Utilization Review Policy 283

POLICY: Oncology (Injectable – CAR-T) – Carvykti Utilization Management Medical Policy
- Carvykti™ (ciltacabtagene autoleucel intravenous infusion – Janssen Biotech)

EFFECTIVE DATE: 6/1/2022
LAST REVISION DATE: 03/22/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW
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.[1]

Dosing Information
Carvykti is supplied in one infusion bag containing a frozen suspension of genetically modified autologous T-cells in 5% dimethyl sulfoxide.[1] The bag is stored in the vapor phase of liquid nitrogen (-184°F). The recommended dose is a single infusion of 0.5 to 1.0 x 10^6 chimeric antigen receptor (CAR)-T cells per kg of body weight, to a maximum dose of 1 x 10^8 CAR-T cells.

Guidelines
The National Comprehensive Cancer Network clinical practice guidelines for multiple myeloma (version 3.2023 – December 8, 2022) recommend Carvykti for the treatment of multiple myeloma in patients who have received four or more previous therapies.[2,3] Patients should receive a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody before receiving Carvykti.

Safety
Carvykti has a boxed warning for cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, parkinsonism and Guillain-Barre syndrome, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and prolonged and/or recurrent cytopenias.[1] Carvykti is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Carvykti REMS.

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Carvykti. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Because of the specialized skills required for evaluation and diagnosis of patients treated with Carvykti as well as the monitoring required for adverse events and long-term efficacy, approval requires Carvykti to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Carvykti is recommended in those who meet the following criteria:

FDA-Approved Indication

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 therapy from each of the following (i, ii, and iii):
     - **i.** Immunomodulatory agent; AND
       Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, and Pomalyst (pomalidomide capsules).
     - **ii.** Proteasome inhibitor; AND
       Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).
     - **iii.** 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. Approve up to 1 x 10^8 CAR-T cells administered intravenous as a single dose.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Carvykti is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Carvykti intravenous infusion [prescribing information]. Horsham, PA: Janssen Biotech; February 2023.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2023.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/02/2022
Update	03/10/2022: Updated Guidelines section with recommendations from the National Comprehensive Cancer Network clinical practice guidelines in oncology (version 5.2022 – March 9, 2022).	NA
Update	08/26/2022: Added: "The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy." to the Policy Statement.	NA
Annual Revision	No criteria changes.	03/22/2023