Carvykti is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell 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. Approved by the FDA in 2022, Carvykti is indicated for the treatment of relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Multiple myeloma is a cancer of the plasma cells in the bone marrow. Abecma (idecabtagene vicleucel) was the first chimeric antigen receptor (CAR) T-cell therapy approved for RRMM.

Carvykti (ciltacabtagene autoleucel) 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 Carvykti REMS program; AND
3. Member has a diagnosis of relapsed or refractory multiple myeloma; AND
4. Member’s disease has progressed within 12 months of their last line of therapy after 3 or more previous lines of therapy or were double refractory to a proteasome inhibitor and an immunomodulatory drug; AND
5. Member has received as part of previous therapy ALL of 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
6. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND
7. Member does not have any of the following:
   a) Prior treatment with CAR-T therapy (directed at any target)
   b) Prior therapy that targeted BCMA (e.g., Blenrep)
   c) History of an allogeneic stem cell transplant in the past 6 months
   d) History of an autologous stem cell transplant in the past 12 weeks
   e) Known active or prior history of central nervous system involvement.
8. **Dosage allowed/Quantity limit:** 0.5-1.0×10^6 CAR-positive viable T cells per kg of body weight, with a maximum dose of 1×10^8 CAR-positive viable T cells per single infusion.

*If all the above requirements are met, the medication will be approved for 3 months.*
For **reauthorization**:

1. Carvykti will not be reauthorized.

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**CareSource considers Carvykti (cilta-cabtagene autoleucel) 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.**

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<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/16/2022</td>
<td>New policy for Carvykti created.</td>
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**References:**


Effective date: 10/01/2022
Revised date: 05/16/2022