VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/08/2024

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 4.2024 – May 9, 2024) 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Anktiva is recommended in those who meet the following criteria:

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 Bacillus Calmette-Guerin (BCG) unresponsive disease; AND
     - **iii.** Patient has carcinoma in situ with or without papillary tumors; 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 RECOMMENDED FOR APPROVAL

Coverage of Anktiva is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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*. 2022 Nov 10. [Epub ahead of print].
3. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 9, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 9, 2024.
4. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nogapendekin. Accessed on May 9, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/08/2024