



 **Anktiva**[®]
(nogapendekin alfa inbakicept-pmln)
400 mcg/0.4 mL, solution for intravesical instillation

Access & Reimbursement Guide

Guidance on coverage, coding, and patient support for healthcare providers prescribing ANKTIVA[®]

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.

Please see Important Safety Information on page 2 and **Full Prescribing Information** for ANKTIVA.

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).



Contents

Overview	4
ImmunityBio CARE™	6
Patient support program for ANKTIVA	
Ordering	8
With intravesical instillation schedule	
Coverage & Payment	10
Considerations for Medicare, commercial insurance, Medicaid, dual eligibility, M3P, and LIS	
Obtaining Coverage	12
With Sample Letter of Medical Necessity and Sample Letter of Appeal	
Coding & Billing	16
Commonly used HCPCS, CPT, and ICD-10-CM codes and modifiers	
Claims & Denials	20
With annotated sample claim forms	

Helping you help your patients

As part of its commitment to supporting healthcare professionals and office staff in practices that prescribe ANKTIVA®, ImmunityBio has developed the ANKTIVA Access & Reimbursement Guide to help you understand administrative aspects of the ANKTIVA access and reimbursement process, including:

- Patient support
- Ordering ANKTIVA
- Benefits verification
- Obtaining prior authorization/appealing a denial
- Coding and billing
- Filing a claim/appealing a denial

Your dedicated Field Reimbursement Manager is available to deliver access and reimbursement support.

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.

Contact us for support

ImmunityBio CARE™ is here to support your patients throughout their treatment

The ImmunityBio CARE™ program offers resources, services, and support to help patients access ANKTIVA®

-  Benefits investigation
-  Financial assistance programs
 - Co-pay Assistance
 - Eligible patients with commercial insurance could pay \$25 per vial*
 - Patient Assistance Program (PAP)
 - Treatment is available free of charge to eligible patients who are uninsured†
-  Prior authorization support and tracking
 - Prior authorization requirements by payer, prior authorization forms when available
-  Coding and billing assistance
-  Claim support if needed, and payer-specific appeal assistance

*This offer is valid only for patients who have commercial insurance. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or other state healthcare programs. Additional terms and conditions apply.

†PAP application required. Patient must meet certain financial and other criteria.

