UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Intravesical) – Adstiladrin Utilization Management Medical Policy
- Adstiladrin® (nadofaragene firadenovec-vncg intravesical suspension – Ferring)

REVIEW DATE: 04/30/2025

OVERVIEW
Adstiladrin, a non-replicating adenoviral vector-based gene therapy, is indicated for the treatment of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive **bladder cancer** (NMIBC) with carcinoma *in situ* (CIS) with or without papillary tumors in adults.[1]

Guidelines
The National Comprehensive Cancer Network (NCCN) **bladder cancer** clinical guidelines (version 1.2025 – March 25, 2025) recommend Adstiladrin for the treatment of BCG-unresponsive, high-risk NMIBC with CIS with or without papillary tumors (category 2A) and BCG-unresponsive, high-risk NMIBC with high-grade papillary Ta/T1 tumors without CIS (category 2B) as initial treatment or for cytology-positive, imaging- and cystoscopy-negative, recurrent or persistent disease.[2,3]

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Adstiladrin. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Adstiladrin as well as the monitoring required for adverse events and long-term efficacy, approval requires Adstiladrin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Adstiladrin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Non-Muscle Invasive Bladder Cancer.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy: Approve for 4 months to allow 2 doses to be given (3 months apart) if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has carcinoma in situ (CIS); OR
       - **b)** Patient has high-grade papillary Ta/T1 tumors without CIS; AND
     - **iv.** Medication is prescribed by or in consultation with a urologist or an oncologist; OR

B) Patient is currently receiving Adstiladrin: Approve for 3 months to allow a single dose to be administered 3 months after the most recent dose if the patient meets BOTH of the following (i and ii):
- **i.** Patient meets ONE of the following (a or b):
  - **a)** Patient is in remission both on cytology and cystoscopic examination; OR
  - **b)** Patient has cytology-positive, imaging- and cystoscopy-negative, recurrent or persistent disease; AND
- **ii.** Medication is prescribed by or in consultation with a urologist or an oncologist.

Dosing. Approve 75 mL of Adstiladrin instilled into the bladder with a urinary catheter once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Adstiladrin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Adstiladrin intravesical suspension [prescribing information]. Kastrup, Denmark: Ferring; August 2024.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – March 25, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 4, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nadofaragene. Accessed on April 4, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/14/2023
Early Annual Revision	**Non-Muscle Invasive Bladder Cancer:** Approval duration changed from 1 year to approve for the duration noted. Added criterion for Initial therapy approval for 4 months and removed option for approval that the patient has cytology- and bladder biopsy-positive, imaging and cystoscopy negative, recurrent or persistent disease. Added option for approval for 3 months for patients currently receiving Adstiladrin if the medication is prescribed by or in consultation with a urologist or an oncologist and the patient is either in remission or has cytology-positive, imaging and cystoscopy-negative, recurrent or persistent disease.	05/08/2024
Update	04/04/2025: The policy name was changed from "Oncology (Other) – Adstiladrin UM Medical Policy" to "Oncology (Intravesical) – Adstiladrin UM Medical Policy".	NA
Annual Revision	**Non-Muscle Invasive Bladder Cancer:** For the requirement that the patient has carcinoma in situ, removed "with or without high-grade papillary Ta/T1tumors".	04/30/2025