Abecma (idecabtagene vicleucel)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

POLICY

Required 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.

Criteria for Approval

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 are met:

1. The member has received prior treatment with at least two lines of therapy, including at least one drug from each of the following categories:
    a. Immunomodulatory agent
    b. Proteasome inhibitor

c. Anti-CD 38 monoclonal antibody

2. 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.
3. The member has an ECOG performance status of 0 to 2.
4. The member has adequate and stable kidney, liver, pulmonary and cardiac function.
5. The member does not have known active or prior history of central nervous system (CNS) involvement (e.g., CNS multiple myeloma) or a history or presence of clinically relevant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, subarachnoid hemorrhage or other CNS bleed, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis.
6. The member does not have clinically significant active infection.
7. The member does not have active graft versus host disease.
8. The member does not have an active inflammatory disorder.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Abecma approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2055 – Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed CAR-positive cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

REFERENCES

- Abecma [package insert]. Summit, NJ: Celgene Corporation; March 2025.
- 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
- Food and Drug Administration (FDA) Drug approvals. FDA approval idecabtagene-vicleucel for multiple myeloma https://www.fda.gov
- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Multiple Myeloma Version 4.2024. Accessed May 16, 2025.
- 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.
- Mikhael J, Ismaila N, Cheung MC, et al. Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline. J Clin Oncol. May 10 2019; 37(14): 1228-1263. PMID 30932732.
- Pick M, Vainstein V, Goldschmidt N, et al. Daratumumab resistance is frequent in advanced-stage multiple myeloma patients irrespective of CD38 expression and is related to dismal prognosis. Eur J Haematol. May 2018; 100(5): 491-501. PMID 29453884.
- Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Multiple Myeloma Clinical Programs. August 2024.

POLICY HISTORY

Policy #: 05.04.74

Original Effective Date: January 1, 2023
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