

Nogapendekin alfa inbakicept (ANKTIVA)

Criteria for Use

June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive nogapendekin alfa inbakicept.

- Current or previous evidence of muscle-invasive or metastatic bladder cancer
- Pregnancy
- Lactating

Inclusion Criteria

ALL the following criteria must be met:

- Formulary agents for BCG-unresponsive disease have been used previously unless there is a contraindication or they are not medically advisable
- In combination with Bacillus Calmette-Guerin (BCG) for BCG-unresponsive¹ non-muscle invasive bladder cancer
- Carcinoma in situ (CIS) with or without papillary tumors (Ta or T1 high-grade tumors)

Additional Inclusion Criteria

All of the following criteria must be met:

- Care is provided by a VA/VA Community Care oncology or urology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2

Additional Inclusion Criteria

- For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 1 week after stopping treatment

Other Justification

¹BCG-unresponsive: Received 2 courses of BCG within 12 months (5 of 6 induction instillations and at least 2 of 3 maintenance doses OR at least 2 of 6 instillations of a second induction when maintenance not given)

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