Part B Prior Authorization Guidelines

BCG-Unresponsive Bladder Cancer

Anktiva (Nogapendekin Alfa Inbakicept-pmln) J9028

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Patient is 18 years of age or older (Label, NCCN 2A); AND
☐ Treatment is using as intravesical instillation; AND
☐ Patient has a diagnosis of Bacillus Calmette-Guerin (BCG) unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC)
  ☐ Disease is carcinoma in situ (CIS), with or without papillary tumors AND
☐ Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; AND
☐ Patient is using in combination with Bacillus Calmette-Guerin (BCG) treatment.
☐ Prescribed by or in consultation with a urologist or an oncologist

- **Requests for Anktiva (nogapendekin alfa inbakicept-pmln) may not be approved for the following:**
  - **Muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e. urethra, ureter, or renal pelvis) urothelial carcinoma.**

☐ **Continuation Requests: (Clinical documentation required for all requests)**

**Treatment for a prior flare may include up to two 900 mg infusions of Spevigo separated by 1 week.*

☐ Patient has an ongoing compete response defined as ONE of the following (a or b):

- ☐ Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]:
  - ☐ Negative urine cytology; OR
  - ☐ Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative; OR
- ☐ Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology; AND

☐ Medication is used in combination with BCG; AND

☐ Medication is prescribed by or in consultation with a urologist or an oncologist.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Anktiva Drug PA

Drug Name(s):

ANKTIVA **NOGAPENDEKIN ALFA INBAKICEPT-PMLN**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Urologist and/or Oncologist

Coverage Duration:

Initial approval for 6 months
Continuation will be approved for 3 months.

FDA Indications:

Anktiva

- Bladder cancer, Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, nonmuscle invasive with carcinoma in situ, with or without papillary tumors, in combination with BCG

Off-Label Uses:

N/A

Age Restrictions:

- Safety and effectiveness of nogapendekin alfa inbakicept-pmln in pediatric patients have not been established

Other Clinical Considerations:

- **Duration, continue until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity, or MAX 37 months**

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=topHome&isToolPage=true#