Clinical Policy: Nogapendekin Alfa Inbakicept-pmln (Anktiva)

Reference Number: PA.CP.PHAR.684
Effective Date: 08/2024
Last Review Date: 07/2024

Description
Nogapendekin alfa inbakicept-pmln (Anktiva®) is an interleukin-15 (IL-15) receptor agonist.

FDA Approved Indication(s)
Anktiva is indicated for use with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Anktiva is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-muscle Invasive Bladder Cancer (must meet all)**:**

1. Diagnosis of NIMBC characterized as one of the following (a or b) (*see Appendix D*):
   a. CIS only;
   b. Ta/T1 high-grade disease with concomitant CIS;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member is refractory to BCG treatment (*see Appendix D*);
   **Prior authorization may be required for BCG immunotherapy*
5. Anktiva is prescribed in combination with BCG;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mcg (1 vial) per week for up to 12 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months (up to 12 doses)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Non-muscle Invasive Bladder Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;

2. Member is responding positively to therapy as evidenced by lack of disease recurrence or progression;
3. Total treatment duration does not exceed 37 months;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 400 mcg (1 vial) per week for up to 24 doses;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months (up to 24 doses)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCG: Bacillus Calmette-Guérin
CIS: carcinoma in situ
FDA: Food and Drug Administration
IL: interleukin
NCCN: National Comprehensive Cancer Network
NMIBC: non-muscle invasive bladder cancer

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Bacillus Calmette-Guerin Vaccine (TICE BCG®)	1 to 8 x 10^8 CFU (a vial) intravesical instillation once per week for 6 weeks	1 to 8 x 10^8 CFU per week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- Refractory or "BCG unresponsive" is defined as being at least one of the following:

1. Persistent or recurrent CIS alone or with recurrent Ta/T1 disease within 12 months of completion of adequate BCG therapy, defined as at least one of the following:
   a. At least 5 of 6 doses of an initial induction course plus at least 2 of 3 doses of maintenance therapy;
   b. At least 5 of 6 doses of initial induction course plus at least 2 of 6 doses of the second induction course.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NMIBC	Induction: 400 mcg administered intravesically with BCG once weekly for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3. Maintenance: 400 mcg administered intravesically with BCG once weekly for 3 weeks at months 4, 7, 10, 13 and 19 (with possible addition of months 25, 31, and 37) Maximum treatment duration of 37 months	400 mcg/week

VI. Product Availability

Single dose vial: 400 mcg/0.4mL

VII. References

1. Anktiva Prescribing Information. Bothell, WA: AGC Biologics; April 2024. Available at https://www.anktiva.com/. Accessed May 13, 2025.
2. Chamie K, Chang SS, Kramolowsky E, et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. *NEJM Evid*. 2023; 2(1):EVIDoa2200167.
3. Chamie K, Chang SS, Kramolowsky EV, et al. Quality of life in the phase 2/3 trial of N-803 plus Bacillus Calmette-Guérin in Bacillus Calmette-Guérin–unresponsive nonmuscle-invasive bladder cancer. *Urol Pract*. 2024 Mar;11(2):367-375. doi: 10.1097/UPJ.0000000000000517.
4. National Comprehensive Cancer Network. Bladder Cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed May 13, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram

Reviews, Revisions, and Approvals	Date
Policy created	07/2024
3Q 2025 annual review: no significant changes; removed irrelevant drugs from Appendix B; HCPCS code added [J9028] and removed codes [J9999, C9399]; references reviewed and updated.	07/2025