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Coverage Policy Number **IP0579**

Nadofaragene firadenovec-vncg

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 2
Authorization Duration 2
Conditions Not Covered 2
Coding Information 2
Background 2
References 3
Revision History 3

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for nadofaragene firadenovec-vncg (Adstiladrin®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Nadofaragene firadenovec-vncg (Adstiladrin®) is considered medically necessary when the following are met:

1. **Non-Muscle Invasive Bladder Cancer.** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Documented diagnois of Non-Muscle Invasive Bladder Cancer
   C. Documentation of **BOTH** of the following:

i. Bacillus Calmette-Guerin (BCG)-unresponsive disease
ii. **ONE** of the following:
    a. Has carcinoma *in situ* (CIS) with or without high-grade papillary Ta/T1 tumors
    b. Has high-grade papillary Ta/T1 tumors without CIS

D. Documentation the medication is used for **ONE** of the following:
    i. Initial treatment
    ii. Recurrent or persistent disease detected by positive cytology or on bladder biopsy despite negative imaging and no visible lesions identified on cystoscopy

E. Medication is prescribed by, or in consultation with, an urologist or oncologist

Dosing. Up to 75 mL of Adstiladrin instilled into the bladder with a urinary catheter once every 3 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of nadofaragene firadenovec-vncg (Adstiladrin) is considered medically necessary for Non-Muscle Invasive Bladder Cancer when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose

Background

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 2.2023 – April 25, 2023) 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- and bladder-biopsy positive, imaging- and cystoscopy-negative, recurrent or persistent disease.[2,3]

References

1. Adstiladrin intravesical suspension [prescribing information]. Kastrup, Denmark: Ferring; December 2022.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 9, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nadofaragene. Accessed on June 9, 2023.

Revision History

Type of Revision	Summary of Changes	Approval Date
New		8/29/2023