

Nadofaragene firadenovec-vncg  
(Adstiladrin®)

Place of Service  
Office Administration  
Outpatient Facility Administration  
Outpatient Facility Infusion  
Administration  
Infusion Center Administration  
Home Infusion Administration

HCPCS: J3590

NDC:  
55566-1050-01 (carton of 4 glass vials)  
55566-1050-00 (vial of 20 mL)

Condition(s) listed in policy (see criteria for details)

- [BCG-unresponsive non-muscle invasive bladder cancer \(NMIBC\)](#)

AHFS therapeutic class: Gene therapy; antineoplastic agent

Mechanism of action: Non-replicating adenoviral vector-based gene therapy

#### (1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

#### (2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Adstiladrin® (nadofaragene firadenovec-vncg) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

##### BCG-unresponsive non-muscle invasive bladder cancer (NMIBC)

1. Diagnosis of high-risk NMIBC with carcinoma in situ (CIS), AND
2. Patient did not respond to Bacillus Calmette-Guérin (BCG) therapy

##### **Covered Doses**

Up to 75 mL of Adstiladrin at a concentration of  $3 \times 10^{11}$  viral particles (vp)/mL, instilled once every three months

##### **Coverage Period**

Indefinitely

##### **ICD-10:**

C67.0-C67.9, D09.0, Z85.51

#### (3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Adstiladrin® (nadofaragene firadenovec-vncg) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

#### (4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

#### **(5) Additional Information**

How supplied:

- $3 \times 10^{11}$  viral particles (vp)/mL in a 20 mL single dose vial
- Provided in a carton containing four vials

#### **(6) References**

- Adstiladrin® (nadofaragene firadenovec-vncg ) [Prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; 12/2022.
- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

#### **(7) Policy Update**

Date of initial review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- New policy

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*