Utilization Review Policy 310

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

EFFECTIVE DATE: 11/15/2023
LAST REVISION DATE: 06/14/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

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 2.2023 – April 25, 2023) 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- and bladder-biopsy 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 Adstilladrin is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Non-Muscle Invasive Bladder Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has carcinoma *in situ* (CIS) with or without high-grade papillary Ta/T1 tumors; OR
     - **ii.** Patient has high-grade papillary Ta/T1 tumors without CIS; AND
   - **D)** Medication is used for ONE of the following (i or ii):

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i. Initial treatment; OR
ii. Cytology- and bladder-biopsy positive, imaging- and cystoscopy-negative, recurrent or persistent disease; AND

E) Medication is prescribed by or in consultation with an 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; December 2022.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 9, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nadofaragene. Accessed on June 9, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/14/2023