Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/05/2025

Abecma® (idecabtagene vicleucel)

HCPCS: Q2055

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indications
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Treatment of patients with relapsed or refractory multiple myeloma after at least 2 prior lines of therapy
   e. Patients must have been treated with all of the following:
      i. An immunomodulatory agent
      ii. A proteasome inhibitor
      iii. An anti-CD38 antibody
   f. Must have active disease defined by at least one of the following:
      i. Serum M-protein greater or equal to 1.0 g/dL
      ii. Urine M-protein greater or equal to 200 mg/24 h
      iii. Serum free light chain (FLC) assay greater or equal to 10 mg/dL provided the baseline serum FLC ratio is abnormal
   g. Patients must meet all of the following
      i. ECOG performance status of 0 - 2
      ii. No known central nervous system involvement with myeloma
      iii. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
      iv. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
      v. Creatinine clearance greater than 30 mL/min
      vi. Alanine aminotransferase less than 5 times upper limit of normal
      vii. Left ventricular ejection fraction greater than 40%
      viii. Platelets greater than 50,000/mm^3
      ix. No second malignancies in addition to myeloma if the second malignancy has required therapy in the last 3 years or is not in complete remission
      x. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
      xi. No thromboembolic events within 6 months

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xii. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening

xiii. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis

h. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy

i. Only to be administered at certified bone marrow/stem cell transplant centers

j. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list

k. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM

l. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the BCBSM Pharmacy and Therapeutics Committee

B. Quantity Limitations, Authorization Period and Renewal Criteria

a. Quantity Limits: Align with FDA recommended dosing

b. Authorization Period: 3 months with the allowance of only one dose per lifetime

c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- CAR-T therapy is a type of treatment the utilizes the body's own immune system to fight cancer. T-cells are collected from the patient via apheresis and are genetically engineered in the laboratory to produce chimeric antigen receptors on the cell surface, allowing the T-cells to recognize an antigen on target cancer cells. Once the tumor cells are identified, they are attacked and killed by the CAR-T therapy.

- CAR-T therapy has not been studied when given following prior treatment with any CAR-T therapy or following any other genetically-modified T-cell therapy.

- Due to the risk of cytokine release syndrome and neurological toxicities, CAR-T therapies are only allowed to be given at treatment centers certified by their REMS programs. CAR-T REMS programs require certified hospitals and their clinics to have on-site, immediate access to tocilizumab and an understanding of how to manage the risks of the associated CAR-T side effects.

- Abecma is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy 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.

- Safety and efficacy for use as third-line therapy in relapsed or refractory multiple myeloma was established in the KarMMa-3 trial, an open-label, phase 3 study of 386 patients with replased/refractory multiple myeloma who had received at least two prior lines of therapy that included an immunomodulatory agent, a proteasome inhibitor and an

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anti-CD38 antibody. The study excluded patients with an ECOG score of 2 or greater, a creatinine clearance of less than or equal to 45 mL/minute, alanine aminotransferase greater than 2.5 times upper limit of normal, and left ventricular ejection fraction less than 45%. Patients were also excluded if absolute neutrophil count less than 1000 cells/mm^3 and platelet count less than 75,000/mm^3. Patients were required to have measurable disease. The primary endpoint was progression free survival (PFS). The median PFS was 13.3 months in the Abecma group compared with 4.4 months in the standard-regimen group (hazard ratio for disease progression or death, 0.49; 95% confidence interval: 0.38, 0.65; p-value < 0.001). A response occurred in 71% of the patients in the Abecma group and in 42% of those in the standard-regimen group (p-value < 0.001); a complete response occurred in 39% and 5%, respectively.

- Disease should be measured/staged with PET-CT. Focal uptake in nodal and extranodal sites is considered involvement with lymphoma, including spleen, liver, bone, thyroid, and so on. A measurable node must have a longest diameter (LDi) greater than 1.5 cm. A measurable extranodal lesion should have an LDi greater than 1.0 cm. All other lesions (including nodal, extranodal, and assessable disease) should be followed as nonmeasured disease (eg, cutaneous, GI, bone, spleen, liver, kidneys, pleural or pericardial effusions, ascites).

