

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Abecma (idecabtagene vicleucel)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Abecma, approved by the FDA in 2021, is a B-cell maturation antigen (BCMA)-directed, autologous chimeric antigen receptor T-cell (CAR-T) immunotherapy. A patient's own T cells are harvested and genetically modified outside of the body. The re-engineered cells are injected back into the patient and will recognize the BCMA on the malignant plasma cells to target and kill them. Abecma is indicated for the treatment of adults with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Multiple myeloma is a cancer of the plasma cells in the bone marrow. Abecma is the first CAR-T therapy approved for multiple myeloma and the first to target the BCMA protein, whereas existing products target the CD19 protein.

Abecma (idecabtagene vicleucel) will be considered for coverage when the following criteria are met:

Multiple Myeloma

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Healthcare facility/provider has enrolled in the Abecma REMS program; AND
3. Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM); AND
4. Member has persistent disease after treatment with 2 or more prior lines of therapy, including ALL the following:
 - a) An immunomodulatory agent (e.g., Revlimid),
 - b) A proteasome inhibitor (e.g., Velcade), and
 - c) An anti-CD38 monoclonal antibody (e.g., Darzalex); AND
5. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND
6. Member has been or will be screened for CMV, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
7. **Dosage allowed/Quantity limit:** A single infusion of 300 to 460 × 10⁶ CAR-positive T cells.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Abecma will not be reauthorized for continued therapy.

CareSource considers Abecma (idecabtagene vicleucel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/22/2021	New policy for Abecma created.
05/20/2022	Added ECOG score to be consistent with other CAR-T policies. Added/updated references. Added billing code.
12/06/2024	Updated refs. Updated indication from 4 prior lines of therapy to 2 prior lines of therapy (label). Removed exclusions of prior HSCT or gene therapy (NCCN). Updated dosing (label). Changed “has been screened” to “has been or will be screened” and added CMV (label).

References:

1. Abecma [package insert] Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; 2024.
2. National Comprehensive Cancer Network. Multiple Myeloma (Version 1.2025). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed December 6, 2024.
3. Munshi NC, Anderson LD Jr, Shah N, et al. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. *N Engl J Med*. 2021;384(8):705-716. doi:10.1056/NEJMoa2024850
4. Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or Standard Regimens in Relapsed and Refractory Multiple Myeloma. *N Engl J Med*. 2023;388(11):1002-1014. doi:10.1056/NEJMoa2213614
5. Martin T, Usmani SZ, Schechter JM, et al. Updated results from a matching-adjusted indirect comparison of efficacy outcomes for ciltacabtagene autoleucel in CARTITUDE-1 versus idecabtagene vicleucel in KarMMa for the treatment of patients with relapsed or refractory multiple myeloma. *Curr Med Res Opin*. 2023;39(1):81-89. doi:10.1080/03007995.2022.2139052
6. Li J, Tang Y, Huang Z. Efficacy and safety of chimeric antigen receptor (CAR)-T cell therapy in the treatment of relapsed and refractory multiple myeloma: a systematic-review and meta-analysis of clinical trials. *Transl Cancer Res*. 2022;11(3):569-579. doi:10.21037/tcr-22-344

Effective date: 07/01/2025

Revised date: 12/06/2024