CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Carvykti (ciltacabtagene autoleucel)
BILLING CODE	J3490/J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient Hospital
STATUS	Prior Authorization Required

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:** $0.5\text{-}1.0\times10^{6}$ 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.

CareSource considers Carvykti (ciltacabtagene 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.

DATE	ACTION/DESCRIPTION
05/16/2022	New policy for Carvykti created.

References:

1. Carvykti [prescribing information]. Janssen Biotech, Inc.; 2022.
2. National Comprehensive Cancer Network. Multiple Myeloma (Version 5.2022). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed May 16, 2022.
3. 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. doi:10.1016/S0140-6736(21)00933-8
4. Martin T, Usmani SZ, Schecter JM, et al. Matching-adjusted indirect comparison of efficacy outcomes for ciltacabtagene autoleucel in CARTITUDE-1 versus idecabtagene vicleucel in KarMMa for the treatment of patients with relapsed or refractory multiple myeloma [published correction appears in Curr Med Res Opin. 2021 Oct 6;:1-12]. *Curr Med Res Opin*. 2021;37(10):1779-1788. doi:10.1080/03007995.2021.1953456
5. Li J, Tang Y, Huang Z. Efficacy and safety of chimeric antigen receptor (CAR)-T cell therapy in the treatment of relapsed and refractory multiple myeloma: a systematic-review and meta-analysis of clinical trials. *Transl Cancer Res*. 2022;11(3):569-579. doi:10.21037/tcr-22-344

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