Reference number(s)
5266-A

Standard Medicare Part B Management Carvykti

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Carvykti	ciltacabtagene autoleucel

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Carvykti is 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions: chart notes or medical record documentation demonstrating failure of previous lines of therapy.

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Coverage Criteria

Multiple Myeloma[1-6]

Authorization of 3 months (one dose) may be granted for treatment of relapsed or refractory multiple myeloma in members 18 years of age and older when all of the following criteria are met:

- The member has received prior treatment with at one line of therapy, including at least one drug from each of the following categories:
    - Immunomodulatory agent
    - Proteasome inhibitor
- The disease is lenalidomide-refractory.
- The member has not received previous treatment with the requested medication or another CAR-T therapy directed at any target.[4-6]
- The member has an ECOG performance status of 0 to 2.
- The member has adequate and stable kidney, liver, pulmonary and cardiac function.
- The member does not have known active or prior history of central nervous system (CNS) involvement, including CNS multiple myeloma.
- The member does not have clinically significant active infection.
- The member does not have active graft versus host disease.
- The member does not have an active inflammatory disorder.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Carvykti.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Multiple myeloma
- National Coverage Determination: Chimeric Antigen Receptor (CAR) T-cell Therapy

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Carvykti are covered.

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

All FDA-approved indications are covered according to the conditions outlined in National Coverage Determination Manual section 110.24 (Chimeric Antigen Receptor [CAR] T-cell Therapy).

References

1. Carvykti [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2024.
2. Berdeja JG, Madduri D, Usmani SZ, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b/2 open-label study. Lancet. 2021 Jul 24;398(10297):314-324.
3. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24-Version 1). http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.24from2=search.asp&bc=gAAAAAgAAAAA& Accessed May 19, 2025.
4. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. September 2021.
5. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology – Multiple Myeloma (MM). December 2023.
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma. Version 2.2025. Accessed May 16, 2024.
7. Patel U, Oluwole OO, Kassim A, et al. Sequencing bispecific antibodies and CAR T cell therapy in multiple myeloma with prior exposure to BCMA-targeted therapies. J Clin Oncol. 2023;41(16):e20049.

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