

How to Order ANKTIVA[®]

A step-by-step guide



Open your camera and point your smart device at the QR code to access Anktiva.com

Step 1

Ordering ANKTIVA®



Product Information	
Name	ANKTIVA®
Generic Name	nogapendekin alfa inbakicept-pmln
Package Presentation	Carton of one dose
Wholesale Acquisition Cost	\$35,800 per dose
Dosage Form	Clear to slightly opalescent and colorless to slightly yellow solution in a single-dose vial
National Drug Code	1-vial package: NDC 81481-803-01
Specialty Distributors	<p>Cencora (AmerisourceBergen) 1-888-711-5469</p> <p>McKesson 1-877-625-2566</p> <p>Cardinal Health 1-855-855-0708</p> <p>CuraScript 877-599-7748</p>
Specialty Pharmacy	<p>Accredo 866-759-1557 www.accredo.com/prescribers/manage-referrals</p>

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (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. **WARNINGS AND PRECAUTIONS: Risk of Metastatic Bladder Cancer with Delayed Cystectomy.** Delaying cystectomy can lead to the development of muscle invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA with BCG, reconsider cystectomy. **DOSAGE AND ADMINISTRATION: For Intravesical Use Only.** Do not administer by subcutaneous or intravenous routes. Instill intravesically only after dilution. Total time from vial puncture to the completion of the intravesical instillation should not exceed 2 hours. **USE IN SPECIFIC POPULATIONS: Pregnancy:** May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. **ADVERSE REACTIONS:** The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

For more information about ANKTIVA, please see the Full Prescribing Information at www.Anktiva.com.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact ImmunityBio at 1-877-ANKTIVA (1-877-265-8482).

Step 2

Coding & Reimbursement (2024)

Drug - First, Second Induction & Maintenance

Pass-Through	OPPS effective October 1, 2024
C9169	Injection, nogapendekin alfa inbakicept-pmln
HCPCS J-Code	Healthcare Common Procedure Coding System (HCPCS) J-Code
J3490	Anktiva® 400mcg, Unlisted Code for Injection Services (Initial Code)
0636	Anktiva® 400mcg, Drug Required Revenue Code for HOPD via OPPS
J9999	Not Otherwise Classified, Antineoplastic Drugs
J3590	Unclassified Biologics
C9399	Unclassified Drugs or Biologicals (OPPS Setting)
J9030	BCG Live Intravesical Instillation, 1mg
A9589	Blue Light Instillation, Hexaminolevulinate Hydrochloride, 100 mg
C9738	Adjunctive Blue Light Cystoscopy with Fluorescent Imaging Agent

Diagnosis & Findings

ICD-10	International Coding For Diseases (ICD) Description
C67.0	Malignant Neoplasm: Trigone of Bladder
C67.1	Malignant Neoplasm: Dome of Bladder
C67.2	Malignant Neoplasm: Lateral Wall of Bladder
C67.3	Malignant Neoplasm: Anterior Wall of Bladder
C67.4	Malignant Neoplasm: Posterior Wall of Bladder
C67.5	Malignant Neoplasm: Bladder Neck
C67.6	Malignant Neoplasm: Ureteric Orifice
C67.7	Malignant Neoplasm: Urachus
C67.8	Malignant Neoplasm: Overlapping Lesion of Bladder
C67.9	Malignant Neoplasm: Bladder - Unspecified
D09.0	Carcinoma In Situ of Bladder
R82.7	Abnormal Findings on Microbiological Examination of Urine
R82.8	Abnormal Findings on Cytological & Histological Examination of Urine
R82.9	Other and Unspecified Abnormal Findings in Urine
Z85.51	Personal History of Malignant Neoplasm of Bladder
Z85.52	Family History of Malignant Neoplasm of Bladder

Procedure: 1st Induction, 2nd Induction, Maintenance & Follow-Up

HCPCS J-Code	Healthcare Common Procedure Coding System (HCPCS) J-Code
51720	Bladder Instillation of Anticarcinogenic Agent, Including Retention Time
52000	Endoscopy-Cystoscopy, Urethroscopy, Cystourethroscopy Procedures on the Bladder
52204	Urethra & Bladder Transurethral Surgical Procedures
52234	Cystourethroscopy, with Fulguration, Including Cryosurgery or Laser Surgery, and/or Resection of Small Bladder Tumor(s) (0.5 up to 2.0 cm)
52235	Cystourethroscopy, with Fulguration, Including Cryosurgery of Laser Surgery, and/or Resection of Medium Bladder Tumor(s) (2.0 to 5.0cm)
52240	Cystourethroscopy, with Fulguration, Including Cryosurgery of Laser Surgery, and/or Resection of Large Bladder Tumor(s) (>5.0cm)
88104	Cytopath Nongynecological Smear
88108	Cytopath Concentrate Technical
88112	Cytopath Cell Enhance Technical

