

# STANDARD MEDICARE PART B MANAGEMENT

## ADSTILADRIN (nadofaragene firadenovec-vncg)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Adstiladrin is 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Bladder Cancer**

Authorization of 12 months may be granted for treatment of bladder cancer when all of the following criteria are met:

1. The member has non-muscle invasive bladder cancer
2. The disease is high-risk
3. The disease is Bacillus Calmette-Guerin (BCG)-unresponsive

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with the requested medication
2. The requested medication is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy. Benefit is defined as:
  - i. No evidence of unacceptable toxicity while on the current regimen AND
  - ii. No evidence of disease recurrence while on the current regimen

Reference number(s)
5714-A

#### IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Adstiladrin.
2. The available compendium
  - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - b. Micromedex DrugDex
  - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
  - d. Lexi-Drugs
  - e. Clinical Pharmacology
3. NCCN Guideline: Bladder cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Adstiladrin are covered.

#### V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

#### VI. REFERENCES

1. Adstiladrin [package insert]. Kastrup, Denmark: Ferring Pharmaceuticals; December 2022.