Adstiladrin® (nadofaragene firadenovec-vncg)
(Intravesical)

Document Number: SHP-0691

Last Review Date: 05/02/2024
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Dates Reviewed: 02/2023, 05/2023, 05/2024

I. Length of Authorization

Coverage will be provided initially for 3 months and may be renewed every 6 months thereafter.

II. Dosing Limits

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

- Adstiladrin suspension 3×10^{11} viral particles (vp)/mL (20 mL single-dose vial): 4 vials every 3 months

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

- 1 billable unit (1 dose) every 3 months

III. Initial Approval Criteria [1]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Medical records may be submitted via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient does not have a hypersensitivity to interferon alfa; **AND**
- Patient is not immunosuppressed or immunodeficient; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**

Bladder Cancer † ‡ [1-4]

- Patient has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ *(with or without papillary tumors)*; **AND**
- Patient has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) *(defined as persistent disease following adequate BCG therapy**, disease recurrence after an initial tumor-free state following adequate BCG therapy**, or T1 disease following a single induction course of BCG)*; **AND**
- Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); **AND**
- Patient does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma

*****Note:** Adequate BCG therapy is defined as ≥5 of 6 induction doses plus ≥2 doses of maintenance or of 2nd induction*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,4]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: disseminated adenovirus infection, etc.; **AND**
    - First Renewal: Patient 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*****; **OR**
    - Subsequent Renewals: Patient has not experienced a high-grade or CIS recurrence

*******Note: If patients with CIS do not have a complete response to treatment after 3 months or if CIS recurs, providers should consider cystectomy.*

V. Dosage/Administration [1]

Indication	Dose
Bladder Cancer	The recommended dose of Adstiladrin is 75 mL at a concentration of 3 x 10^{11} viral particles (vp)/mL by intravesical instillation once every three (3) months via a urinary catheter ***Note**:* • *Premedication with an anticholinergic is recommended before each instillation.* • *Adstiladrin is not for intravenous use, topical use, or oral administration.*

- *Adstiladrin is a non-replicating adenoviral vector-based gene therapy. Follow universal biosafety precautions for handling.*
- *Individuals who are immunosuppressed or immune-deficient, should not prepare, administer, or come into contact with Adstiladrin.*
- *Adstiladrin is provided as a sterile frozen suspension.*
- *Thaw four (4) vials of Adstiladrin at room temperature (20°C to 25°C [68°F to 77°F]) until Adstiladrin is liquid. Do not expose the vials to higher temperatures. Protect from light.*
- *Adstiladrin must be brought to room temperature (20°C to 25°C [68°F to 77°F]) prior to use.*
- *The time for thawing and bringing Adstiladrin to room temperature is approximately 8-10 h when thawing in the cardboard nest and approximately 3-5 h when thawing the vials outside the cardboard nest. DO NOT Refreeze.*
- *Once the vial thawing procedure is initiated, the vials may be stored for up to 24 hours at room temperature or refrigerated at 2°C to 8°C (36°F to 46°F). Visually inspect all 4 vials for visible particles and discoloration. The suspension is clear to slightly opalescent and may contain opalescent flecks. Do not use if visible particles or discoloration are observed. Mix gently. Do not shake.*

VI. Billing Code/Availability Information

HCPCS Code:

- J9029 – Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose; 1 billable unit = 1 dose

NDC:

- Adstiladrin suspension, with nominal concentration of 3×10^{11} viral particles (vp)/mL in a carton of four frozen single-dose vials with an extractable volume of 20 mL/vial: 55566-1050-xx

VII. References

1. Adstiladrin [package insert]. Kuopio, Finland; Ferring Pharm, Inc; September 2023. Accessed April 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for nadofaragene firadenovec. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 2.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2024.

4. Boorjian SA, Alemozaffar M, Konety BR, et al. Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial. Lancet Oncol. 2021 Jan;22(1):107-117. doi: 10.1016/S1470-2045(20)30540-4. Epub 2020 Nov 27.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC