Medical Policy:

Abecma® (idecabtagene vicleucel) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.330	March 3, 2025	June 9, 2021

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth 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). EmblemHealth 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 and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. 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 web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Abecma, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, 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. Abecma is supplied in one or more frozen infusion bags contain a suspension of genetically modified autologous chimeric antigen receptor (CAR)-positive T-cells in 5% dimethyl sulfoxide. Abecma is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Abecma REMS.

Length of Authorization

Coverage will be provided for one treatment course (1 dose of Abecma) and may not be renewed.

Dosing Limits [Medical Benefit]

- 1 dose of up to 510 million autologous CAR-positive viable T-cells *(supplied as one or more infusion bags in metal cassettes)*

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 dose of up to 510 million autologous CAR-positive viable T-cells)

Guideline

****For Medicare members – Abecma-please refer to our separate LCD/NCD Medicare criteria**

I. INITIAL CRITERIA

1. **Multiple Myeloma, relapsed or refractory:**

   Approve a single dose if the patient meets the following criteria (A, B, C, D, E, F, and G):

   A. Patient is ≥ 18 years of age; **AND**
   B. The medication is prescribed by or in consultation with an oncologist or hematologist; **AND**
   C. The administering facility has been certified to dispense Abecma and is enrolled in the Abecma REMS program; **AND**
   D. Patient has not been previously treated with chimeric antigen receptor (CAR-T) therapy; **AND**
      Note: CAR-T therapy includes Abecma, Breyanzi® (lisocabtagene maraleucel suspension for intravenous infusion), Kymriah® (tisagenlecleucel suspension for intravenous infusion), Tecartus™ (brexucabtagene suspension for intravenous infusion), and Yescarta® (axicabtagene suspension for intravenous infusion); **AND**
   E. Patient does not have an active infection or inflammatory disorder; **AND**
   F. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during idecabtagene vicleucel treatment, and until immune recovery following treatment; **AND**
   G. Patient has been screened for cytomegalovirus (CMV), 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**
   H. Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
   I. Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
   J. Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant CNS pathology; **AND**
   K. Patient does not have active or a history of plasma cell leukemia; **AND**
   L. Patient has an ECOG performance status of 0-1; **AND**
   M. Patient has received two or more lines of systemic therapy, including one from at least **TWO** of the following (i, ii, and iii):
      i. Patient has received an **immunomodulatory agent**; **AND**
      Note: Immunomodulatory agents include Thalomid® (thalidomide capsules), Revlimid® (lenalidomide capsules), Pomalyst® (pomalidomide capsules).
      ii. Patient has received a **proteasome inhibitor**; **AND**
      Note: Proteasome inhibitors include Velcade® (bortezomib injection), Kyprolis® (carfilzomib injection), Ninlaro® (ixazomib capsules).
      iii. Patient has received an **anti-CD38 monoclonal antibody**; **AND**
      Note: Anti-CD38 monoclonal antibodies include Darzalex® (daratumumab intravenous infusion), Darzalex Faspro™ (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa® (isatuximab-irfc intravenous infusion).
   N. The requested use is supported by FDA-approved prescribing information **OR** the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

Limitations/Exclusions:

1. Abecma is not indicated for the treatment of patients with primary central nervous system lymphoma.

Applicable Procedure Codes

Code	Description
Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Applicable NDCs

Code	Description
59572-0515-02	Infusion bag 250 mL
59572-0515-03	Infusion bag 500 mL
59572-0515-01	Infusion bag 50 mL

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/3/2025	Annual Review: Updated dosing limits. Removed Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Abecma; from initial therapy. **Addition of** Patient does not have an active infection or inflammatory disorder; **AND** Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during idecabtagene vicleucel treatment, and until immune recovery following treatment; **AND** Patient has been screened for cytomegalovirus (CMV), 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** Prophylaxis for infection will be followed according to standard institutional guidelines; **AND** Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND** Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant CNS pathology; **AND**Patient does not have active or a history of plasma cell leukemia; **AND** Patient has an ECOG performance status of 0-1. Addition of dosing/administration chart.
EmblemHealth & ConnectiCare	5/2/2024	Annual Review: Updated dosing limits. Added the following statement: "**For Medicare members – Abecma-please refer to our separate LCD/NCD

		Medicare criteria" Initial Criteria: Multiple Myeloma, relapsed or refractory: Updated the following from "four" or more lines to two as follows: "Patient has received two or more lines of systemic therapy, including one from at least TWO of the following (i, ii, and iii):" Added Limitations/Exclusions: Abecma is not indicated for the treatment of patients with primary central nervous system lymphoma.
EmblemHealth & ConnectiCare	7/19/2023	Added coverage back to the Medicaid population; added codes C90.10, C90.12, C90.20, C90.22, C90.30, C90.32 and Z85.79. Removed code: Z51.12
EmblemHealth & ConnectiCare	04/07/2023	Annual Review – No Change
EmblemHealth & ConnectiCare	01/01/2023	Removed coverage from our Medicaid population.
EmblemHealth & ConnectiCare	07/05/2022	Annual Review. Multiple Myeloma: Added "or plan to receive" to the requirement that the patient has received lymphodepleting chemotherapy prior to infusion of Abcema
EmblemHealth & ConnectiCare	3/17/2022	Updated Procedure Code to Q2055 and put on new template
EmblemHealth & ConnectiCare	6/9/2021	New Policy

References

1. ABECMA® (idecabtagene vicleucel) suspension for intravenous infusion [package insert]. Summit, NJ. Celgene Corporation. Updated June 25, 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b90c1fe7-f5cc-464e-958a-af36e9c26d7c. Accessed April 16, 2021.
2. ABECMA® (idecabtagene vicleucel). IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated April 7, 2021. Accessed April 16, 2021.