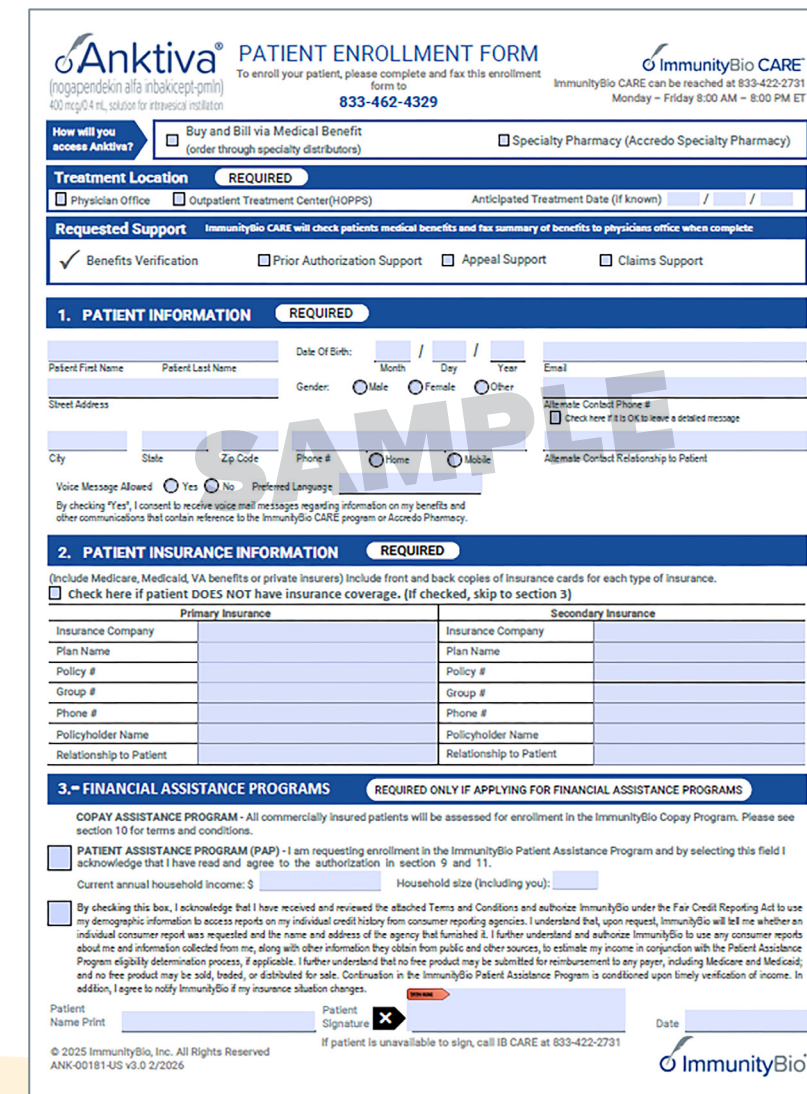


Contact us

For more information or to request a Patient Enrollment Form:

833-422-2731 (phone) | 833-462-4329 (fax)

Hours of operation: Monday - Friday 8:00 AM - 8:00 PM ET



Anktiva® PATIENT ENROLLMENT FORM
To enroll your patient, please complete and fax this enrollment form to **833-462-4329**
ImmunityBio CARE can be reached at 833-422-2731 Monday - Friday 8:00 AM - 8:00 PM ET

How will you access Anktiva? Buy and Bill via Medical Benefit (order through specialty distributors) Specialty Pharmacy (Accredo Specialty Pharmacy)

Treatment Location REQUIRED
 Physician Office Outpatient Treatment Center (HOPPS) Anticipated Treatment Date (if known) / /

Requested Support ImmunityBio CARE will check patients medical benefits and fax summary of benefits to physicians office when complete.
 Benefits Verification Prior Authorization Support Appeal Support Claims Support

1. PATIENT INFORMATION REQUIRED

Patient First Name Patient Last Name Date Of Birth: / / Month Day Year Email
Street Address Gender: Male Female Other Alternate Contact Phone #
City State Zip Code Phone # Home Mobile Alternate Contact Relationship to Patient
Voice Message Allowed Yes No Preferred Language
By checking "yes", I consent to receive voice mail messages regarding information on my benefits and other communications that contain reference to the ImmunityBio CARE program or Accredo Pharmacy.

2. PATIENT INSURANCE INFORMATION REQUIRED
(Include Medicare, Medicaid, VA benefits or private insurers) Include front and back copies of insurance cards for each type of insurance.
 Check here if patient DOES NOT have insurance coverage. (If checked, skip to section 3)

Primary Insurance		Secondary Insurance	
Insurance Company		Insurance Company	
Plan Name		Plan Name	
Policy #		Policy #	
Group #		Group #	
Phone #		Phone #	
Policyholder Name		Policyholder Name	
Relationship to Patient		Relationship to Patient	

3. FINANCIAL ASSISTANCE PROGRAMS REQUIRED ONLY IF APPLYING FOR FINANCIAL ASSISTANCE PROGRAMS

COPY ASSISTANCE PROGRAM - All commercially insured patients will be assessed for enrollment in the ImmunityBio Copay Program. Please see section 10 for terms and conditions.

