

**Intravesical Bladder Cancer Agents**  
**Anktiva (nogapendekin alfa inbakicept-pmln)**  
**Effective 01/06/2025**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Anktiva (nogapendekin alfa inbakicept-pmln) is a first-in-class interleukin (IL)-15 superagonist complex consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha. This agent is indicated with Bacillus Calmette-Guérin (BCG) for adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of non-muscle-invasive bladder cancer (NMIBC)
2. Disease is high-risk with carcinoma in situ (CIS)
3. Prescriber is an oncologist or urologist
4. Appropriate dosing
5. Inadequate response, adverse reaction, or contraindication to BCG
6. For Anktiva, inadequate response or adverse reaction to ONE or contraindication to BOTH of the following:
  - a. Adstiladrin (nadofaragene firadenovec-vncg)
  - b. Keytruda (pembrolizumab)

### Continuation of Therapy

Resubmission by prescriber will infer positive response to therapy.

### Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

### References

1. Anktiva® (nogapendekin alfa inbakicept-pmln) [package insert]. Culver City (CA): Altor BioScience, LLC; 2024 May.
2. National Cancer Institute SEER Program. Cancer Stat Facts: Common Cancer Sites. <https://seer.cancer.gov/statfacts/html/common.html>. Accessed November 22, 2022.
3. FDA approves first gene therapy for the treatment of high-risk, non-muscle-invasive bladder cancer [press release on the Internet]. U.S. Food & Drug Administration. 2022 Dec 16 [cited 2022 Dec 19]. Available from: FDA Approves First Gene Therapy for the Treatment of High-Risk, Non-MuscleInvasive Bladder Cancer (govdelivery.com).
4. Kassouf W, Black P. Treatment of primary non-muscle invasive urothelial bladder cancer. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2024 [cited 2024 Jun 18]. Available from: <http://www.utdol.com/utd/index.do>.
5. European Association of Urology (EAU) Guidelines for non-muscle-invasive bladder cancer (TAT1 and CIS), update 2021. Edn. presented at the EAU Annual Congress Amsterdam 2022. Available from: <https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer>. ISBN 978-94-92671-16-5.
6. Chang SS, Boorjian SA, Chou R et al: Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline. J Urol. 2016; 196: 1021 (amended 2020).
7. NCCN. Bladder Version 4.2024; 2024 May 9 [cited 2024 Jun 17]. Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/kidney.pdf](https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf).

#### Review History

12/11/24 – Created for P&T. Adopted MH criteria for Anktiva (MB PA). Effective 1/6/25

