

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable – CAR-T) – Carvykti Prior Authorization Policy

- Carvykti™ (ciltacabtagene autoleucel intravenous infusion – Janssen Biotech)

**REVIEW DATE:** 03/02/2022

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### 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.<sup>1</sup>

Carvykti is supplied in one infusion bag containing a frozen suspension of genetically modified autologous T-cells in 5% dimethyl sulfoxide.<sup>1</sup> The bag is stored in the vapor phase of liquid nitrogen (-184°F).

### Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for multiple myeloma (version 5.2022 – March 9, 2022) recommend Carvykti for the treatment of multiple myeloma in patients who have received four or more previous therapies.<sup>2,3</sup> 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.<sup>1</sup> 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 prescription benefit coverage of Carvykti. All approvals are provided for the duration noted below. 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  $\geq 18$  years of age; AND

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- 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.

#### **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 2022.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 10, 2022.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 10, 2022.