PATIENT ASSISTANCE PROGRAM (PAP) - I am requesting enrollment in the ImmunityBio Patient Assistance Program and by selecting this field I acknowledge that I have read and agree to the authorization in section 9 and 11.
Current annual household income: \$ Household size (including you):

By checking this box, I acknowledge that I have received and reviewed the attached Terms and Conditions and authorize ImmunityBio under the Fair Credit Reporting Act to use my demographic information to access reports on my individual credit history from consumer reporting agencies. I understand that, upon request, ImmunityBio will let me whether an individual consumer report was requested and the name and address of the agency that furnished it. I further understand and authorize ImmunityBio to use any consumer reports about me and information collected from me, along with other information they obtain from public and other sources, to estimate my income in conjunction with the Patient Assistance Program eligibility determination process, if applicable. I further understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; and no free product may be sold, traded, or distributed for sale. Continuation in the ImmunityBio Patient Assistance Program is conditioned upon timely verification of income. In addition, I agree to notify ImmunityBio if my insurance situation changes.

Patient Name Print Patient Signature Date
© 2025 ImmunityBio, Inc. All Rights Reserved ANK-00181-US v3.0 2/2026 ImmunityBio

Our dedicated Field Reimbursement Managers are available to deliver access and reimbursement support.

Patient Enrollment Forms can be obtained from your Field Reimbursement Manager, online at www.anktivaenrollment.com, or by calling ImmunityBio CARE™ at 833-422-2731.

Ordering ANKTIVA®



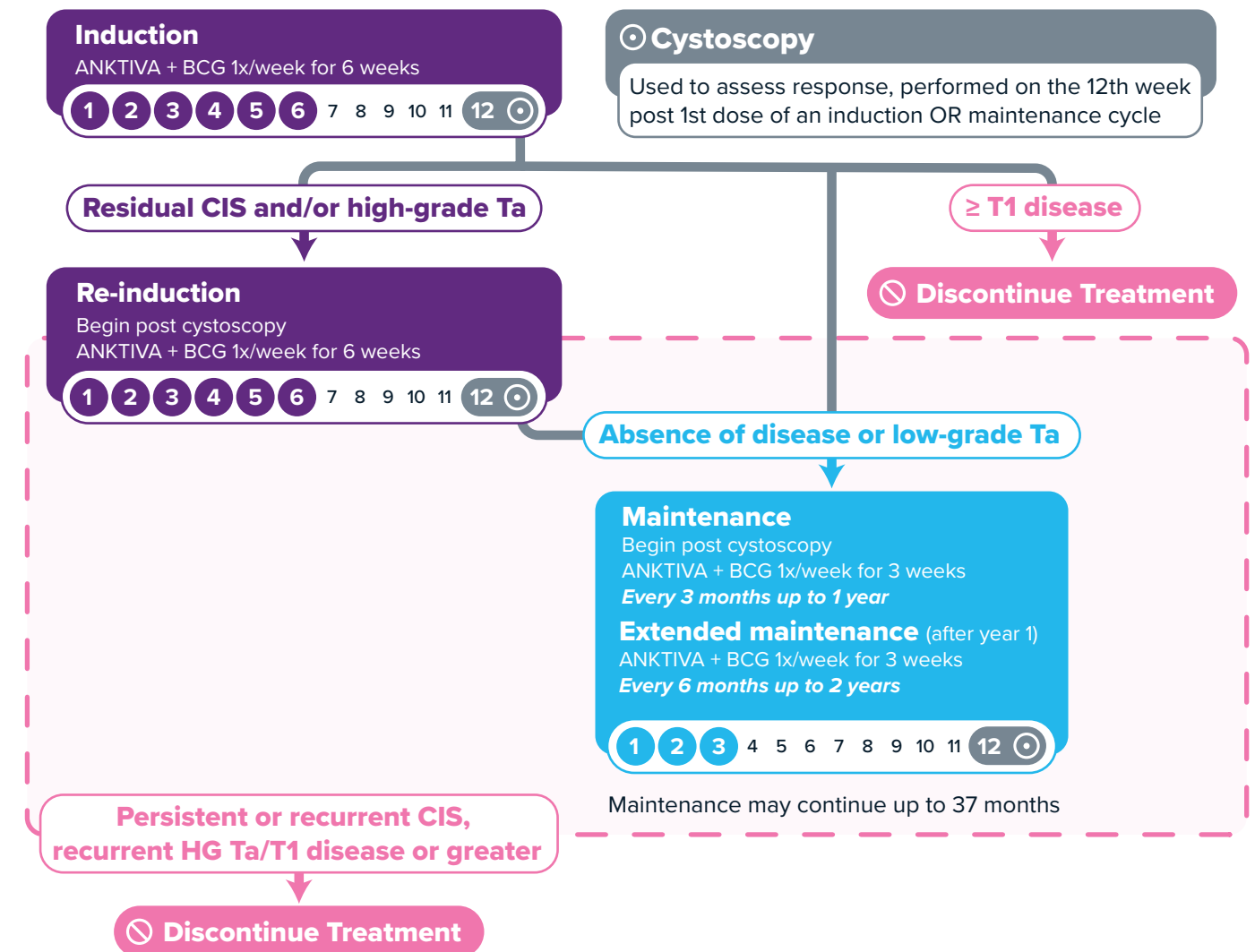
ANKTIVA is available directly through specialty distributors for buy and bill

