CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Nogapendekin alfa inbakicept-pmln (Anktiva®)

Version: 1.0

EFFECTIVE DATE: 6/1/2024

NantHealth® | Eviti®

Please note the following:

Nogapendekin alfa inbakicept-pmln (Anktiva®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Nogapendekin alfa inbakicept-pmln (Anktiva): Discussion

Nogapendekin alfa inbakicept-pmln is approved by the Food and Drug Administration (FDA) as an interleukin-15 (IL-15) receptor agonist indicated with bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.[1]

The immune cell-activating interleukin-15 (IL-15) superagonist nogapendekin alfa inbakicept may act synergistically with BCG to elicit durable complete responses. IL-15 is a cytokine growth factor that regulates lymphocyte function and homeostasis. Overall survival at two years was 94.3% and the two-year progression free survival was 84.7%. The complete response rates respectively at 3 months and 6 months were 55% and 56%. The overall complete response rate at any time was achieved in 71% of the trial patient population.[2,3]

The National Comprehensive Cancer Network (NCCN) endorses nogapendekin alfa inbakicept-pmln in the following cancer types: bladder cancer.[4]

Nogapendekin alfa inbakicept-pmln: Definitions

- **National Comprehensive Cancer Network (NCCN) -** An alliance of over 30 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Food and Drug Administration (FDA) -** The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

Nogapendekin alfa inbakicept-pmln: Policy

Note: Coverage of nogapendekin alfa inbakicept-pmln will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Nogapendekin alfa inbakicept-pmln will be considered for coverage when the following criteria are met:

Bladder Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. BCG-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) (with or without papillary) tumors; AND

For FDA required criteria coverage:

4. For induction: 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3; OR
5. For maintenance: 400 mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19. For patients with an ongoing complete response at month 25 and later, additional maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37.[4]

For NCCN required criteria coverage:

6. As initial management; OR
7. For cytology-positive, imaging- and cystoscopy-negative, bladder positive recurrent or persistent disease.[1]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Nogapendekin alfa inbakicept-pmln: References

1. National Comprehensive Cancer Network. Bladder Cancer. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed June 5, 2024.
2. Chamie et al. IL-15 Superagonist NAI in BCG-Unresponsive Non–Muscle-Invasive Bladder Cancer. https://evidence.nejm.org/doi/full/10.1056/EVIDoa2200167. Accessed June 5, 2024.
3. Fehniger et al. Interleukin-2 and interleukin-15: immunotherapy for cancer. https://www.sciencedirect.com/science/article/abs/pii/S1359610101000211. Accessed June 5, 2024.
4. Nogapendekin alfa inbakicept-pmln (Anktiva) Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf. Accessed June 5, 2024.

Nogapendekin alfa inbakicept-pmln: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C67	Malignant neoplasm of bladder
J9999	Nogapendekin alfa inbakicept-pmln (Anktiva)

Nogapendekin alfa inbakicept-pmln: Revision and Review History

NO.	DESCRIPTION	DATE(S)
1	Original Effective Date:	6/1/2024
2	Policy Review Dates:	
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee:	6/13/2024
6	Revision Changes:	