# Anktiva® (nogapendekin alfa inbakicept-pmln)
## (Intravesical)

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Document Number: IC-0788

**Date Approved: 03/04/2025**
**Date of Origin:** 03/04/2025
**Dates Reviewed: 02/2025**

## I. Length of Authorization

Coverage will be provided 6 months and may be renewed up to a max of 37 months of therapy *(i.e., up to a total of 36 doses).*

## II. Dosing Limits

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

- Induction: 400 billable units once weekly up to 12 doses.
- Maintenance: 400 billable units once weekly for three weeks at months 4, 7, 10, 13, 19, 25, 31, and 37 (total of 24 doses).

## III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

**Bladder Cancer † ‡ [1-4,1e]**

- Patient has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) *(with or without papillary tumors)*; **AND**
- Patient has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) *(defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of completion of adequate BCG therapy**)*; **AND**
- Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components) *(Note: Patients with residual CIS that is not amenable to complete resection, fulguration, or cauterization is permitted)*; **AND**
- Patient does NOT have muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e., urethra, ureter, or renal pelvis) bladder cancer; **AND**

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| • Use of nogapendekin alfa inbakicept-pmln will be restricted to patients with a contraindication or intolerance to nadofaragene firadenovec-vncg |

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

**Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.**

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

## IV. Renewal Criteria [1-4]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. 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: grade 3 or 4 hematuria, etc.; **AND**

  First Renewal:
  - Patient has a complete response (CR) to 6 doses of initial therapy (after 3 months) defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; **OR**
  - Patient has not had a complete response (CR) to 6 doses of initial therapy (after 3 months) and requires a second 6-dose course of induction therapy*****

  Subsequent Renewals:
  - Patient has not experienced a high-grade or CIS recurrence; **AND**
  - *For patients at treatment month 25 or later*: Patient is experiencing an ongoing (CR) and will require continued treatment; **AND**
  - Patient has not received greater than 37 months of therapy (24 doses as maintenance therapy)

***Note: If patients with CIS do not have a complete response to treatment after a second induction course of Anktiva with BCG, reconsider cystectomy.*

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| Bladder Cancer | • For induction: Anktiva is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3. |

| | |
|---|---|
| | • For maintenance: After BCG and Anktiva induction therapy, Anktiva is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19 (for a total of 15 doses). For patients with an ongoing complete response at month 25 and later, maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.<br>*Note: The recommended duration of treatment is until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity, or a maximum of 37 months.* |
| – *For Intravesical Use Only. Do NOT administer by subcutaneous or intravenous or intramuscular routes.*<br>– *The admixture of Anktiva in combination with BCG is instilled into the bladder via a catheter. After instillation is complete, the catheter is removed. The admixture is retained in the bladder for 2 hours and then voided. Patients unable to retain the suspension for 2 hours should be allowed to void sooner, if necessary. Do not repeat the dose if the patient voids before 2 hours.* | |

## VI. Billing Code/Availability Information

HCPCS Code:

- J9028 – Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram; 1 billable unit = 1 mcg

NDC:

- Anktiva 400 mcg/0.4 mL solution in a single-dose vial: 81481-0803-xx

## VII. References (STANDARD)


1. Anktiva [package insert]. Culver City, CA; Altor BioSciences, LLC; April 2024. Accessed February 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for nogapendekin alfa inbakicept. National Comprehensive Cancer Network, 2025. 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 February 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 6.2024. National Comprehensive Cancer Network, 2025. 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 February 2025.
4. Karim Chamie et al. Final clinical results of pivotal trial of IL-15RαFc super-agonist N-803 with BCG in BCG-unresponsive CIS and papillary non-muscle-invasive bladder cancer (NMIBC). JCO 40, 4508-4508(2022). DOI:10.1200/JCO.2022.40.16_suppl.4508.

## VIII. References (ENHANCED)


1e. 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. *The Lancet Oncology*. 2021;22(1):107-117. doi:https://doi.org/10.1016/S1470-2045(20)30540-4

2e. Balar AV, Kamat AM, Kulkarni GS, et al. Pembrolizumab monotherapy for the treatment of high-risk non-muscle-invasive bladder cancer unresponsive to BCG (KEYNOTE-057): an open-label, single-arm, multicentre, phase 2 study. *The Lancet Oncology*. 2021;22(7):919-930. doi:https://doi.org/10.1016/S1470-2045(21)00147-9

3e. Prime Therapeutics Management. Anktiva Clinical Literature Review Analysis. Last updated February 2025. Accessed February 2025.


## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| C67.0 | Malignant neoplasm of trigone of bladder |
| C67.1 | Malignant neoplasm of dome of bladder |
| C67.2 | Malignant neoplasm of lateral wall of bladder |
| C67.3 | Malignant neoplasm of anterior wall of bladder |
| C67.4 | Malignant neoplasm of posterior wall of bladder |
| C67.5 | Malignant neoplasm of bladder neck |
| C67.6 | Malignant neoplasm of ureteric orifice |
| C67.7 | Malignant neoplasm of urachus |
| C67.8 | Malignant neoplasm of overlapping sites of bladder |
| C67.9 | Malignant neoplasm of bladder, unspecified |
| D09.0 | Carcinoma in situ of bladder |
| Z85.51 | Personal history of malignant neoplasm of bladder |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |