Medical Policy

Abecma™ (idecabtagene vicleucel)	
MEDICAL POLICY NUMBER	Med_Clin_Ops_066
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Abecma™ (idecabtagene vicleucel) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Abecma will be provided for a one-time, single administration and cannot be renewed.
Dosing Limit: The patient's dose will not exceed 460 × 106 CAR-positive T cells.

1. Patient is 18 years of age or older; **AND**
2. Abecma is prescribed by or in consultation with an oncologist.; **AND**
3. Patient has a documented diagnosis of multiple myeloma; **AND**
4. Patient's disease is relapsed or refractory defined, and documented, as receiving four

(4) or more prior lines of therapy, including **all** of the following:

a. An immunomodulatory agent (e.g., Thalomid [thalidomide], Revlimid [lenalidomide], Pomalyst [pomalidomide])
b. A proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])
c. An anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab], Empliciti [elotuzumab], Sarclisa [isatuximab]); **AND**

5. Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
6. Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
7. Abecma will be administered two (2) days after completion of lymphodepletion (low-dose fludarabine [30 mg/m2 IV infusion] and cyclophosphamide [300 mg/m2 IV infusion] for 3 days); **AND**
8. Patient will receive Abecma at a treatment center that is certified to administer Abecma therapy; **AND**
9. Treatment center has enrolled in the Abecma REMS and training has been given to providers on the management of cytokine release syndrome (CRS), neurological toxicities (NT), and hemophagocytic lymphohistiocytosis/Macrophage Activation Syndrome; **AND**
10. Patient will be monitored for signs and symptoms of CRS and NT daily for at least 4 weeks after treatment with Abecma and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
11. Patient will stay within proximity (within 2 hours) of the Abecma infusion center for at least 4 weeks following infusion.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. History of chimeric antigen receptor therapy (CAR-T) or other genetically modified T-cell therapy.
3. Patient with clinically significant active systemic infection or inflammatory disorders.

BACKGROUND

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.

DEFINITIONS

1. ABECMA (idecabtagene vicleucel), suspension for intravenous infusion. Initial U.S. Approval: 2021
    a. ABECMA is supplied in one or more infusion bag(s) (see below) containing a frozen suspension of genetically modified autologous T cells in 5% DMSO.

b. Each infusion bag of ABECMA is individually packed in a metal cassette. ABECMA is stored in the vapor phase of liquid nitrogen and supplied in a liquid nitrogen dry vapor shipper. An RFI Certificate is affixed inside the shipper.
   i. 50 mL infusion bag and metal cassette (NDC 59572-515-01)
   ii. 250 mL infusion bag and metal cassette (NDC 59572-515-02)
   iii. 500 mL infusion bag and metal cassette (NDC 59572-515-03)

CODING

Applicable NDC Codes	
59572-0515-01	Abecma (idecabtagene vicleucel) 50 mL infusion bag and metal cassette
59572-0515-02	Abecma (idecabtagene vicleucel) 250 mL infusion bag and metal cassette
59572-0515-03	Abecma (idecabtagene vicleucel) 500 mL infusion bag and metal cassette

Applicable Procedure Code	
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose. Q-Code effective date: 01/01/2022

Applicable ICD-10 Codes	
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
Z51.12	Encounter for antineoplastic immunotherapy

EVIDENCE BASED REFERENCES

1. Abecma suspension for intravenous infusion [prescribing information]. Summit, NJ: Bristol-Myers Squibb; June 2021.

POLICY HISTORY

Approved by P&T Committee 2/28/23

Original Effective Date	July 19, 2021
Revised Date	• January 7, 2022 – Added Q-Code (Q2055): Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose Effective Date: January 1, 2022 • February 28, 2023 – Annual review