- While use of Abecma has not been established in patients with a creatinine clearance of less than 45 mL/minute, other CAR-T therapies have been studied in subjects with a creatinine clearance of 30 mL/minute. The National Institute of Health/National Cancer Institute Common Terminology Criteria of Adverse Events (CTCAE) classify grade 2 chronic kidney disease as a creatinine clearance of 30 – 59 mL/minute. As the classification system uses 30 mL/minute as a cutoff for grade 2 disease and data from other CAR-T therapies support their use in these patients, Abecma should be able to be tolerated in this population. As there is no data to support administration of CAR-T at levels lower than 30 mL/minute, therapy should not be given in patients not meeting the 30 mL/minute threshold.

- While use of Abecma has not been established in patients with an alanine aminotransferase of greater than 2.5 times the upper limit of normal (ULN), other CAR-T therapies have been studied in subjects with an alanine aminotransferase of up to 5 times the ULN and the CTCAE recommendations have set 5 times the ULN as the cutoff for grade 2 adverse reactions. As the classification system uses 5 times the ULN and other CAR-T therapies have data supporting use in this patient population, Abecma should be tolerated in these patients as well. As there is no data to support administration of CAR-T at levels higher than 5 times the ULN, therapy should not be given to patients not meeting that threshold.

- The CTCAE recommendations set the grade 2 cutoff for left ventricular ejection fraction (LVEF) at 40%. While Abecma has only been studied in patients with a LVEF greater than or equal to 45%, there is data from other CAR-T therapies to support use in those with a LVEF of 40% of greater. Therefore, Abecma should be tolerated in these patients as well. There is no data supporting use at LVEF levels less than 40%.

- A provider portal is used to capture clinical outcome information for patients on select high-cost treatments, such as gene and cellular therapies. If a patient meets medical necessity as defined by this policy and is approved for treatment, the requesting physician must attest to providing clinical outcome information within the appropriate provider portal at the requested cadence.

References:

1. Abecma [prescribing information]. Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; July 2024.
2. National Comprehensive Cancer Network. Multiple myeloma (Version 1.2025). 2024 Sept 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on March 21, 2025.
3. Munshi NC, Anderson Jr LD, Shah N, et al. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. NEJM. 2021 Feb 25; 384 (8): 705 - 16.
4. U.S. Department of Health and Human Services. Common terminology criteria for adverse events (Version 5.0). 2017 Nov 27. Available at:

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https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf. Accessed on July 6, 2022.
5. Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or standard regimens in relapsed and refractory multiple myeloma. NEJM. 2023 March 16; 388: 1002 – 14.

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<tr><td colspan="3">Policy History</td></tr>
<tr><td>#</td><td>Date</td><td>Change Description</td></tr>
<tr><td>1.8</td><td>Effective Date: 06/05/2025</td><td>Updated to change the provider portal from Audaire Health to the appropriate provider portal</td></tr>
<tr><td>1.7</td><td>Effective Date: 06/06/2024</td><td>Updated to include the new indication for use as third line therapy</td></tr>
<tr><td>1.6</td><td>Effective Date: 10/12/2023</td><td>Updated to include preliminary criteria to allow use as third line therapy</td></tr>
<tr><td>1.5</td><td>Effective Date: 06/08/2023</td><td>Updated to require physicians provide clinical outcomes data using the Audaire Health platform</td></tr>
<tr><td>1.4</td><td>Effective Date: 08/04/2022</td><td>Updated to align criteria across all CAR-T policies</td></tr>
<tr><td>1.3</td><td>Effective Date: 08/12/2021</td><td>New policy

This policy replaces previously approved criteria that was embedded in Chimeric Antigen Receptor-T Cell Class policy which will be retired</td></tr>
<tr><td>1.2</td><td>Effective Date: 05/06/2021</td><td>UM medical management system update for BCBS

<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.1</td><td>Effective Date: 04/20/2021</td><td>UM medical management system update for BCN

<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date: 04/05/2021</td><td>UM medical management system update for BCNA and MAPPO

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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

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