Medical Drug Clinical Criteria

Subject:	Abecma (idecabtagene vicleucel)		
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Overview

This document addresses the use of Abecma (idecabtagene vicleucel), an autologous chimeric antigen receptor (CAR) T-cell therapy, for relapsed or refractory multiple myeloma.

The FDA approved indication for Abecma is 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.

Abecma (idecabtagene vicleucel) is a first-in-class CAR-T cell therapy with B-cell maturation antigen (BCMA)-targeting single-domain antibodies for individuals with multiple myeloma. Abecma works by binding to the BCMA protein, which is widely expressed on malignant plasma cells in multiple myeloma, leading to cancer cell death.

Abecma has a black box warning for cytokine release syndrome (CRS) and should not be administered in patients with active infection or inflammatory disorders due to risk of life-threatening reactions and death. Severe or life-threatening CRS should be treated with tocilizumab with or without corticosteroids. Abecma also has black box warning for causing neurological toxicities, which could also be severe and life-threatening. Monitoring for neurological events after administration is recommended. Additionally, there are black box warnings for hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), including fatal and life-threatening reactions, and warnings regarding prolonged cytopenias with bleeding and infection, including fatal outcomes. Due to these black box warnings, Abecma is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the following uses:

- Multiple myeloma

Definitions and Measures
Allogeneic cells: Harvested from a histocompatible donor.
Autologous cells: Harvested from the individual's own cells.
Bone marrow: A spongy tissue located within flat bones, including the hip and breast bones and the skull. This tissue contains stem cells, the precursors of platelets, red blood cells, and white cells.
Chemotherapy: The medical treatment of a disease, particularly cancer, with drugs or other chemicals.
Chimerism: Cell populations derived from different individuals; may be mixed or complete.
Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

Cytotoxic: Treatment that is destructive to cells, preventing their reproduction or growth.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Hematopoietic stem cells: Primitive cells capable of replication and formation into mature blood cells in order to repopulate the bone marrow.
Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Abecma (idecabtagene vicleucel)

Requests for Abecma (idecabtagene vicleucel) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of relapsed or refractory multiple myeloma; **AND**
III. If individual has a history of an allogeneic stem cell transplant, there are no current signs of active graft versus host disease (GVHD);
AND
IV. Individual has adequate bone marrow reserve defined by *all* of the following:
    A. Absolute neutrophil count (ANC) ≥ 1000 cells/uL; **AND**
    B. Platelet count ≥ 50,000 cells/uL; **AND**
III. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; **AND**
IV. Individual has not received prior treatment with CAR T-cell or B-cell maturation antigen (BCMA) targeted therapy; ~~**OR**~~**AND**
V. Individual is using as a one-time, single administration treatment.

Abecma (idecabtagene vicleucel) may not be approved for the following (Protocol for Munshi NC et al 2021):

I. Repeat administration; **OR**
II. Active presence or history of central nervous system involvement with myeloma; **OR**
III. Presence or history of plasma cell leukemia; **OR**
IV. Individual has solitary plasmacytomas or non-secretory myeloma without other evidence of measurable disease; **OR**
V. Using in combination with other chemotherapy agents (not including the use of lymphodepleting chemotherapy prior to infusion); **OR**
VI. If prescribe in combination with other CAR T-cell immunotherapy (e.g. Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta); **OR**
VII. Individual has active GVHD; **OR**
VIII. History of chimeric antigen receptor therapy or other genetically modified T-cell therapy; **O**
IX. History of cardiac conditions, such as New York Heart Association (NYHA) stage III or IV congestive heart failure, myocardial infarction or coronary artery bypass graft (CABG) within the past 6 months, history of clinically significant ventricular arrhythmia or unexplained syncope, not believed to be vasovagal in nature or due to dehydration, or history of severe non-ischemic cardiomyopathy; **OR**
X. Left ventricular ejection fraction (LVEF) less than 45% (scan performed ~~≤~~within 8 weeks of leukapheresis); **OR**
XI. Active hepatitis B, active hepatitis C, human immunodeficiency virus (HIV) positive, or other active, uncontrolled infection; **OR**
XII. When the above criteria are not met, and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
Q2055	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.
ICD-10 Diagnosis	
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
Z51.12	Encounter for antineoplastic immunotherapy

Document History

Revised: 11/19/2023
Document History:

- 11/19/2023 – Annual Review: Clarified RN III to state “current” signs of active GVHD are not present. Replaced “OR” with “AND” between RN VIII and IX to ensure appropriate use. Clarified criteria around apheresis in may not be approved criteria. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: Update criteria to simplify diagnosis criteria to R/R MM; add criteria about prior CAR T-cell therapy or B-cell maturation antigen therapy; add language to the may not be approved criteria: individual has active or primary CNS disease, combination therapy with another CAR T-cell therapy, and individual has active GVHD. Added language to existing criteria for those with a history of an allogenic stem cell transplant. Clarified cardiac criteria for consistency across CAR T agents. Removed requirements for CrCl ≤ 45 ml/min and ALT levels. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: Update criteria to require progression of disease after 4 lines of prior therapy per label and guidelines. Formatting changes. Coding Reviewed: Added HCPCS Q2055 Effective 1/1/2022. Removed J3490, J3590, J9999, C9081 Effective 12/31/2021. Added ICD-10-CM codes C90.00, C90.02, Z51.12.
- 05/21/2021 – Select Review: No changes. Coding Reviewed: No changes. Effective 10/1/2021 Added HCPCS code C9081. Deleted HCPCS code C9399. Added ICD-10-CM C90.00-C90.02.
- 03/31/2021 – Annual Review: Add new clinical criteria document for Abecma (idecabtagene vicleucel). Coding update: Added HCPCS C9399, J3490, J3590, J9999, Added All diagnoses pend.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.