

Medical Policy



Title: Adstiladrin

Professional / Institutional
Original Effective Date: December 1, 2026
Latest Review Date:
Current Effective Date: December 1, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

Indication	Dose
Bladder Cancer	The recommended dose of Adstiladrin is 75 mL at a concentration of 3×10^{11} viral particles (vp)/mL by intravesical instillation once every three (3) months via a urinary catheter te: • Premedication with an anticholinergic is recommended before each instillation. • Adstiladrin is not for intravenous use, topical use, or oral administration. – Adstiladrin is a non-replicating adenoviral vector-based gene therapy. Follow universal biosafety precautions for handling. – Individuals who are immunosuppressed or immune-deficient, should not prepare, administer, or come into contact with Adstiladrin. – Adstiladrin is provided as a sterile frozen suspension. – All four (4) vials of Adstiladrin must be thawed and brought to room temperature (20°C to 25°C [68°F to 77°F]) prior to use. Do not expose the vials to higher temperatures (>25°C [77°F]).

- *Protect from light. DO NOT refreeze.*
- *The vials may be moved between refrigerator and room temperature if the total storage time at each condition is not exceeded (24 hours at room temperature and 7 days refrigerated including thawing time).*
- **When thawing in a water bath:**
 - *Frozen Adstiladrin vials will thaw in approximately 25 minutes outside the cardboard nest when placed directly in a water bath maintained at 25°C [77°F]. Place the vials in the water bath, ensuring that the water level is sufficient to cover the product within the vials.*
 - *Following thawing, remove vials from the water bath and dry with a clean paper towel to remove any residual moisture prior to further handling.*
- **When thawing at room temperature:**
 - *Frozen Adstiladrin vials will thaw in approximately 3 to 5 hours outside the cardboard nest when placed at room temperature (up to 25°C [77°F]) (8 to 10 hours inside the nest).*
- **When thawing in refrigerator:**
 - *Frozen Adstiladrin vials will thaw in approximately 4 to 5 hours outside the cardboard nest when placed in the refrigerator (up to 8°C [46°F]) (11 to 13 hours inside the nest). Subsequent time for bringing thawed Adstiladrin to room temperature is approximately 2 hours 30 minutes outside of the cardboard nest (6 hours inside the nest).*
- *Visually inspect all 4 vials for visible particles and discoloration. The suspension is clear to slightly opalescent and may contain opalescent flecks. Do not use if visible particles or discoloration are observed. Mix gently. Do not shake.*

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 dose) every 3 months

III. Initial Approval Criteria ¹

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria ¹

- Member does not have a hypersensitivity to interferon alfa; **AND**
- Member is not immunosuppressed or immunodeficient; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**

Bladder Cancer † ‡ ¹⁻⁴

- Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC); **AND**
 - Member has carcinoma in situ (CIS) (*with or without papillary tumors*); **OR**
 - Member has high-grade papillary Ta/T1 tumors without CIS; **AND**
- Member has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) (*defined as persistent disease following adequate BCG therapy**, disease recurrence after an initial tumor-free state following adequate BCG therapy**, or T1 disease following a single induction course of BCG*); **AND**
- Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); **AND**
- Member does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma

****Note:** Adequate BCG therapy is defined as ≥5 of 6 induction doses plus either ≥2 doses of maintenance therapy or of 2nd induction therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ø Orphan Drug

IV. Renewal Criteria ^{1,4}

- Prior authorization validity may be renewed based upon the following criteria:
- Member continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: disseminated adenovirus infection, etc.; **AND**
 - First Renewal: Member has a complete response (CR) to initial therapy defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; **OR**
 - Subsequent Renewals: Member has not experienced a high-grade or CIS recurrence

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.

CLINICAL RATIONALE

See package insert for FDA pres<https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPSC Code(s):

- J9029 – Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose; 1 billable unit = 1 dose

NDC:

- Adstiladrin suspension, with nominal concentration of 3×10^{11} viral particles (vp)/mL in a carton of four frozen single-dose vials with an extractable volume of 20 mL/vial: 55566-1050-xx

REVISIONS

Posted: 10-22-2026 Effective: 12-01-2026	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.
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REFERENCES

1. Adstiladrin [package insert]. Kastrup, Denmark; Ferring Pharmaceuticals; March 2026. Accessed April 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for nadofaragene firadenovec. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2026.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®.

NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2026.

4. 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 Jan;22(1):107-117. doi: 10.1016/S1470-2045(20)30540-4. Epub 2020 Nov 27.