PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Carvykti (ciltacabtagene autoleucel)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Carvykti, approved by the FDA in 2022, 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. Carvykti is indicated for the treatment of 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.
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 after receiving at least 1 prior line of therapy including ALL of the following:
   a) Proteasome inhibitor
   b) Immunomodulatory agent
   c) Refractory to lenalidomide; AND
5. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
6. **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.
12/09/2024	Updated refs. Changed at least 3 prior lines of therapy to at least 1 prior line of therapy (label). Removed exclusions (label, NCCN).

References:

1. Carvykti [prescribing information]. Janssen Biotech, Inc.; 2024.
2. National Comprehensive Cancer Network. Multiple Myeloma (Version 1.2025). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed December 9, 2024.
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. San-Miguel J, Dhakal B, Yong K, et al. Cilta-cel or Standard Care in Lenalidomide-Refractory Multiple Myeloma. *N Engl J Med*. 2023;389(4):335-347. doi:10.1056/NEJMoa2303379
5. Martin T, Usmani SZ, Schecter JM, et al. Updated results from a 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. *Curr Med Res Opin*. 2023;39(1):81-89. doi:10.1080/03007995.2022.2139052
6. 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

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