CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Abecma (idecabtagene vicleucel)
BILLING CODE	Q2055
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient hospital
STATUS	Prior Authorization Required

Abecma 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 was approved in March 2021 and is indicated for the treatment of relapsed or refractory multiple myeloma after 4 or more prior therapies. 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 4 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 does not have history of an allogeneic hematopoietic stem cell transplantation (HSCT) or treatment with any gene therapy-based therapeutic for cancer; AND
7. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
8. **Dosage allowed/Quantity limit:** A single infusion of 300 to 460 × 10^6 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.

References:

1. Abecma [package insert] Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; 2021.
2. National Comprehensive Cancer Network. Multiple Myeloma (Version 5.2022). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed May 20, 2022.
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. Martin T, Usmani SZ, Schecter JM, et al. 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 [published correction appears in Curr Med Res Opin. 2021 Oct 6;:1-12]. *Curr Med Res Opin*. 2021;37(10):1779-1788. doi:10.1080/03007995.2021.1953456
5. 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

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