Medical Policy

Carvykti™ (ciltacabtagene autoleuce	
MEDICAL POLICY NUMBER	MED_Clin_Ops-122
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan*: ALL *Small Group:* ALL *Medicare Advantage*: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Carvykti™ (ciltacabtagene autoleucel) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Carvykti will be provided for one treatment course (1 dose of Carvykti) and may not be
renewed.

- Max Units (per dose and over time): 1 billable unit (1 dose of up to 100 million autologous CAR-positive viable T-cells)

Initial

A. Patient is at least 18 years of age; **AND**

B. 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; **AND**
C. Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy; **AND**
D. Patient has not received prior allogeneic hematopoietic stem cell transplant within 6 months prior to therapy; **AND**
E. Patient does not have an active infection or inflammatory disorder; **AND**
F. 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**
G. 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**
H. Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
I. Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
J. Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant, active, CNS pathology; **AND**
K. Patient does not have active or a history of plasma cell leukemia; **AND**
L. Patient has an ECOG performance status of 0-1; **AND**

Multiple Myeloma

A. Patient has relapsed or refractory disease; **AND**
B. Patient has received at least four (4) prior therapies, including a proteasome inhibitor (e.g., bortezomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.).

Renewal

A. Coverage cannot be renewed.

LIMITATIONS/EXCLUSIONS

1) Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. CARVYKTI™ (ciltacabtagene autoleucel) suspension for intravenous infusion. Initial U.S. Approval: 2022

CODING

Applicable NDC Codes	
57894-0111-xx	Carvykti suspension for intravenous infusion [A single dose of Carvykti contains a cell suspension of up to 1 x 108 CAR-positive T cells in one or more infusion bags]; 30 mL and 70 mL infusion bags and metal cassettes

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Applicable Procedure Code	
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 ICD-10 Codes	
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
D47.2	Monoclonal gammopathy
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

EVIDENCE BASED REFERENCES

1. Carvykti [package insert]. Horsham, PA; Janssen Biotech, Inc., March 2022. Accessed July 2022.

Policy History

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan Care's policies on clinical criteria and policy development.

Approval Body	Pharmacy and Therapeutics Committee
Original Effective Date	July 26, 2022
Revision Date	February 28, 2023 - Updated HCPCS for Carykti (Q2056) March 01, 2023 – Adopted by MA UMC January 01, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan