Medical Policy:

Anktiva (nogapendekin alfa inbakicept-pmln) intravesical solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.412	June 28, 2024	June 28, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Anktiva in combination with Bacillus Calmette-Guérin (BCG) is indicated 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.

Length of Authorization

Coverage will be provided 6 months and may be renewed up to a max of 37 months of therapy (i.e., up to a total of 36 doses)

Dosing Limits [Medical Benefit]

Dosing: Approve the following dosing regimens (A or B):

A. Induction Therapy: Approve 400 mcg administered intravesically once a week for 6 weeks. A second course of induction therapy can be administered at month 3 if a complete response was not achieved with the first course; OR

B. Maintenance Therapy: Approve 400 mcg administered intravesically once a week for 3 weeks at months 4, 7, 10, 13, and 19. Additional course can be given at months 25, 31, and 37.

Max Units (per dose and over time) [HCPCS Unit]:

- Induction: 400 mcg once weekly up to 12 doses.
- Maintenance: 400 mcg once weekly for three weeks at months 4, 7, 10, 13, 19, 25, 31, and 37 (total of 24 doses).

Guideline

I. INITIAL CRITERIA

1. Non-Muscle Invasive Bladder Cancer.

A. Patient is at least 18 years of age; **AND**

B. Patient has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (with or without papillary tumors); **AND**

C. Patient has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG)(defined as persistent disease following adequate BCG therapy [≥5 of 6 induction doses plus ≥2 doses of maintenance or of 2nd induction], disease recurrence after an initial tumor-free state following adequate BCG therapy, or Ta/T1 disease following a single induction course of BCG; **AND**

D. Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components)
Note: Patients with residual carcinoma in situ that is not amenable to complete resection, fulguration, or cauterization is permitted; **AND**

E. Patient does NOT have muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e., urethra, ureter, or renal pelvis) urothelial carcinoma

II. RENEWAL CRITERIA

A. Patient continues to meet initial criteria; **AND**

B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

C. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: grade 3 or 4 hematuria, etc.*; **AND**

D. First Renewal:

i. Patient has a complete response (CR) to initial therapy (after 3 months) defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; **OR**

ii. Patient has not had a complete response (CR) to initial therapy (after 3 months) and requires a second course of induction therapy*

E. Subsequent Renewals:

i. Patient has not experienced a high-grade or CIS recurrence; **AND**

ii. For patients at treatment month 25 or later: Patient is experiencing an ongoing(CR) and will require continued treatment; **AND**

iii. Patient has not received greater than 37 months of therapy (24 doses as maintenance therapy)

**Note: If patients with CIS do not have a complete response to treatment after a second induction course of Anktiva with BCG, reconsider cystectomy.*

Applicable Procedure Codes

Code	Description
J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram (effective 1/1/2025)
C9169	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram (effective 10/1/2025 – 12/31/2024)

Applicable NDCs

Code	Description
81481-0803-01	Anktiva 400mcg/0.4mL

ICD-10 Diagnoses

Code	Description
C67.0	Malignant Neoplasm Of Trigone Of Bladder
C67.1	Malignant Neoplasm Of Dome Of Bladder
C67.2	Malignant Neoplasm Of Lateral Wall Of Bladder
C67.3	Malignant Neoplasm Of Anterior Wall Of Bladder
C67.4	Malignant Neoplasm Of Posterior Wall Of Bladder
C67.5	Malignant Neoplasm Of Bladder Neck
C67.6	Malignant Neoplasm Of Ureteric Orifice
C67.7	Malignant Neoplasm Of Urachus
C67.8	Malignant Neoplasm Of Overlapping Sites Of Bladder
C67.9	Malignant Neoplasm Of Bladder, Unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	06/28/2024	New Policy

References

1. Anktiva intravesical solution [prescribing information]. Culver City, CA: ImmunityBio; April 2024.