Certain insurance plans may allow for ANKTIVA to be dispensed through our specialty pharmacy. Submit the enrollment form to assess patients' eligibility.



Product Information	Descriptor
Name	ANKTIVA
Generic Name	Nogapendekin alfa inbakicept-pmln
Package Presentation	Carton of one 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) Oncology Supply: 800-633-7555 ASD: 800-746-6273 Besse Medical: 800-543-2111</p> <p>McKesson McKesson Plasma & Biologics: 877-625-2566 McKesson Specialty Health: 800-482-6700</p> <p>Cardinal Health 855-855-0708</p> <p>CuraScript 877-599-7748</p>
Specialty Pharmacy	<p>Accredo Phone: 877-298-6186 Fax: 888-302-1028 ePrescribe: NCPDP ID: 4436920 Address: 1620 Century Center Parkway Memphis, TN 38134 Website: www.accredo.com/prescribers/manage-referrals</p>

Intravesical Instillation Schedule of ANKTIVA¹



Coverage & Payment for ANKTIVA®



Coverage Considerations for Patients With Medicare

Medicare coverage of ANKTIVA may be available to beneficiaries if reasonable and necessary. Medicare will reimburse separately payable drugs at an allowable rate of 106% of the average sales price (ASP). ImmunityBio will report to the Centers for Medicare & Medicaid Services (CMS) an ASP for ANKTIVA.

Coverage Considerations for Patients With Commercial Insurance or Medicaid

Commercial payers and Medicaid agencies generally follow coverage determinations by Medicare. When ANKTIVA is prescribed for a US Food and Drug Administration (FDA)–approved indication and is medically necessary, commercial payers and Medicaid are likely to provide coverage. However, as commercial payers and state Medicaid agencies develop their own coverage and reimbursement policies, it is important for physicians to understand payer contracts affecting patient access and product coverage.

Commercial payers and state Medicaid agencies may require additional documentation to grant coverage or obtain prior authorization for ANKTIVA. This documentation may include:

- The patient’s medical history
- A letter of medical necessity (see example on page 13)

Coverage and payment for ANKTIVA may depend on individual insurance plans and negotiated contracts with physicians and hospitals. Contracted prices may be based on fee schedules, invoices, or other payment methodologies such as ASP. Patients may be responsible for a copayment and deductible based on their individual insurance plan. For Medicaid beneficiaries, patient cost-share will vary based on the state Medicaid policies but may require patients to submit a copayment or coinsurance for ANKTIVA.

Dual Eligibility

Coverage for patients eligible for both Medicare and Medicaid will be determined based on Medicare coverage guidelines. **Medicare will always be the primary payer for patients with dual eligibility, and Medicaid may only cover a portion of the remaining cost-share.**² There are different categories of dual eligibility, and it is important for healthcare professionals to investigate a patient’s specific benefits and possible cost-share prior to treatment with ANKTIVA.

