a single dose.

Guideline

I. Initial Criteria

1. **Multiple Myeloma.** Approve a single dose if the patient meets the following criteria (A, B, C, D, **and** E):
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has received four or more lines of systemic therapy, including one from each of the following (i, ii, **and** iii):
 - i. Patient has received an immunomodulatory agent; **AND**
Note: Immunomodulatory agents include Thalomid (thalidomide capsules), Revlimid (lenalidomide capsules), and Pomalyst (pomalidomide capsules).
 - ii. Patient has received a proteasome inhibitor; **AND**
Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).
 - iii. Patient has received an anti-CD38 monoclonal antibody; **AND**
Note: Anti-CD38 monoclonal antibodies include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), and Sarclisa (isatuximab-irfc intravenous infusion).
 - 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.

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
J9999	Not otherwise classified, antineoplastic drugs
C9399	Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)
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
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Revision History

Company(ies)	DATE	REVISION
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.