Medical Drug Clinical Criteria

Subject:	Adstiladrin (nadofaragene firadenovec-vncg)		
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Overview

This document addresses the use of Adstiladrin (nadofaragene firadenovec-vncg), a novel adenovirus vector-based gene therapy, for the treatment of adult patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. This is the first gene therapy approved in bladder cancer.

National Comprehensive Cancer Network (NCCN) provides a 2A recommendation for the following:

- Used for the treatment of patients with BCG-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors:
  - as initial management
  - for cytology-positive, imaging- and cystoscopy-negative, bladder positive recurrent or persistent disease

Adstiladrin is an intravesical therapy that is administered every 3 months. It is designed to deliver a copy of the interferon-alfa 2b (*IFNα2b*) gene to the bladder urothelium, leading to transient local expression of IFNα2b, which is thought to have anti-tumor effects.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Adstiladrin (nadofaragene firadenovec-vncg)

Requests for Adstiladrin (nadofaragene firadenovec-vncg) may be approved if the following criteria are met:

I. Individual is 18 years of age or older (Label); **AND**
II. Individual is using as intravesical instillation; **AND**
III. Individual has a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive or intolerant, high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors; **AND**
IV. Individual is using in one of the following ways (NCCN 2A):
    A. Individual is using as initial management; **OR**
    B. Individual is using for treatment of recurrent or persistent disease that is bladder cytology-positive, imaging-negative, and cystoscopy-negative.

Requests for Adstiladrin (nadofaragene firadenovec-vncg) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Adstiladrin (nadofaragene firadenovec-vncg) Quantity Limits

Drug	Limit
Adstiladrin (nadofaragene firadenovec-vncg) 3 $X10^{11}$ viral particles (vp)/mL vial	4 vials every 90 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose [Adstiladrin]

ICD-10 Diagnosis

C67.0-C67.9	Malignant neoplasm of bladder
Z51.11-Z51.12	Encounter for antineoplastic immunotherapy

Document History

Revised: 02/23/2024
Document History:

- 02/23/2024 – Annual Review: Add criteria for 2A recommendation from NCCN for treatment in cytology positive, imaging-and cystoscopy-negative, bladder positive recurrent or persistent disease. Coding Reviewed: No Changes.
- 08/18/2023 – Select Review: Update QL to 4 vials per 90 days. Coding Reviewed: No changes.
- 02/24/2023– Select Review: New criteria document for Adstiladrin (nadofaragene firadenovec-vncg) gene therapy. Coding Reviewed: Added J9999. All diagnoses pend. Effective 7/1/2023 Added HCPCS J9029. Added ICD-10-CM C67.0-C67.9, Z51.11-Z51.12. Deleted HCPCS J9999.

References

1. Adstiladrin (nadofaragene firadenovec-vncg) suspension, for intravesical use [prescribing information]. Kastrup, Denmark. Ferring Pharmaceuticals; December 2022. Available at https://www.fda.gov/media/164029/download.
2. Boorjian SA, Alemozaffar M, Konety BR, et al. Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial. *Lancet Oncol*. 2021;22(1):107-117. doi:10.1016/S1470-2045(20)30540-4 Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988888/pdf/nihms-1681543.pdf.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 28, 2023.
    a. Bladder Cancer. V3.2023. Revised May 25, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.