Abecma® (idecabtagene vicleucel)
(Intravenous)

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I. Length of Authorization

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

Coverage and policy application may be contingent on federal or state laws or regulations. In the event of a conflict between this policy and applicable federal or state laws or regulations, state law should apply.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 dose of up to 460 million autologous CAR-positive viable T-cells *(supplied as one or more infusion bags in metal cassettes)*

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

- 1 billable unit (1 dose of up to 460 million autologous CAR-positive viable T-cells)

III. Initial Approval Criteria [1-7]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Healthcare facility has enrolled in the ABECMA REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**

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- Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy; **AND**
- 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; **AND**

Multiple Myeloma † Φ [1-3]

- Patient has relapsed or refractory disease; **AND**
- Patient has received at least four (4) prior therapies, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide, etc.), and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration [1]

Indication	Dose
Multiple Myeloma	<u>Lymphodepleting chemotherapy</u>: • Administer cyclophosphamide 300 mg/m^2 and fludarabine 30 mg/m^2 intravenously daily for three days. <u>Abecma infusion</u>: • Infuse 2 days after completion of lymphodepleting chemotherapy. Delay the infusion up to 7 days if a patient has unresolved serious adverse events, active infections, or inflammatory disorders.

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	• A single dose of Abecma contains a cell suspension of 300 to 460 x 10^6 chimeric antigen receptor (CAR)-positive T cells in one or more infusion bags.
For autologous use only. For intravenous use only. • Abecma is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. • One treatment course consists of lymphodepleting chemotherapy followed by an infusion of one or more bags of Abecma. • Confirm Abecma availability prior to starting the lymphodepleting regimen. • Confirm the patient's identity with the patient identifiers on the shipper and the respective Certificate of Release for Infusion (RFI Certificate) prior to infusion.	
<u>Premedication:</u> • Premedicate with acetaminophen (650mg orally) and diphenhydramine (12.5 mg IV, 25-50 mg orally, or another H1-antihistamine) 30-60 minutes prior to infusion. Avoid prophylactic system corticosteroids which may interfere with Abecma activity. <u>Monitoring after infusion</u>: • Monitor patients daily at a certified healthcare facility during the first week following infusion for signs and symptoms of CRS and neurologic toxicities. • Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion. • Instruct patients to refrain from driving or hazardous activities for at least 8 weeks following infusion.	
• Store infusion bag in the vapor phase of liquid nitrogen (less than or equal to minus 130°C). Thaw prior to infusion. • In case of manufacturing failure, a second manufacturing may be attempted. • Additional chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product. • Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period. • Abecma contains human blood cells that are genetically modified with replication incompetent self-inactivating lentiviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal.	

VI. Billing Code/Availability Information

<u>HCPCS Code:</u>

- 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

<u>NDC:</u>

- Abecma suspension for intravenous infusion [A single dose of ABECMA contains a cell suspension of 300 to 460 x 10^6 CAR-positive T cells in one or more infusion bags]:
  - 50 mL, 250 mL, and 500 mL infusion bags and metal cassettes: 59572-0515-xx

VII. References

1. Abecma [package insert]. Summit, NJ; Celgene., Inc., March 2021. Accessed September 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) idecabtagene vicleucel. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network,

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Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2023.

3. Munshi NC, Anderson LD Jr, Shah N, et al. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2021 Feb 25;384(8):705-716. doi: 10.1056/NEJMoa2024850.
4. Majzner RG, Mackall CL. Tumor Antigen Escape from CAR T-cell Therapy. *Cancer Discov* 2018;8:1219-1226.
5. Lee DW, Gardner R, Porter DL, et al. Current concepts in the diagnosis and management of cytokine release syndrome. Blood 2014; 124(2): 188-95. Errata in Blood: 2015;126(8):1048. and 2016;128(11):1533.
6. Kumar S, Paiva B, Anderson KC, et al. International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma. Lancet Oncol 2016; 17(8): e328-46.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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