MetroPlus Health

Policy and Procedure

Title: Abecma (idecabtagene vicleucel)	Division: Medical Management Department: Utilization Management
Approval Date: 4/26/2022	LOB: Medicaid, HIV SNP, HARP, CHP, MetroPlus Gold, GoldCare, Marketplace, Essential
Effective Date: 4/26/2022	Policy Number: UM-MP334
Review Date: 4/23/2024	Cross Reference Number:
Retired Date:	Page 1 of 5

I. POLICY DESCRIPTION:

Medical Oncology – CAR-T immunotherapy, Abecma (idecabtagene vicleucel)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

III. DEFINITIONS:

Abcema is a chimeric antigen receptor (CAR)-positive T-cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain, and a 4-1BB costimulatory domain. Antigen-specific activation of ABECMA results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells.

Abecma is 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.

All other uses for Abecma are considered experimental and investigational.

IV. POLICY:

For the Medicare and UltraCare lines of business, MetroPlusHealth determines medical necessity based on applicable Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD).
https://www.cms.gov/medicare-coverage-database/search.aspx

For all non-Medicare LOBs:
Abecma will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

INITIAL REQUEST:

1. **Adult relapsed or refractory Multiple Myeloma**
   - **A.** Member is 18 years of age or older;
   - **AND**

B. Member has a diagnosis confirmed by submitted documentation including clinical chart notes of relapsed or refractory Multiple Myeloma;

AND

C. Member has received prior treatment with at least FOUR prior lines of therapy, including at least ONE drug from ALL of the following categories:

- **a.** Immunomodulatory agent (e.g., Thalomid (thalidomide capsules), Revlimid (lenalidomide capsules), Pomalyst (pomalidomide capsules));

  AND

- **b.** Proteasome inhibitor (e.g., Velcade (bortezomib injection), Kyprolis (carfilzomib injection), Ninlaro (ixazomib capsules));

  AND

- **c.** Anti-CD38 monoclonal antibody (e.g., Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous infusion));

AND

D. Member has measurable disease shown by at least ONE of the following:

- **a.** Serum monoclonal paraprotein (M-protein) ≥ 1 g/dL;

  OR

- **b.** Urine M-protein ≥ 200 mg/24 hours;

  OR

- **c.** Serum immunoglobulin free light chain ≥ 10 mg/dL and abnormal serum free light chain ratio;

AND

E. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

AND

F. Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

AND

G. Member has not received any live vaccines within the past 6 weeks;

AND

H. Member does not have an active systemic infection or inflammatory disorder**;**

AND

I. Member has not previously been treated with Abecma or any other CAR-T therapy;

AND

J. The requesting provider belongs to a healthcare facility that has enrolled in the

Abecma REMS (Risk Evaluation and Mitigation Strategy) program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (treatment centers can be found here);

AND

K. Authorization is for no more than one dose

RENEWAL REQUEST:

Repeat administration of Abecma is investigational and will not be covered.

V. LIMITATIONS/ EXCLUSIONS:

- Repeat administration of Abecma is considered to be experimental or investigational because there have been no established studies to demonstrate effectiveness
- History of central nervous system (CNS) disease (such as (such as seizure or cerebrovascular ischemia)
- Requiring ongoing treatment with chronic immunosuppression

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
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

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
Z51.12	Encounter for antineoplastic immunotherapy

VIII. REFERENCES:

1. Abecma [package insert]. Summit, NJ: Celgene Corporation; January 2024.
2. Munshi NC, Anderson LD, Shah N, et al. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. N Engl J Med. 2021; 348(8): 705-716.
3. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 3.2024; March 8, 2024).© 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org.

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REVISION LOG:

REVISIONS	DATE
Creation date	4/14/2022
Annual review	4/25/2023
Annual review	4/23/2024
Update LOBs to remove Medicare and Ultracare	8/9/2024

Approved: **Date:**

David Ackman

Digitally signed by David Ackman
Date: 2024.08.29 09:58:01 -04'00'

David Ackman, MD **VP of Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.