# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Intravesical) – Anktiva Prior Authorization Policy
- Anktiva® (nogapendekin alfa inbakicept-pmln intravesical solution – ImmunityBio)

**REVIEW DATE:** 04/30/2025

***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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Anktiva, an interleukin-15 (IL-15) receptor agonist, is indicated with Bacillus Calmette-Guerin (BCG) for the treatment of **BCG-unresponsive non-muscle invasive bladder cancer** (NMIBC) in adults with carcinoma in situ with or without papillary tumors.[1]

### Guidelines

The National Comprehensive Cancer Network (NCCN) **bladder cancer** clinical guidelines (version 1.2025 – March 25, 2025) recommend Anktiva for the treatment of BCG-unresponsive, high-risk NMIBC with CIS with or without papillary tumors (category 2A) as initial treatment or for cytology-positive, imaging- and cystoscopy-negative, recurrent or persistent disease.[3,4]

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Anktiva. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Anktiva as well as the monitoring required for adverse events and long-term efficacy, approval requires Anktiva to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### FDA-Approved Indication

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 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     Note: This allows enough time for a patient to complete two courses of induction therapy if needed.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has high risk Bacillus Calmette-Guerin (BCG) unresponsive disease; AND
     - **iii.** Patient has carcinoma in situ (CIS); AND
     - **iv.** Medication is used in combination with BCG; AND
     - **v.** Medication is prescribed by or in consultation with a urologist or an oncologist; OR
   - **B)** Maintenance Therapy: Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has an ongoing compete response defined as ONE of the following (a or b):
       - **a)** Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]:
         - **(1)** Negative urine cytology; OR
         - **(2)** Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative; OR
       - **b)** Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology; AND
     - **ii.** Medication is used in combination with BCG; AND
     - **iii.** Medication is prescribed by or in consultation with a urologist or an oncologist.

## CONDITIONS NOT COVERED

- **Anktiva® (nogapendekin alfa inbakicept-pmln intravesical solution (ImmunityBio)**

**is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

## REFERENCES


1. Anktiva intravesical solution [prescribing information]. Culver City, CA: ImmunityBio; April 2024.
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. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – March 25, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.ncc.org. Accessed on April 9, 2025.
4. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.ncc.org. Search term: nogapendekin. Accessed on April 9, 2025.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 05/08/2024 |
| Update | 04/04/2025: The policy name was changed from "Oncology (Other) – Anktiva PA Policy" to "Oncology (Intravesical) – Anktiva PA Policy". | NA |
| Annual Revision | **Non-Muscle Invasive Bladder Cancer:** For the requirement that the patient has Bacillus Calmette-Guerin (BCG) unresponsive disease, added "high-risk" as a qualifier. For the requirement that the patient has carcinoma in situ, removed "with or without papillary tumors". | 04/30/2025 |