Idecabtagene Vicleucel (Abecma®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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 four 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 four prior 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Abecma [package insert]. Summit, NJ: Celgene Corporation; March 2021.
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.

EFFECTIVE DATE 7/31/2024

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