PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Other) – Adstiladrin Prior Authorization Policy
- Adstiladrin® (nadofaragene firadenovec-vncg intravesical suspension – Ferring)

REVIEW DATE: 05/08/2024

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 3.2024 – April 16, 2024) 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 prescription benefit coverage of Adstiladrin. 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

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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) with or without high-grade papillary Ta/T1 tumors; 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.
   - **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.

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; September 2023.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – April 16, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 30, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nadofaragene. Accessed on April 30, 2024.