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 four or more 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, medical record documentation or claims history supporting lines of therapy including lab work and diagnostic testing within 7 to 14 days of the approval request to determine the member has adequate organ and bone marrow function and meets the medical necessity criteria.

Criteria for Initial Approval

Authorization of 3 months may be granted for a one-time treatment of Abecma for members with a confirmed diagnosis of relapsed or refractory multiple myeloma by bone marrow evaluation based on medical documentation 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 four prior lines of therapy, including at least one drug from each of the following categories:
    a. Immunomodulatory agent (e.g., Thalomid [thalidomide], Revlimid [lenalidomide], Pomalyst [pomalidomide])
    b. Proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])
    c. Anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab], Empliciti [elotuzumab], Sarclisa [isatuximab])
2. The member has not received a previous treatment course of the requested medication, another chimeric antigen receptor (CAR) T-cell therapy directed at any target, or any therapy that is targeted to B-cell maturation antigen (BCMA).
3. The member has an ECOG performance status of 0 to 2. (Member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.)
4. The member has adequate and stable kidney, liver, pulmonary and cardiac function as demonstrated by all of the following:
    a. Creatinine clearance >45mL/minute
    b. Alanine aminotransferase (ALT) less than 2.5 times upper limit of normal
    c. Ejection fraction ≥45%
    d. Neutrophil count ≥1000 cells/mm^3
    e. Platelet count ≥50,000/mm^3
5. The member does not have clinically significant active infection, including confirmation member does not have active hepatitis B (HBsAG negative) or hepatitis C virus (anti-HCV negative); (a history of hepatitis B or hepatitis C virus is permitted if the viral load is undetectable per quantitative PCR and/or nucleic acid testing).
6. The member does not have an active inflammatory disorder.
7. The member does not have central nervous system (CNS) involvement with myeloma.
8. The member does not have a history or presence of CNS disorders such as epilepsy/seizure disorder, paresis, aphasia, stroke, cerebral edema, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis.
9. The member will receive Abecma at a treatment center that is certified to administer Abecma per Abecma REMS requirements.

Continuation of Therapy

Repeat treatment of Abecma for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

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 2021
- 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) Multiple Myeloma Version 5.2022. https://www.nccn.org
- KarMMA Clinical Trial NCT03361748
- 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.

POLICY HISTORY

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