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Section:	Prescription Drugs	**Effective Date:**	July 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 25, 2022
Subject:	Carvykti	**Page:**	1 of 5

Last Review Date: June 12, 2025

Carvykti

Description

Carvykti (ciltacabtagene autoleucel)

Background
Carvykti (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed, genetically modified autologous T cell immunotherapy, which involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA. Upon binding to BCMA-expressing cells, the CAR promoted T cell activation, expansion, and elimination of target cells (1).

Regulatory Status
FDA-approved indication: Carvykti is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide (1).

Carvykti has boxed warnings regarding: (1)

- Cytokine release syndrome (CRS)
  - Carvykti should not be administered to patients with active infection or inflammatory disorders
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
  - Patients should be monitored for neurologic events after treatment with Carvykti
- Parkinsonism and Guillain-Barré syndrome and their associated complications
- Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS)

- Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery
- Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with Carvykti. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including Carvykti
- Carvykti is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Carvykti REMS

Because of the risk of CRS and neurologic toxicities, Carvykti is available only through the Carvykti REMS program. Healthcare facilities that dispense and administer Carvykti must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab (Actemra), and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after Carvykti infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer Carvykti are trained in the management of CRS and neurologic toxicities (1).

Serious infections, including life-threatening or fatal infections, occurred in patients after Carvykti infusion. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients with hypogammaglobulinemia. Perform screening for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing (1).

The safety and effectiveness of Carvykti in pediatric patients have not been established (1).

Related policies
Abecma

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Carvykti may be considered **medically necessary** if the conditions indicated below are met.

Carvykti may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory multiple myeloma

AND ALL of the following:

a. Patient must have received **ONE** or more prior lines of therapy including:
   i. Proteasome inhibitor
   ii. Immunomodulatory agent
b. Patient is refractory to lenalidomide (Revlimid)
c. Patient has adequate organ and bone marrow function as determined by the prescriber
d. Absence of active infection (including TB, HBV, HCV, and HIV)
e. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
f. Prescriber agrees to monitor the patient for signs and symptoms of cytokine release syndrome (CRS) and administer tocilizumab (Actemra) if needed
g. Prescriber agrees to monitor the patient for signs and symptoms of neurological toxicities
h. Administered in a healthcare facility enrolled in the Carvykti REMS program
i. **NO** prior therapy with any other gene therapy (e.g., Abecma, Breyanzi, Kymriah, Tecartus, Yescarta)
j. **NO** dual therapy with any other gene therapy (e.g., Abecma, Breyanzi, Kymriah, Tecartus, Yescarta)

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity One infusion (only one PA approval for one infusion per lifetime)

Rationale

Summary

Carvykti is an autologous T cell immunotherapy that is intended for the treatment of relapsed or refractory multiple myeloma. Carvykti may cause cytokine release syndrome (CRS) and neurological toxicities. Carvykti should not be administered in patients with an active infection or any inflammatory disorders. The safety and effectiveness of Carvykti in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Carvykti while maintaining optimal therapeutic outcomes.

References

1. Carvykti [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2024.
2. NCCN Drugs & Biologics Compendium® Ciltacabtagene autoleucel 2025. National Comprehensive Cancer Network, Inc. Accessed on April 28, 2025.

Policy History

Date	Action
March 2022	Addition to PA
June 2022	Annual review and reference update
October 2022	Per FEP, removed duration from PA
December 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual editorial review and reference update
May 2024	Per PI update, change requirement of 4 prior lines of therapy to 1, and changed required categories of therapy to proteasome inhibitor and

	immunomodulatory agent, requiring patient be refractory to lenalidomide. Added T cell malignancies to boxed warning in the regulation section.
June 2024	Annual review and reference update
March 2025	Annual review and reference update
June 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.