Medical Drug Clinical Criteria

Subject:	Adstiladrin (nadofaragene firadenovec-vncg)		
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Table of Contents

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.

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 has a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors; **AND**
III. Individual is ineligible for or have elected not to undergo cystectomy (NCCN Bladder Cancer Guidelines); **AND**
IV. Used as intravesical instillation; **AND**
V. Individual has an Eastern Cooperative Oncology Group (ECOG) status of 0-2.

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	75 ml (3 X 10^{11} vp) 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

J9999	Not otherwise classified, antineoplastic drugs (when specified as [Adstiladrin] (nadofaragene firadenovec-vncg))

ICD-10 Diagnosis

	All diagnoses pend

Document History

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- 02/24/2023– Select Review: New criteria document for Adstiladrin (nadofaragene firadenovec-vncg) gene therapy. Coding Reviewed: Added J9999. All diagnoses pend.

References

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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.
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6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 17, 2023.
    a. Bladder Cancer. V3.2022. Revised December 21, 2022.