Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 16, 2022

CARVYKTI™ (ciltacabtagene autoleucel)

LENGTH OF AUTHORIZATION: Date of Service

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a documented diagnosis of relapsed or refractory multiple myeloma.
- Must have tried and failed at least four lines of systemic therapy including the following:
    - Proteasome inhibitors (e.g., bortezomib, Kyprolsis, Ninlaro)
    - Immunomodulatory agents (e.g., lenalidomide, Pomalyst, thalidomide)
    - Anti-CD38 monoclonal antibodies (e.g., Darzalex/Darzalex Faspro, Sarclisa)

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- A single dose of CARVYKTI™ 0.5 to 1.0 x 10^6 CAR-positive viable T cells per kg of body weight.
- Because of the risk of cytokine release syndrome (CRS) and neurologic toxicities, Carvykti is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI REMS. Further information is available at www.carvyktirems.com or 1-844-672-0067.