Corporate Medical Policy: Nadofaragene firadenovec-vncg (Adstiladrin®) **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- nadofaragene firadenovec-vncg (Adstiladrin®) intravesical suspension for administration by a healthcare professional

FDA Approved Use:

- For the treatment of adults with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient is 18 years of age or older; **AND**
2. The patient has a diagnosis of non-muscle invasive bladder cancer (NMIBC) **[medical record documentation required]**; **AND**
3. The patient has carcinoma in situ (CIS) **[medical record documentation required]**; **AND**
4. The patient is Bacillus Calmette-Guérin (BCG)-unresponsive defined by ONE of the following **[medical record documentation required]**:
    a. BOTH of the following:
        i. The patient has had at least five of six doses of an initial induction course AND ONE of the following:
            1. At least two of three doses of maintenance therapy; **OR**
            2. At least two of six doses of a second induction course; **AND**
        ii. ONE of the following:
            1. The patient had persistent disease following BCG therapy; **OR**
            2. The patient had disease recurrence after an initial tumor-free state following BCG therapy; **OR**
    b. The patient has T1 disease following a single induction course of BCG; **AND**
5. The patient has had all resectable disease (Ta and T1 components) removed **[medical record documentation required]**; **AND**
6. The patient does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive, or metastatic urothelial carcinoma **[medical record documentation required]**; **AND**
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, urologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
8. The patient is NOT immunocompromised nor has immunodeficiency **[medical record documentation required]**; **AND**
9. The patient does NOT have any FDA labeled contraindications to the requested agent **[medical record documentation required]**; **AND**

10. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

    Duration of Approval: 365 days (1 year)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. The patient has had continued clinical benefit while receiving treatment with the requested agent, as demonstrated by tumor response or lack of disease progression and an acceptable toxicity profile **[medical record documentation required]**; **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, urologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
5. The patient is NOT immunocompromised nor has immunodeficiency **[medical record documentation required]**; **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent **[medical record documentation required]**; **AND**
7. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

    Duration of Approval: 365 days (1 year)

** Please note, for certain identified gene and cellular therapies such as nadofaragene firadenovec-vncg (Adstiladrin®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC** to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
nadofaragene firadenovec-vncg (Adstiladrin®) intravesical suspension	High-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) in adults with carcinoma in situ	Administer by intravesical instillation with recommended dose of 75 mL at a concentration of 3 x 10^{11} viral particles (vp)/mL, instilled once every 3 months into the bladder via urinary catheter. Allow instillation to be left	J9029	5

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
	(CIS) with or without papillary tumors	in the bladder for 1 hour following administration.		

***Maximum units allowed for duration of approval**

Other revenue codes that may be applicable to this policy: 0891, 0892

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q3 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). Added Gene/Cellular Therapy distribution channel management language according to benefit booklet for clarity. **Policy notification given 2/1/2026 for effective date 4/1/2026**.
November 2025: Criteria update: Minor formatting updates with no change to policy intent.
July 2023: Coding change: Added HCPCS code J9029 to dosing reference table effective 7/1/2023; deleted C9399, J3490, J3590, and J9999 termed 6/30/2023. Updated maximum units based on code definition.
March 2023: Original medical policy criteria issued.