Medical Policy:

Carvykti™ (ciltacabtagene autoleucel) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.351	March 25, 2024	May 12, 2022

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 10^8 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

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 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; **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 $0.5–1.0 \times 10^{6}$ 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

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	3/25/2024	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 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 autoleucel 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"
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.