Reference number(s)
5256-A

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, 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.

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

IV. 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. 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.