

Abecma[®] (idecabtagene vicleucel)



Pharmacy Coverage Policy

Effective Date: January 01, 2023

Revision Date: January 01, 2023

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Review Date: September 22, 2022

Line of Business: Medicaid - Louisiana

Policy Type: Prior Authorization

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Disclaimer Description Coverage Determination

Background Medical Terms References

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at <http://www.cms.hhs.gov/>. The member's health plan benefits in effect on the date services are rendered must be used. 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. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Abecma (idecabtagene vicleucel), a chimeric antigen receptor T cell therapy (CAR-T), is BCMA-directed for patients with multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an antiCD38 monoclonal antibody.

Multiple myeloma (MM) is a rare hematologic malignancy. National Cancer Institute's SEER data, in 2020, estimated there would be 32,270 new cases of myeloma and 12,830 people would die of this disease. This accounts for 2.1% of all Cancer deaths in U.S. The 5-year survival is at 54% while the median age is 69 years at diagnosis.

Abecma is a cell suspension for intravenous infusion. A single dose of Abecma contains a cell suspension of 300 to 460 x 10⁶ CAR-positive T cells in one or more infusion bags labeled for the specific recipient.

Coverage

Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and

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Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- **National Comprehensive Cancer Network (NCCN) Drugs and Biologics**
- **Compendium**
- **Truven Health Analytics Micromedex DrugDEX**
- **Elsevier/Gold Standard Clinical Pharmacology**
- **Wolters Kluwer Lexi-Drugs**

Abecma (idecabtagene vicleucel) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Multiple Myeloma

- **The member has a diagnosis of multiple myeloma AND**
- **The member has relapsed or refractory disease, defined by International Myeloma Working Group (IMWG) criteria AND**
- **The member has had at least four lines of previous systemic therapies including an immunomodulatory agent (e.g. lenalidomide, pomalidomide), a proteasome inhibitor (e.g. bortezomib, carfilzomib), and an anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) AND**

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may not be included. This document is for informational purposes only.

- The member is greater than or equal to 18 years of age AND
- The member will be using Abecma in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m² daily for 3 days and cyclophosphamide 300 mg/m² daily for 3 days) AND
- The member will be using Abecma (idecabtagene vicleucel) at a treatment center

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that is certified to administer Abecma (idecabtagene vicleucel)

Abecma (idecabtagene vicleucel) will be approved for 60 days duration or as determined through clinical review. A maximum of one dose per lifetime will apply.

Coverage
Limitations

Abecma (idecabtagene vicleucel) therapy is not considered medically necessary for members with the following concomitant conditions:

- The member has active hepatitis B (HBs AG-positive) or hepatitis C infection
- The member has received prior allogeneic transplant
- The member has received prior treatment with a chimeric antigen receptor T (CART) cell therapy

• Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature. Background This is a prior authorization policy about Abecma (idecabtagene vicleucel).

Refer all requests or questions regarding Abecma (idecabtagene vicleucel) to the Corporate Transplant Department at 1-866-421-5663 . Fax: 502-508-9300
Email: transplant@humana.com

Abecma (idecabtagene vicleucel) is only available at certain centers. For more information, please visit: <https://www.abecma.com/find-a-treatment-center/>.

Black Box Warnings

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- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Abecma. Do not administer Abecma to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurological toxicities, which may be severe or life-threatening, can occur following treatment with Abecma, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurological events after treatment with Abecma. Provide supportive care and/or corticosteroids as needed.**
- **Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS, including fatal life-threatening reactions, occurred in patients following treatment with Abecma.**
- **Prolonged cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with Abecma.**
- **Abecma is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.**

The American Society of Clinical Oncology HBV screening and management provisional clinical opinion (ASCO [Hwang 2020]) recommends HBV screening with hepatitis B surface antigen, hepatitis B core antibody, total Ig or IgG, and antibody to hepatitis B surface antigen prior to beginning (or at the beginning of) systemic anticancer therapy; do not delay treatment for screening/results. Detection of chronic or past HBV infection requires a risk assessment to determine antiviral prophylaxis requirements, monitoring, and follow-up.

Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. *J Clin Oncol*. 2020;38(31):3698-3715. doi:10.1200/JCO.20.01757[[PubMed 32716741](#)]

Abecma® (idecabtagene vicleucel)

Effective Date: 1/1/2023

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Provider For medically billed requests, please visit www.humana.com/PAL. Select applicable
Claims Codes Preauthorization and Notification List(s) for medical and procedural coding
information.

Medical Terms Abecma; idcabtagene vicleucel; MM; Multiple Myeloma; CAR-T; BCMA; pharmacy

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References Abecma (idecabtagene vicleucel) [prescribing information]. Celgene Corporation.
Cambridge, MA. March 2021.

Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL:
<http://www.clinicalpharmacology.com>. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated
periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo:
Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National
Comprehensive Cancer Network (NCCN); Updated periodically.

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