Mass General Brigham
Health Plan

Abecma
(Idecabtagene vicleucel)

Policy Number: 063

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			

Abecma is a chimeric antigen receptor T cell therapy (CAR-T), designed to harness the power of the patient's immune system to recognize and attack their cancer cells. CAR-T is a type of treatment where white blood cells (T cells) are modified in a laboratory to add a gene that helps the patient's own T cells target their cancer.

FDA-Approved Indication
Abecma is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy for the treatment of:

- Adult patients with relapsed or refractory multiple myeloma after four or more lines of systemic therapy including at least one drug from each of the following categories:
  - Immunomodulatory agent
  - Proteasome inhibitor
  - Anti-CD38 monoclonal antibody

Criteria

1. Criteria for Initial Approval
   Authorization may be granted to patients 18 years of age or older for treatment of **multiple myeloma** when ALL of the following criteria are met:
   A. The disease is relapsed or refractory to treatment after four or more lines of systemic therapy.
   B. The patient did not receive a previous treatment course of the requested medication, or another B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T-cell therapy.
   C. The patient does not have active infections or inflammatory disorders.
   D. The healthcare facility that dispenses and administers Abecma must be enrolled and comply with the Abecma Risk Evaluation and Mitigation Strategy known as REMS.
   E. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

2. Required Documentation
   - Confirmed diagnosis and clinical features of the diagnosis (including laboratory results confirming the diagnosis), relevant history and physical and prior cancer treatment history.
   - Documentation of four prior lines of therapy
   - Provider/patient REMS certification/enrollment

3. Duration of Therapy
   - Single treatment course
   - Additional courses of therapy are considered experimental/investigational.

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has an **NCD for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
Q2055	Idecabtagene vicleucel, up to 460 million autologous anti-BCMA CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Effective
February 2024: Annual update.
February 2023: Annual update. Added Medicare Advantage to table. Medicare variation language added. References updated.
February 2022: Annual update. NDC Information removed. References updated.
October 2021: Code update.
September 2021: Effective Date.

References
Abecma [package insert]. Summit, NJ: Celgene Corporation; 2021.

Anderson LD Jr. Idecabtagene vicleucel (ide-cel) CAR T-cell therapy for relapsed and refractory multiple myeloma. Future Oncol. 2022 Jan;18(3):277-289. doi: 10.2217/fon-2021-1090. Epub 2021 Dec 2. PMID: 34854741.

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD): Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Implementation Date: 09/20/2021. Updated November 2020. Available: https://www.cms.gov/medicare-coverage-database/search.aspx

Delforge M, Shah N, Miguel JSF. et. al. Health-related quality of life with idecabtagene vicleucel in relapsed and refractory multiple myeloma. Blood Adv. 2022 Feb 22;6(4):1309-1318. doi: 10.1182/bloodadvances.2021005913. PMID: 34933328; PMCID: PMC8864645.

Jagannath S, Lin Y, Goldschmidt H, et al. KarMMa-RW: comparison of idecabtagene vicleucel with real-world outcomes in relapsed and refractory multiple myeloma. Blood Cancer J. 2021 Jun 18;11(6):116. doi: 10.1038/s41408-021-00507-2. PMID: 34145225; PMCID: PMC8213772.

Logue JM, Peres LC, Hashmi H, et al. Early cytopenias and infections after standard of care idecabtagene vicleucel in relapsed or refractory multiple myeloma. Blood Adv. 2022 Dec 27;6(24):6109-6119. doi: 10.1182/bloodadvances.2022008320. PMID: 35939783; PMCID: PMC9768247.

Munshi NC, Anderson LD Jr, Shah N, et al. Idecabtagene vicleucelin relapsed and refractory multiple myeloma. *N Engl J Med*. 2021;384(8):705-716.

NCCN Clinical Practice Guidelines in Oncology- Multiple Myeloma Version 3.2023- December 8, 2022. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. January 16, 2023.

Rodriguez-Otero P, Ayers D, et al. Matching adjusted indirect comparisons of efficacy outcomes for idecabtagene vicleucel (ide-cel, bb2121) versus selinexor + dexamethasone and belantamab mafodotin in relapsed and refractory multiple myeloma. Leuk Lymphoma. 2021 Oct;62(10):2482-2491. doi: 10.1080/10428194.2021.1913143. Epub 2021 Apr 24. PMID: 33896344.

Shah N, Delforge M, San-Miguel J. et al. Patient experience before and after treatment with idecabtagene vicleucel (ide-cel, bb2121): qualitative analysis of patient interviews in the KarMMa trial. Leuk Res. 2022 Sep;120:106921. doi: 10.1016/j.leukres.2022.106921. Epub 2022 Jul 21. PMID: 35930999.