SENTARA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Carvykti™ (ciltacabtagene autoleucel) **(J9999/C9399) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 dose of up to 100 million autologous CAR-positive viable T-cells (supplied as an infusion bag in a metal cassette)

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 dose of up to 100 million autologous CAR-positive viable T-cells

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization Criteria:

- ❑ Member is 18 years of age or older
- ❑ Provider is an oncologist and the administrating healthcare facility has enrolled in the Carvykti™ REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- ❑ Member has **NOT** received prior CAR-T therapy
- ❑ Member has **NOT** received prior allogeneic hematopoietic stem cell transplantation (HSCT) within 6 months of therapy
- ❑ Member does **NOT** have a clinically significant active systemic infection or inflammatory disorder
- ❑ Member has **NOT** received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- ❑ Member has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- ❑ Prophylaxis for infection has been followed according to local guidelines or clinical practice
- ❑ Provider attests Carvykti™ will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- ❑ Member does **NOT** have known central nervous system involvement, including a history or presence of clinically relevant pathology, with myeloma
- ❑ Member does **NOT** have active or a history of plasma cell leukemia
- ❑ Member has an ECOG performance status of 0-1
- ❑ Member has a diagnosis of relapsed or refractory multiple myeloma
- ❑ Member has measurable disease, as demonstrated by at least **ONE** of the following:
  - ❑ Serum M-protein ≥ 1.0 g/dL
  - ❑ Urine M-protein ≥ 200 mg/24 h
  - ❑ Serum free light chain (FLC) assay: involved FLC ratio level ≥ 10 mg/dL (provided serum FLC ratio is abnormal)
- ❑ Member must have received at least 4 prior treatment regimens satisfying **ALL** of the following:
  - ❑ Past regimens must have included a proteasome inhibitor (e.g., bortezomib), an immunomodulatory agent (e.g., lenalidomide, thalidomide), and an anti-CD38 antibody (e.g., daratumumab, isatuximab)

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- ❑ Disease must be refractory to the last treatment regimen
- ❑ None of the past treatment regimens contained a BCMA-directed agent (e.g., belantamab mafodotin-blmf)

Reauthorization Criteria - Coverage cannot be renewed

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step-edit/preauthorization criteria.*

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: 5/19/2022
REVISED/UPDATED: ~~5/6/2022; 6/3/2022;~~ **6/21/2022**