MEDICATION POLICY:
Adstiladrin (nadofaragene firadenovec-vncg)

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.*

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.