Adstiladrin® (nadofaragene firadenovec-vncg) (Intravesical)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

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

- 1 billable unit (1 dose) every 3 months

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

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

Universal Criteria [1]

- Member does not have a hypersensitivity to interferon alfa; **AND**
- Member 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]

- Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC); **AND**
  - Member has carcinoma in situ (CIS) *(with or without papillary tumors)*; **OR**
  - Member has high-grade papillary Ta/T1 tumors without CIS; **AND**

- Member 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**
- Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); **AND**
- Member 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 either ≥2 doses of maintenance therapy or of 2nd induction therapy*

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

IV. Renewal Criteria [1,4]

Prior authorization validity may be renewed based upon the following criteria:

- Member 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: Member has a complete response (CR) to initial therapy defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; **OR**
  - Subsequent Renewals: Member has not experienced a high-grade or CIS recurrence

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.* – *All four (4) vials of Adstiladrin must be thawed and brought to room temperature (20°C to 25°C [68°F to 77°F]) prior to use. Do not expose the vials to higher temperatures (>25°C [77°F]).* – *Protect from light. DO NOT refreeze.*	

- *The vials may be moved between refrigerator and room temperature if the total storage time at each condition is not exceeded (24 hours at room temperature and 7 days refrigerated including thawing time).*
- ***When thawing in a water bath:***
  - *Frozen Adstiladrin vials will thaw in approximately 25 minutes outside the cardboard nest when placed directly in a water bath maintained at 25°C [77ºF]. Place the vials in the water bath, ensuring that the water level is sufficient to cover the product within the vials.*
  - *Following thawing, remove vials from the water bath and dry with a clean paper towel to remove any residual moisture prior to further handling.*
- ***When thawing at room temperature:***
  - *Frozen Adstiladrin vials will thaw in approximately 3 to 5 hours outside the cardboard nest when placed at room temperature (up to 25°C [77ºF]) (8 to 10 hours inside the nest).*
- ***When thawing in refrigerator:***
  - *Frozen Adstiladrin vials will thaw in approximately 4 to 5 hours outside the cardboard nest when placed in the refrigerator (up to 8°C [46ºF]) (11 to 13 hours inside the nest). Subsequent time for bringing thawed Adstiladrin to room temperature is approximately 2 hours 30 minutes outside of the cardboard nest (6 hours inside the nest).*
- *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]. Kastrup, Denmark; Ferring Pharmaceuticals; March 2026. Accessed April 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for nadofaragene firadenovec. National Comprehensive Cancer Network, 2026. 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 2026.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2026. National Comprehensive Cancer Network, 2026. 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 2026.

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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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)
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