

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

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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

A. Quantity Limit (max daily dose) [NDC Unit]:

- Anktiva 400 mcg/0.4 mL solution in SDV: 1 vial weekly for six weeks (may repeat once) as induction, followed by one vial weekly for three weeks at months 4, 7, 10, 13, 19, 25, 31, and 37.

B. 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

- Patient has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (*with or without papillary tumors*); **AND**
- Patient has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) (*defined as persistent disease following adequate BCG therapy [≥ 5 of 6 induction doses plus ≥ 2 doses of maintenance or of 2nd induction], disease recurrence after an initial tumor-free state following adequate BCG therapy, or Ta/T1 disease following a single induction course of BCG*); **AND**
- Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components) – *Note: Patients with residual carcinoma in situ 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) urothelial carcinoma

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

IV. Renewal Criteria ¹⁻⁴

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific 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: grade 3 or 4 hematuria, etc.; **AND**

First Renewal:

- Patient has a complete response (CR) to 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 initial therapy (after 3 months) and requires a second 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	<ul style="list-style-type: none"> • <u>For induction:</u> 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. • <u>For maintenance:</u> 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. <p><i>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.</i></p>
<p>– For Intravesical Use Only. Do NOT administer by subcutaneous or intravenous or intramuscular routes.</p>	

– 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 (*Effective 01/01/2025*)
- J9999 – Not otherwise classified, antineoplastic drugs (*Discontinue use on 01/01/2025*)
- C9169 – Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram; 1 billable unit = 1 mcg (*Discontinue use on 01/01/2025*)

NDC:

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

VII. References

1. Anktiva [package insert]. Culver City, CA; Altor BioSciences, LLC; April 2024. Accessed April 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for nogapendekin alfa inbakicept. National Comprehensive Cancer Network, 2024. 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 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 3.2024. National Comprehensive Cancer Network, 2024. 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 2024.
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.

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

ICD-10	ICD-10 Description
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