

# Adstiladrin (nadofaragene firadenovec-vncg)



## Pharmacy Coverage Policy

**Effective Date:** January 19, 2024  
**Revision Date:** August 28, 2024  
**Review Date:** August 21, 2024  
**Line of Business:** Medicaid - Louisiana  
**Policy Type:** Prior Authorization

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### Products Affected

Adstiladrin intravesical suspension

### Listed Indications

Non-muscle invasive bladder cancer (NMIBC)

### Non-muscle invasive bladder cancer (NMIBC)

**Does the member meet all of the following criteria?**

Criteria #1	Member is 18 years of age or older
Criteria #2	Member has a diagnosis of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive disease, which is defined as persistent or recurrent disease following adequate BCG therapy** **Adequate BCG is defined as the administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course
Criteria #3	Member has non-muscle invasive bladder cancer (NMIBC) with documented carcinoma in situ (CIS)
Criteria #4	Member is ineligible for or has elected not to undergo cystectomy

**Does the member have any of the following exclusions? If yes, approval may not be appropriate.**

**NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.**

Exclusion #1	Member has experienced disease progression while on Adstiladrin (nadofaragene firadenovec-vncg)
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### Approval Duration

Initial	6 months or as determined by clinical review
Renewal	6 months or as determined by clinical review

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### Background

This is a prior authorization policy about Adstiladrin (nadofaragene firadenovec-vncg).

Adstiladrin (nadofaragene firadenovec-vncg) is for **intravesical instillation only**.

Adstiladrin is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

### Warnings and Precautions:

- Delaying cystectomy could lead to the development of metastatic bladder cancer, which can be lethal.
- Risk of disseminated adenovirus infection: Persons who are immunocompromised or immunodeficient may be at risk for disseminated infection from Adstiladrin due to low levels of replication-competent adenovirus. Avoid Adstiladrin exposure to immunocompromised or immunodeficient individuals.

For specific recommendations on warnings and precautions, patient monitoring and on dose adjustments, omissions, and discontinuation, please refer to the current prescribing information.

## Adstiladrin (nadofaragene firadenovec-vncg)

Effective Date: 1/19/2024

Revision Date: 8/28/2024

Review Date: 8/21/2024

Line of Business: Medicaid - Louisiana

Policy Type: Prior Authorization

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Nadofaragene firadenovec-vncg is available as Adstiladrin in a suspension for intravesical instillation, supplied as single-use vials; all vials have a nominal concentration of  $3 \times 10^{11}$  viral particles (vp)/ml.

### Provider Claim Codes

For medically billed requests, please visit [www.humana.com/PAL](http://www.humana.com/PAL). Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

### Medical Terms

Adstiladrin; Nadofaragene firadenovec-vncg; NMIBC; BCG; intravesical; gene therapy

### References

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Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; URL: <https://www.clinicalkey.com/pharmacology/>. Updated periodically.  
Merative Micromedex DRUGDEX [database online]. Ann Arbor, MI: Merative L.P.; URL: <https://www.micromedexsolutions.com/>. Updated periodically.  
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NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

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