SENTARA HEALTH PLANS

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: Amtagvi® (lifileucel) (J9999) (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.

Dosing Limits:

❑ **Quantity Limit (max daily dose) [NDC Unit]:**

- Amtagvi contains 7.5 x 10^9 to 72 x 10^9 viable cells suspended in 1 to 4 patient-specific infusion bag(s): 73776-0001-xx
- 1 treatment course (1 dose) per lifetime

❑ **Max Units (per dose and over time) [HCPCS Unit]:**

- A single dose of Amtagvi containing a minimum of 7.5 x 10^9 of viable cells suspended in one or more patient-specific infusion bags

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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: One treatment course (1 dose) per lifetime. Coverage may NOT be renewed

- ❑ Member is 18 years of age and older
- ❑ Provider requesting therapy is an oncologist, or a dermatologist with consult/specialty in oncology
- ❑ Member has a diagnosis of unresectable or metastatic melanoma
- ❑ Member does **NOT** have uveal melanoma
- ❑ Requested medication will be used as subsequent therapy after the following therapies:
  - ❑ Programmed cell death protein-1 (PD-1) blocking antibody
  - ❑ If BRAF V600 mutation-positive, a BRAF inhibitor with or without a MEK inhibitor
- ❑ Member does **NOT** have uncontrolled brain metastases
- ❑ Member does **NOT** have signs and symptoms of acute renal failure prior to treatment
- ❑ Member does **NOT** have hemorrhage (grade 2 or higher) within 14 days prior to therapy
- ❑ Member does **NOT** have a left ventricular ejection fraction (LVEF) less than 45% or New York Heart Association (NYHA) functional classification greater than Class 1
- ❑ Member does **NOT** have forced expiratory volume in one second (FEV1) of less than or equal to 60%
- ❑ Member does **NOT** have a clinically significant active systemic infection
- ❑ Member is deemed eligible for IL-2 (aldesleukin) therapy according to the manufacturer's prescribing label
- ❑ Member will **NOT** receive concomitant prophylactic systemic corticosteroid therapy

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Reauthorization: Coverage may NOT 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 – Proprium Rx**

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**: 5/23/2024
REVISED/UPDATED/REFORMATTED: ~~5/13/2024;~~ **6/5/2024**