

5.21.221

Section:	Prescription Drugs	Effective Date:	April 1, 2025
Subsection:	Antineoplastic Agents	Original Policy Date:	May 17, 2024
Subject:	Anktiva	Page:	1 of 4

Last Review Date: March 7, 2025

Anktiva

Description

Anktiva (nogapendekin alfa inbakicept-pmIn)

Background

Anktiva (nogapendekin alfa inbakicept-pmIn) 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).

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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)

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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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 16, 2025.

Policy History

Date	Action
May 2024	Addition to PA

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June 2024	Annual review
September 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review and reference update

[Keywords](#)

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.