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.

Effective Date: 08/12/2021

Abecma® (idecabtagene vicleucel)

FDA approval: 03/26/2021
HCPCS: J3590
Benefit: Medical

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 4 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 not have the following
      i. ECOG performance status of greater than 2
      ii. Known central nervous system involvement with myeloma as determined by appropriate testing. Examples include: MRI and/or CSF analysis (including cytology plus molecular analysis, for example FISH)
      iii. Active infection including hepatitis B, hepatitis C, HIV, or systemic fungal, bacterial, or viral infection
      iv. Creatinine clearance < 45 mL/min
      v. Alanine aminotransferase > 2.5 times upper limit of normal
      vi. Left ventricular ejection fraction < 45%
      vii. Absolute neutrophil count < 1000 cells/mm^3
      viii. Platelets < 50,000/mm^3

ix. Second malignancies in addition to myeloma if the second malignancy has required therapy in the last 3 years or is not in complete remission

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 prescriber needs to submit documentation of response to Abecma within 3 months following therapy as a follow-up to the prior approval request

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 Limit: Align with FDA recommended dosing

b. Authorization Period: 2 months with the allowance of only one dose per lifetime

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

***Note: Coverage 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.

Therapeutic considerations:

A. **FDA approved indication / Diagnosis**

**Please refer to most recent prescribing information.*

B. **Background Information**

a. 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.

b. 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.

c. 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.

d. 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 four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

e. Safety and efficacy were established in the KarMMa trial, an open-label, single-arm, multicenter study of 127 patients with relapsed or refractory multiple myeloma who had received at least three prior lines of therapy including 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/mm^3 and platelet count less than 50,000/mm^3. Patients were required to have measurable disease. The primary endpoints included overall response rate (ORR), complete response (CR), and duration of response (DOR). The ORR was 72% (95% CI: 62 - 81) with 28% of patients achieving a stringent complete response (sCR; 95% CI: 19 - 38). Responses were rapid and durable with a median time to response of 30 days (range: 15 to 88 days) and median duration of response of 11 months (95% CI: 10.3 – 11.4) for all responders and 19 months (95% CI: 11.4 – NE) for those who achieved a sCR. Of the 28 patients who achieved sCR, an estimated 65% (95% CI: 42% - 81%) had remission lasting at least 12 months.

f. 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).

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

**Please refer to most recent prescribing information.*

E. **Dosing and administration**

**Please refer to most recent prescribing information.*

F. **How supplied**

**Please refer to most recent prescribing information.*

References:

1. Abecma [prescribing information]. Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; March 2021.
2. National Comprehensive Cancer Network. Multiple myeloma (Version 7.2021). 2021 April 26. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on June 17, 2021.
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.

<table>
<tr><th colspan="3">Policy/UM Medical Management System Update History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></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

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<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.*