Mass General Brigham
Health Plan

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

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	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.

Review History

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