Programs That Can Help Patients With Medicare Costs

Medicare Prescription Payment Plan (M3P)³

The M3P helps patients budget their out-of-pocket costs for Medicare Part D medications obtained through pharmacy benefit (Accredo Specialty Pharmacy).

- Patients can enroll in a monthly payment plan to spread out their out-of-pocket expenses over the year
- Patients pay no additional fees or interest with M3P
- Patients must opt into M3P as it is not included automatically

Learn more at <https://www.medicare.gov/prescription-payment-plan/will-this-help-me>

Extra Help: Low-Income Subsidy (LIS)^{4,5}

The LIS program helps Medicare patients pay for Part D costs, including premiums, deductibles, co-insurance, and co-pays.

To qualify, a patient must:

- Be enrolled in Medicare Part D
- Have an annual income below 150% of the federal poverty level, and
- Meet the resource requirements

Patients should look into the LIS program whenever they update their Medicare plan, especially if their income has recently changed.

Learn more at [medicare.gov/basics/costs/help/drug-costs](https://www.medicare.gov/basics/costs/help/drug-costs).

Independent Foundations⁶

For patients having trouble paying for medications they need, consider foundations that offer help with out-of-pocket costs for prescription drugs.

Keep in mind:

- Foundations are usually set up to support a specific condition
- Each has its own eligibility requirements
- Funding can fluctuate over time

Obtaining Coverage

Verifying Benefits





Initiate a patient-specific insurance benefits verification through ImmunityBio CARE™ or conduct one with the patient's health insurance payer(s).

Obtaining Prior Authorization

Follow steps to obtain authorization (if required). It is important to review the current PA guidelines on the insurer's website or to contact the insurer's customer service for process information, including forms and contacts.

The following checklist highlights general information that may typically be required for a PA decision. Note that the information is not intended to be definitive or exhaustive. The provider is solely responsible for appropriate care and treatment of each patient.

Prior Authorization Checklist

-  **Completed PA request form (if required)**
-  **Letter of Medical Necessity (if needed), including information such as:**
 - Patient information: name, policy number, and date of birth
 - Physician information: name and tax ID/provider number
 - Patient diagnosis with ICD-10 code and date of diagnosis
-  **Documentation supporting the treatment decision, such as:**
 - Patient clinical notes detailing relevant diagnosis
 - Previous treatments/therapies
 - Relevant laboratory results
 - Product package insert
-  **You may be asked to provide additional information like facility information and relevant procedure, HCPCS, and NDC codes for services to be performed and products to be provided**

Sample Letter of Medical Necessity

[Use Provider's Letterhead]

[Date]

[Health Plan Name]
[Health Plan Address]
[City, State, Zip Code]

Member Name: [Insert Patient Name]
Member Date of Birth: [Patient DOB]
Patient Policy Number: [Insert Policy Number]

Request: Prior Authorization Request/Letter of Medical Necessity for treatment with ANKTIVA® J9028.
Diagnosis Code: [Insert ICD-10 code for NMIBC]

To [Health Plan Director/Prior Authorization department],

I am writing on behalf of my patient, [Patient Full Name], [to document the medical necessity/request Prior Authorization] for the use of ANKTIVA® (nogapendekin alfa inbakicept-pmln). This treatment is being prescribed for the FDA-approved indication of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Patient Clinical Summary

- **Diagnosis:** [Patient's Full Name] was diagnosed with high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.
- **Prior Treatment/History:** This patient has a documented history of prior therapy, including [List previous treatments, e.g., transurethral resection of bladder tumor (TURBT), intravesical BCG therapy. Include responses to therapy, medical description of patient's current symptoms/condition which has led to the current recommendation for a bladder-preserving treatment, which is consistent with the patient's preferences. Include your professional opinion of the patient's likely prognosis or disease progression without treatment with ANKTIVA®.]
- **Medication Requested Specifics:** ANKTIVA® Recommended Dose: [Include the specific dosage and administration frequency, e.g., 400 mcg, administered intravesically once weekly for 6 weeks, in combination with BCG.]

