

SPECIALTY GUIDELINE MANAGEMENT

CARVYKTI (ciltacabtagene autoleucel)

POLICY

I. 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 Indication

Carvykti is indicated for the treatment of adult patients 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.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart notes, medical record documentation or claims history supporting previous lines of therapy

III. CRITERIA FOR INITIAL APPROVAL

Multiple Myeloma

Authorization of 3 months 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:

- A. The member has received prior treatment with at least four prior lines of therapy, including at least one drug from each of the following categories:
 1. Immunomodulatory agent
 2. Proteasome inhibitor
 3. Anti-CD38 monoclonal antibody
- B. The member has not received previous treatment with the requested medication or another CAR-T therapy directed at any target.
- C. The member has an ECOG performance status of 0 to 2.
- D. The member has adequate and stable kidney, liver, pulmonary and cardiac function.
- E. The member does not have known active or prior history of central nervous system (CNS) involvement, including CNS multiple myeloma.
- F. The member does not have clinically significant active infection.
- G. The member does not have active graft versus host disease.
- H. The member does not have an active inflammatory disorder.

IV. REFERENCES

1. Carvykti [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2023.

Reference number(s)
5256-A

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. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma. Version 2.2024. Accessed December 14, 2023.
4. 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.