| Reference number(s) |
| --- |
| 5256-A |

# Specialty Guideline 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 are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review: chart notes or medical record documentation demonstrating failure of previous lines of therapy.

| Reference number(s) |
| --- |
| 5256-A |

# 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 least 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.

# 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. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. September 2021.
4. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology – Multiple Myeloma (MM). December 2023.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma. Version 2.2025. Accessed May 16, 2025.
6. 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.