In summary, please cover treatment without delay. ANKTIVA® is medically necessary and appropriate for this patient. If you require any additional information, please do not hesitate to contact me at [Physician's Phone Number].

Sincerely,

[Physician's Full Name, M.D.]

Enclosures: [Attach FDA Prescribing Information and any additional documentation as referenced]

Supporting Documentation [i.e. Relevant medical records/Pathology reports confirming the diagnosis of NMIBC with CIS/Documentation of prior treatment and confirmation of BCG-unresponsiveness]

Obtaining Coverage (cont'd)

Addressing a Prior Authorization Denial

If a PA request is denied, it is important to fully understand the reason. If you choose to appeal, know that the process varies by payer. It's important to fully understand all requirements your patient's insurer may have before proceeding.

The checklist below highlights items and information that may be needed when filing an appeal to the insurer. It is neither medical guidance nor a suggestion that you submit an appeal. Note that the information is not intended to be definitive or exhaustive. The provider is solely responsible for appropriate care and treatment of each patient.

Prior Authorization Appeals Process Checklist



Completed appeal forms and required documentation

If required, complete and submit the appeal form to the insurer. Appeal forms can be obtained through the insurer's website or by contacting the insurer's customer service.



Formal Letter of Appeal

The sample letter on page 15 shows information to provide such as:

- Patient information
- Summary of diagnosis
- Address specific denial reason
- Summary of patient history
- Treatment rationale



Additional relevant information supporting treatment with ANKTIVA®:

- ANKTIVA prescribing information
- NDC number

Sample Letter of Appeal for Prior Authorization

[Use Provider's Letterhead]

[Date]

[Contact Name]

[Payer Name]

[Payer Address]

Re: [Patient First Name] [Patient Last Name]

[Policy Number]

[Group Number]

[Diagnosis Code 1]

[Case ID Number]

[Date(s) of Service]

Re: Appeal for Denial of Coverage for ANKTIVA® (nogapendekin alfa inbakicept-pmln)

Dear [Name or Contact]:

This letter serves as a formal appeal for reconsideration of coverage for ANKTIVA® (nogapendekin alfa inbakicept-pmln), which was originally denied to [Patient First Name] [Patient Last Name] on [Denial Date]. [Patient First Name] [Patient Last Name], has been under treatment for [Diagnosis Description 1]. [Insurance Company Name] has stated that ANKTIVA is not covered because of [Denial Reason].

Treatment Information

ANKTIVA (nogapendekin alfa inbakicept-pmln), is FDA-approved and is indicated for the treatment of patients who have been diagnosed with [FDA approved indication].

Patient History, Diagnosis, and Treatment Plan

[Patient First Name] is a [Age]-year-old [male/female] who has been under treatment for [Diagnosis Description 1; include ICD-10-CM codes] since [Date]. During this time, [he/she] has been treated with other therapies including [list prior treatments, duration and responses to each treatment, rationale for discontinuation, as well as other factors (underlying health issues, responses) that have affected your treatment plan]. [Continue with patient history and clinical support for medical necessity...]

Summary

I believe ANKTIVA is appropriate and medically necessary for this patient. Please provide coverage at your earliest convenience in order to treat their disease. If you have any further questions about this manner, please contact me at [Physician Phone Number] or via email at [Physician Email]. Thank you for your time.

Sincerely,

[Treating Provider First Name] [Treating Provider Last Name], [Treating Provider Title]

Enclosures: [List enclosures, which may include a previous Letter of Medical Necessity, ANKTIVA prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, FDA approval letter, scans showing progressive disease, pathology reports, or clinical practice guidelines]

Coding & Billing



The information within this section reviews some of the codes commonly associated with the administration of ANKTIVA®. However, your office should check directly with the patient's insurance plan to verify coding recommendations.

