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of the Blue Cross and Blue Shield Association

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: 04/16/2026

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. The member has no active infection (e.g. viral, bacterial, fungal) such as HIV, active hepatitis B or active hepatitis C
 - iv. No prior treatment with allogeneic hematopoietic stem cell transplant
 - v. No prior treatment with autologous stem cell transplantation within the last 12 weeks
 - vi. Creatinine clearance greater than 30 mL/min
 - vii. Left ventricular ejection fraction greater than 40%
 - 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

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- 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: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time 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 that 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 relapsed/refractory multiple myeloma who had received at least two prior lines of therapy that included an immunomodulatory agent, a proteasome inhibitor and an 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/mm³ and platelet count less than 75,000/mm³. 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

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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.
- 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% or 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; November 2025.
2. National Comprehensive Cancer Network. Multiple myeloma (Version 5.2026). 2026 Jan 9. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on March 1, 2026.
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: 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.

Policy History												
#	Date	Change Description										
1.9	Effective Date: 06/01/2026 P&T Date: 04/16/2026	Updated to remove no HIV, hepatitis C or B infection, no uncontrollable infection or infection requiring long term antibiotics, liver function testing, platelet counts, no secondary malignancies, no significant cardiac events, no thromboemolic events within 6 months, no pulmonary disease, and no clinically significant CNS disease. Also added requirements of no active infection, no prior allogenic stem cell transplant, no prior autologous stem cell transplant within 12 weeks, and updated the approval length to 6 months										
1.8	Effective Date: 06/05/2025	Updated to change the provider portal from Audaire Health to the appropriate provider portal										
1.7	Effective Date: 06/06/2024	Updated to include the new indication for use as third line therapy										
1.6	Effective Date: 10/12/2023	Updated to include preliminary criteria to allow use as third line therapy										
1.5	Effective Date: 06/08/2023	Updated to require physicians provide clinical outcomes data using the Audaire Health platform										
1.4	Effective Date: 08/04/2022	Updated to align criteria across all CAR-T policies										
1.3	Effective Date: 08/12/2021	New policy This policy replaces previously approved criteria that was embedded in Chimeric Antigen Receptor-T Cell Class policy which will be retired										
1.2	Effective Date: 05/06/2021	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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.1	Effective Date: 04/20/2021	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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.0	Effective Date: 04/05/2021	UM medical management system update for BCNA and MAPPO <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>No</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	Yes	BCNA	Yes
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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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Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021