

SPECIALTY GUIDELINE MANAGEMENT

ABECMA (idecabtagene vicleucel)

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

Abecma is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, 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 are met:

- A. The member has received prior treatment with at least two lines of therapy, including at least one drug from each of the following categories:
 - 1. Immunomodulatory agent
 - 2. Proteasome inhibitor
 - 3. Anti-CD 38 monoclonal antibody
- B. The member has not received a previous treatment course of the requested medication or another chimeric antigen receptor (CAR) T-cell 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 has no history or presence of clinically relevant central nervous system (CNS) pathology
- 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. Abecma [package insert]. Summit, NJ: Celgene Corporation; April 2024.

Reference number(s)
4642-A

2. Munshi NC, Anderson LD Jr, Shah N, et al. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. *N Engl J Med*. 2021 Feb 25;384(8):705-716.
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.