# 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: Adstiladrin®** (nadofaragene firadenovec-vncg) **(J9029) (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]:**
  - Adstiladrin suspension $3 \times 10^{11}$ viral particles (vp)/mL (20 mL single-dose vial): 4 vials every three months for four doses only
  - 1 treatment = 4 vials
  - NDC: 55566-1050-01
- ❑ **Max Units (per dose and over time) [HCPCS Unit]:**
  - 1 billable unit (1 dose) every 3 months x 4 four doses

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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.

**Initial Authorization: 3 months (1 treatment)**

- ❑ Member is 18 years of age and older
- ❑ Provider requesting therapy is an oncologist, or a urologist with consult/specialty in oncology
- ❑ Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors [workup and evaluation is required to document that the member does **NOT** have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma]
- ❑ Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components)
- ❑ Member has high-risk disease that is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy evidenced by **ONE** of the following:
  - ❑ Having an initial complete response to BCG, and a relapse with CIS within 12 months of their last intravesical treatment
  - ❑ High-grade recurrence within 12 months after BCG was initiated
  - ❑ Relapse with high-grade Ta/T1 NMIBC within 6 months of their last intravesical treatment with BCG
- ❑ Member has had adequate therapy with Bacillus Calmette-Guerin (BCG) therapy which consists of two previous courses of BCG within a 12-month period, with **ONE** of the following being met:
  - ❑ Received at least five of six induction BCG instillations and at least two out of three instillations of maintenance BCG
  - ❑ Received at least two of six instillations of a second induction course
  - ❑ IF high-grade Ta/T1 without CIS, relapse is documented within 6 months of last exposure to BCG
- ❑ Requested medication will be used as a single agent in therapy, for intravesical instillation only
- ❑ Member does **NOT** have any hypersensitivity to interferon alfa

**Reauthorization: 6 months (2 treatments).** 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.

- ❑ Member continues to meet applicable initial authorization criteria
- ❑ Member has experienced disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., disseminated adenovirus infection)

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- ❑ For First Renewal: Member has a complete response (CR) to initial therapy (after 3 months) defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology
- ❑ For Subsequent Renewals: Member has **NOT** experienced a high-grade or CIS recurrence

**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**: 9/21/2023
**REVISED/UPDATED/REFORMATTED**~~: 9/11/2023;~~ **10/17/2023**