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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 2, 2023
Subject:	Adstiladrin	**Page:**	1 of 4

Last Review Date: March 7, 2025

Adstiladrin

Description

Adstiladrin (nadofaragene firadenovec-vncg)

Background
Adstiladrin (nadofaragene firadenovec-vncg) is a non-replicating adenoviral vector-based gene therapy designed to deliver a copy of a gene encoding a human interferon-alfa 2b (INFα2b) to the bladder urothelium. Intravesical instillation of Adstiladrin results in cell transduction and transient local expression of the INFα2b protein that is anticipated to have anti-tumor effects (1).

Regulatory Status
FDA-approved indication: Adstiladrin is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors (1).

Delaying cystectomy could lead to the development of metastatic bladder cancer, which can be lethal (1).

Patients 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 (1).

The safety and effectiveness of Adstiladrin in patients less than 18 years of age have not been established (1).

Related Policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Adstiladrin may be considered **medically necessary** if the conditions indicated below are met.

Adstiladrin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)

AND ALL of the following:

1. Bacillus Calmette-Guerin (BCG)-unresponsive
2. Patient is considered high-risk

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Adstiladrin (nadofaragene firadenovec-vncg) is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. Delaying cystectomy could lead to metastatic bladder cancer, which can be lethal. Adstiladrin exposure should be avoided in immunocompromised or immunodeficient individuals (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Adstiladrin while maintaining optimal therapeutic outcomes.

References

1. Adstiladrin [package insert]. Kastrup, Denmark: Ferring Pharmaceuticals; August 2024.
2. NCCN Drugs & Biologics Compendium® Nadofaragene firadenovec-vncg 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.

Policy History

Date	Action
June 2023	Addition to PA
September 2023	Annual review
December 2023	Annual review and reference update
March 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.