Office Visit

E/M Code	Evaluation and Management Description
99203	New Patient Office or Other Outpatient Visit, 30-44 Minutes
99204	New Patient Office or Other Outpatient Visit, 45-59 Minutes
99213	Established Patient Office or Other Outpatient Visit, 20-29 Minutes
99214	Established Patient Office or Other Outpatient Visit, 20-29 Minutes

Billing Information Sheet
Anktiva® National Drug Code (NDC): 81481-803-01

- Clinic:** Freestanding Clinic Reimbursement is Based on Local MAC Payment Methodology
- Hospital:** Hospital Outpatient Prospective Payment System, Pass-Through Payment In-Process

Disclaimers

The billing and coding information in this guide is for general informational purposes only. This should not be relied upon for purposes of determining payer coverage and coding. This information represents no promise, commitment, statement or guarantee by ImmunityBio concerning proper billing or coding practices or levels of reimbursement, payment, or charges.

The materials referenced and provided are based upon coding experience and research of current general coding practices. The existence of codes does not guarantee coverage or payment for any procedure by any payer. The final decision for coding of any procedure must be made by the provider of care after considering the medical necessity of the services and supplies provided as well as the regulations and local, state, or federal laws that may apply.

The information contained in this guide is provided to help you understand the reimbursement information and is not intended to suggest any way you can increase or maximize reimbursement from any payer. Reimbursement information is gathered from third-party sources and is subject to change. We recommend that you consult with payers for specific coverage and billing requirements.

All Current Procedural Terminology (CPT®) codes, Healthcare Common Procedural Coding System (HCPCS) codes, Ambulatory Payment Classifications (APCs) and National Drug Codes (NDC) are provided for your information only and ImmunityBio does not represent that these codes are or will be appropriate or that reimbursement will be made if using them or any other codes. CPT® codes and descriptions only are copyrighted by the American Medical Association (AMA). CPT®, APC and other codes do not include fee schedules, relative values, or related listings. The Centers for Medicare & Medicaid Services (CMS) updates coverage, coding, and payment information frequently, and it is the responsibility of each health service provider to confirm the appropriate billing required by the local Medicare contractor.

Providers should refer to authoritative coding sources, such as the CPT® codes and HCPCS codes. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. The information provided in this guide is for informational purposes only. Information included does not guarantee coverage or payment. Payment will vary by geographic locality. It is always the provider's responsibility to determine coding and claims information for the services that were provided.

Step 3

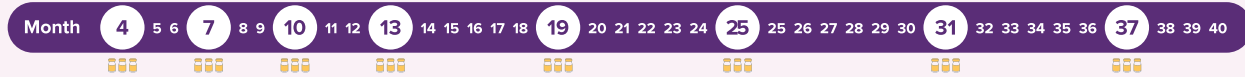
Intravesical Instillation Schedule of ANKTIVA®

FIRST INDUCTION



■ ANKTIVA 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course is not required if a complete response is achieved at month 3. Cystoscopy and cytology performed for drug administration every three months and follow-up per office practice.

MAINTENANCE



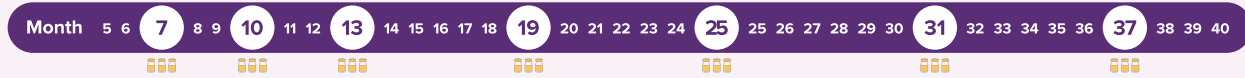
For Maintenance: After BCG and ANKTIVA induction therapy, ANKTIVA is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19 (for a total of 15 doses). For patients with an ongoing complete response at month 25 and later, maintenance instillations may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.

FIRST & SECOND INDUCTION



■ ANKTIVA 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course is not required if a complete response is achieved at month 3. Cystoscopy and cytology performed for drug administration every three months and follow-up per office practice.

MAINTENANCE

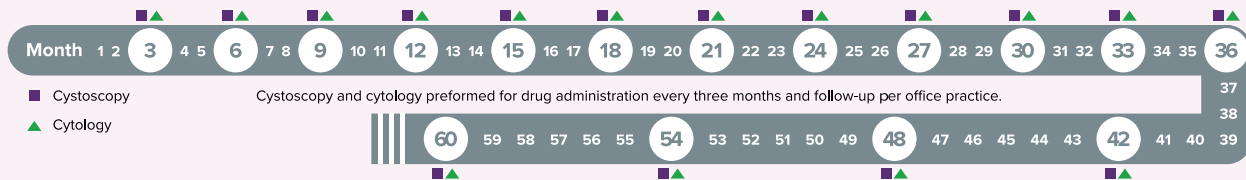


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Step 4

Cystoscopy Schedule, Follow-Up and Long-Term Follow-Up (5 Years)

PROCEDURE SCHEDULE: EVERY THREE MONTHS



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