Drug Coverage Policy

Effective Date 8/15/2024
Coverage Policy Number.....IP0579
Policy Title.....Adstiladrin

Oncology (Other) – Adstiladrin

- Adstiladrin® (nadofaragene firadenovec-vncg intravesical suspension – Ferring)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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 3.2024 – April 16, 2024) 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-positive, imaging- and cystoscopy-negative, recurrent or persistent disease.[2,3]

Medical Necessity Criteria

Adstiladrin® is considered medically necessary when the following are met:

FDA-Approved Indication

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1. **Non-Muscle Invasive Bladder Cancer.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy: Approve for 4 months to allow 2 doses to be given (3 months apart) if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has carcinoma *in situ* (CIS) with or without high-grade papillary Ta/T1 tumors; OR
       - **b)** Patient has high-grade papillary Ta/T1 tumors without CIS; AND
     - **iv.** Medication is prescribed by or in consultation with a urologist or an oncologist.
   - **B)** Patient is currently receiving Adstiladrin: Approve for 3 months to allow a single dose to be administered 3 months after the most recent dose if the patient meets BOTH of the following (i and ii):
     - **i.** Patient meets ONE of the following (a or b):
       - **a)** Patient is in remission both on cytology and cystoscopic examination; OR
       - **b)** Patient has cytology-positive, imaging- and cystoscopy-negative, recurrent or persistent disease; AND
     - **ii.** Medication is prescribed by or in consultation with a urologist or an 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.

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

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

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

References

1. Adstiladrin intravesical suspension [prescribing information]. Kastrup, Denmark: Ferring; September 2023.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – April 16, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 30, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nadofaragene. Accessed on April 30, 2024.

Revision History

Type of Revision	Summary of Changes	Date
New		8/29/2023
Annual Review	**Non-Muscle Invasive Bladder Cancer:** Approval duration changed from 1 year to approve for the duration noted. Added criterion for Initial therapy approval for 4 months and removed option for approval that the patient has cytology- and bladder biopsy-positive, imaging and cystoscopy negative, recurrent or persistent disease. Added option for approval for 3 months for patients currently receiving Adstiladrin if the medication is prescribed by or in consultation with a urologist or an oncologist and the patient is either in remission or has cytology-positive, imaging and cystoscopy-negative, recurrent or persistent disease.	8/15/2024