Reference number(s)
5714-A

Standard Medicare Part B Management Adstiladrin

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adstiladrin	nadofaragene firadenovec-vncg

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 Indications[1]

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.

Compendial Use[2]

Non-muscle invasive bladder cancer without carcinoma in situ

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

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Coverage Criteria

Bladder Cancer[1,2]

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

- The member has non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) or high-grade papillary Ta/T1 tumor without CIS
- The disease is high-risk
- The disease is Bacillus Calmette-Guerin (BCG)-unresponsive

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:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease recurrence while on the current regimen

Summary of Evidence

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

- The prescribing information for Adstiladrin.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- 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 in addition to high-risk NMIBC with high-grade papillary Ta/T1 tumors without CIS.

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Explanation of Rationale

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

Support for using Adstiladrin to treat high-risk NMIBC with high-grade papillary Ta/T1 tumors without CIS can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Adstiladrin [package insert]. Kastrup, Denmark: Ferring Pharmaceuticals; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed May 19, 2025.

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