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 with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, OR
- Adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide.

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 MM when ALL of the following criteria are met:
   A. The member meets one of the following two criteria:
      - Relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, OR
      - Relapsed or refractory multiple myeloma, after at least 1 prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and refractory to lenalidomide.

   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 prior lines of therapy
   - Provider/patient REMS certification/enrollment

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

MassHealth Variation
Mass General Brigham Health Plan uses the MassHealth Drug List for coverage determinations for members of the MGB ACO. Criteria for Carvykti are found in Table 75: T-Cell Immunotherapies.

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
38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous
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 2025: Annual update. Codes updated. Updated criteria per NCCN guidelines and updated FDA indication. Updated references.

September 2024: Ad hoc update. Added MassHealth variation.
February 2024: Annual update.
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

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