Carvytki™
(Ciltacabtagene autoleucel)

Policy Number: 061

<table>
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<tr>
<th>Authorization required</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth Advantage</th>
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</thead>
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Authorization required: X

No Prior Authorization: X

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 Carvykti must be enrolled and comply with the Carvykti 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.

<table>
<thead>
<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>Q2056</td>
<td>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</td>
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Effective
February 2024: Annual update
October 2022: Coding updated.
July 2022: Effective Date.

References