Product and Services

ANKTIVA National Drug Codes (NDC)¹

Code	Descriptor
10-digit: 81481-803-01	Carton containing 400 mcg/0.4 mL, single-dose vial
11-digit: 81481-0803-01	

Healthcare Common Procedure Coding System (HCPCS) Codes⁷

CMS has issued a permanent HCPCS J-Code for ANKTIVA for use in all treatment settings. Additional codes may also be appropriate, including a code for live Bacillus Calmette-Guerin (BCG) within the treatment admixture.

Type	Code	Descriptor
ANKTIVA J Code	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 mcg Please note: 400 mcg/0.4 mL single dose vial is equivalent to 400 billing units
Additional HCPCS Codes	J9030	BCG live intravesical instillation, 1 mg

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.

Medicare Pass-Through Status: ANKTIVA® (HCPCS Code J9028, APC Code 0767) was granted Transitional Pass-Through status by CMS effective October 1, 2024. ImmunityBio expects this status may continue until September 30, 2027. The Pass-Through status allows for separate Medicare payments under OPSS for some biologic drugs. This information can be found in the OPSS Addendum D1 with status indicator (G).

CMS: Centers for Medicare & Medicaid Services; OPSS: Outpatient Prospective Payment System.

Administration and Other Procedures

First induction, second induction, maintenance and follow-up.

Current Procedural Terminology (CPT) Codes⁸

CPT codes are used to bill for drug administration services provided in both the physician's office and outpatient settings. Appropriate code requirements may vary by payer and should be confirmed by the provider.

Code	Description
51720	Bladder instillation of anticarcinogenic agent, including retention time

Include the appropriate codes if other procedures are performed.

Our dedicated Field Reimbursement Managers are available to deliver access and reimbursement support.



Contact us at 833-422-2731

Monday - Friday 8:00 am - 8:00 pm ET

Coding & Billing (cont'd)



Diagnosis and Findings

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes⁹

Select the most clinically appropriate diagnosis code for each patient. ANKTIVA[®] is 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.

Code	Description
D09.0	Carcinoma in situ of bladder
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

Modifiers¹⁰

Use modifiers to report that a service or procedure has been altered by some specific circumstance, without a change to its code. The JZ modifier is required on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

Code	Description
JZ	Zero drug amount discarded/not administered to any patient

AHA Revenue Codes¹¹

When ANKTIVA is administered in the hospital outpatient setting, payers and hospitals will have specific policies on what revenue code they require. Providers should confirm the appropriate revenue code assignment per patient.

Code	Description
0636	Drugs requiring detailed coding

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.

AHA: American Hospital Association; AMA: American Medical Association; FARS/DFARS: Federal Acquisition Regulation Supplement/Defense Federal Acquisition Regulation Supplement.

Claims & Denials

When the patient has received ANKTIVA®, your office may submit a claim to the patient’s insurance plan. Depending on the patient’s benefits, your office may submit a claim for the drug, for the administration services, or both. Check directly with the patient’s insurance plan to verify coding recommendations.

Completing Claim Forms^{1, 10, 12, 13}

Accurate completion of CMS claim forms is important for timely and appropriate claims processing and to avoid claim denials. Detailed guidance on completing these forms is available in the Medicare Claims Processing Manual.

- For CMS-1500 form items, please see Chapter 26, available at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf>
- For CMS-1450 form items, please see Chapter 25, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

Sample CMS-1500 Form: Reminders

- A** **Item 21:** Indicate primary and other appropriate ICD-10 diagnosis code(s).
- B** **Item 24D:** Indicate appropriate CPT and HCPCS codes and modifiers, if required. Be sure to enter the correct CPT codes by payer.
- C** **Item 24D:** JZ modifier should be applied to attest that zero of the drug from a single-dose container was discarded or wasted, confirming the full dose was used.
- D** **Item 24F:** Indicate \$ charges.
- E** **Item 24G:** Indicate the appropriate billing units. **For ANKTIVA: 400 mcg/0.4 mL single dose vial is equivalent to 400 billing units.**

