Mass General Brigham
Health Plan

Carvytki™
(Ciltacabtagene autoleucel)

Policy Number: 061

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

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

- Adult patients (18 years of age or older) with relapsed or refractory multiple myeloma after four or more prior lines of therapy including:
  - Immunomodulatory agent;
  - Anti-CD38 monoclonal antibody;
  - Proteasome inhibitor.

Criteria

1. Criteria for Initial Approval
   Authorization of a single treatment 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 member has not received any prior FDA approved CAR-T cell therapy directed against B-cell maturation antigen (BCMA).
   C. The patient will receive lymphodepleting chemotherapy (cyclophosphamide and fludarabine) prior to infusion of Carvykti.
   D. The patient has stable and adequate kidney, liver, pulmonary, and cardiac function as determined by the treating oncologist or hematologist.
   E. The patient does not have clinically significant active infectious or inflammatory disorders.
   F. The patient does not have active graft versus host disease.
   G. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. Any performance status above 2 can be considered on a case by case basis.
   H. The healthcare facility that dispenses and administers Carvytki must be enrolled and comply with the Carvytki Risk Evaluation and Mitigation Strategy known as REMS.
   I. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

2. Required Documentation
   - 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
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (BCMA) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Effective
February 2023: Annual update. Added Medicare Advantage to table. Added age language under FDA-approved indication. Medicare variation language added. References updated.
October 2022: Coding updated.
July 2022: Effective Date.

References
Berdeja JG, Madduri D, Usmani SZ, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): A phase 1b/2 open-label study [published correction appears in Lancet. 2021 Oct 2;398(10307):1216]. Lancet. 2021;398(10297):314-324.

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

Janssen Biotech, Inc. Carvykti (ciltacabtagene autoleucel) suspension for intravenous infusion. Prescribing Information. Horsham, PA; Janssen Biotech: revised February 2022.

Martin T, Lin Y, Agha M. et al. Health-related quality of life in patients given ciltacabtagene autoleucel for relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b-2, open-label study. Lancet Haematol. 2022 Dec;9(12):e897-e905. doi: 10.1016/S2352-3026(22)00284-8. Epub 2022 Oct 7. PMID: 36215989.

National Comprehensive Cancer Network (NCCN). Multiple Myeloma. NCCN Clinical Practice Guidelines in Oncology, Version 3.2023. Plymouth Meeting, PA: NCCN, December 8, 2022. Accessed January 17, 2023.

Ri M, Suzuki K, Ishida T, Kuroda J. et. al. Ciltacabtagene autoleucel in patients with relapsed/refractory multiple myeloma: CARTITUDE-1 (phase 2) Japanese cohort. Cancer Sci. 2022 Dec;113(12):4267-4276. doi: 10.1111/cas.15556. Epub 2022 Oct 7. PMID: 36052883; PMCID: PMC9746030.