MEDICATION POLICY:

Adstiladrin (nadofaragene firadenovec-vncg)

Generic Name: nadofaragene firadenovec-vncg

Therapeutic Class or Brand Name: Adstiladrin

Applicable Drugs: Adstiladrin (nadofaragene firadenovec-vncg)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/4/2026

Date Last Reviewed / Revised: 8/4/2026

Prior Authorization Criteria

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-muscle invasive bladder cancer (NMIBC)

i. Documentation of high-risk disease.

ii. Documentation of carcinoma in situ (CIS) with or without papillary tumors.

iii. Documentation of disease progression on or following Bacillus Calmette Guérin (BCG).

II. Minimum age requirement: 18 years old or older.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

Adstiladrin is available as a 3×10^{11} viral particles (vp)/mL intravesical instillation vial.

- Quantity limit: 4 vials per 3 months.

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

1. Adstiladrin. Prescribing Information. Ferring Pharmaceuticals; 2026. Accessed August 4, 2026. https://www.fda.gov/media/164029/download
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Prostate Cancer. Version 6.2026. Updated *July 28, 2026*. Accessed *August 4, 2026*.