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| **Section:** | Prescription Drugs | **Effective Date:** | October 1, 2024 |
| **Subsection:** | Antineoplastic Agents | **Original Policy Date:** | May 17, 2024 |
| **Subject:** | Anktiva | **Page:** | 1 of 4 |

***Last Review Date:*** September 6, 2024

# Anktiva

## Description

### Anktiva (nogapendekin alfa inbakicept-pmln)

**Background**
Anktiva (nogapendekin alfa inbakicept-pmln) is an interleukin-15 (IL-15) receptor agonist. Binding of Anktiva to its receptor results in proliferation and activation of NK, CD8+, and memory T cells without proliferation of immunosuppressive Treg cells. In vivo, Anktiva alone or in combination with Bacillus Calmette-Guerin (BCG) showed anti-tumor activity when compared to BCG alone, in a carcinogen-induced model of bladder cancer in immunocompetent rats (1).

**Regulatory Status**
FDA-approved indication: Anktiva is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors (1).

Delaying cystectomy in patients with BCG-unresponsive CIS could lead to the development of muscle invasive or metastatic bladder cancer, which can be lethal. The risk of developing muscle invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of persisting CIS (1).

Anktiva is for intravesical use only. Do not administer by subcutaneous or intravenous or intramuscular routes (1).

The safety and effectiveness of Anktiva in pediatric patients less than 18 years of age have not been established (1).

**Related Policies**

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Anktiva may be considered **medically necessary** if the conditions indicated below are met.

Anktiva may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

Nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)

**AND ALL** of the following:

1. Bacillus Calmette-Guerin (BCG)-unresponsive
2. Used in combination with Bacillus Calmette-Guerin (BCG)

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

Nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)

**AND** the following:

1. Used in combination with Bacillus Calmette-Guerin (BCG)

2. Prescriber agrees that the patient will not receive more than 37 months total of treatment with Anktiva

## Policy Guidelines

### Pre - PA Allowance
None

### Prior - Approval Limits

**Duration** 2 years

### Prior – Approval *Renewal* Limits

**Duration** 2 years*

*__ONE__ renewal __ONLY__

## Rationale

**Summary**
Anktiva is an IL-15 agonist. It is indicated in combination with Bacillus Calmette-Guerin (BCG) for the treatment of adults with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. Anktiva is for intravesical use only. The safety and effectiveness of Anktiva in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Anktiva while maintaining optimal therapeutic outcomes.

**References**
1. Anktiva [package insert]. Culver City, CA: Altor BioScience, LLC; April 2024.
2. NCCN Drugs & Biologics Compendium® Nogapendekin alfa inbakicept-pmln 2024. National Comprehensive Cancer Network, Inc. Accessed on July 11, 2024.

## Policy History

| Date | Action |
|---|---|
| May 2024 | Addition to PA |

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|---|---|
| June 2024 | Annual review |
| September 2024 | Annual review and reference update |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.**