Sample CMS-1500 Form

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA/BLK LUNG OTHER

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE (MM | DD | YY) SEX (M | F) 4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED (Self | Spouse | Child | Other) 7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10. IS PATIENT'S CONDITION RELATED TO: (a. EMPLOYMENT? (Current or Previous) b. AUTO ACCIDENT? c. OTHER ACCIDENT?) 11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.) 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) 15. OTHER DATE 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) 20. OUTSIDE LAB? \$ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD-10 Ind. A. **C67.9** B. **D09.0** C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO. 23. PRIOR AUTHORIZATION NUMBER

1	2	3	4	5	6
MM DD YY MM DD YY 11	J9028	JZ	A	400	NPI
MM DD YY MM DD YY 11	J9030		A	XX	NPI
MM DD YY MM DD YY 11	51720		A	1	NPI
					NPI
					NPI
					NPI

24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. ERSDI (Explain) I. ID. QUAL. J. RENDERING PROVIDER ID. #

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For gov't claims, see back) YES NO 28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rsvd. for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH# ()

SIGNED DATE a. NPI b. NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Clear Form

Claims & Denials (cont'd)

Sample CMS-1450 (UB-04) Form

1 PATIENT NAME		2 PATIENT ADDRESS		3a PAT. CNTL. # b. MED. REC. #		4 TYPE OF BILL	
8 PATIENT NAME		9 PATIENT ADDRESS		5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
10 BIRTHDATE	11 SEX	12 DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE	
35 OCCURRENCE DATE		36 OCCURRENCE DATE		37 OCCURRENCE DATE		38 OCCURRENCE DATE	
39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT		42 VALUE CODES AMOUNT	
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 mcg	J9028-JZ	MM-DD-YY	400			
0636	BCG live intravesical instillation, 1 mg	J9030	MM-DD-YY	XX			
	Bladder instillation of anticarcinogenic agent, including retention time	51720	MM-DD-YY	1			
PAGE OF		CREATION DATE		TOTALS			
50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO		53 ASG. BEN.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 PREL.		60 INSURED'S UNIQUE ID		61 GROUP NAME	
62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66 ICD-10 CODE		67 ICD-10 CODE		68 ICD-10 CODE		69 ICD-10 CODE	
69 ADMIT REASON DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI	
73 OTHER PROCEDURE DATE		74 OTHER PROCEDURE DATE		75 OTHER PROCEDURE DATE		76 ATTENDING NPI	
77 OPERATING NPI		78 OTHER NPI		79 OTHER NPI		80 REMARKS	

Sample CMS-1450 (UB-04) Form: Reminders

- A** Item 42: Indicate revenue codes.
- B** Item 43: Describe procedure.
- C** Item 44: Indicate appropriate CPT and HCPCS codes and modifiers, if required.
- D** Item 44: JZ modifier should be applied to attest that zero of the drug from a single-dose container was discarded or wasted, confirming the full dose was used.
- E** Item 46: Indicate the appropriate billing units. **For ANKTIVA: 400 mcg/0.4 mL single dose vial is equivalent to 400 billing units.**
- F** Item 47: Indicate \$ charges.
- G** Item 66: Indicate appropriate ICD-10 diagnosis code(s).

Addressing a Claim Denial

If a claim is denied, it is important to fully understand the reason, usually given in the Explanation of Benefits. If you decide to appeal, note that the process varies by payer. Review your patient's insurer requirements before proceeding:

- Correct and resubmit the claim if the original submission was inaccurate
- Check the insurer's website for current appeal guidelines and instructions
- Complete all required forms and include requested supporting documents
- Track deadlines for filing and review timelines

Refer to sample appeal letter on page 15 for reference

References

1. ANKTIVA®. Prescribing Information. ImmunityBio, Inc. 2024.
2. Medicare.gov. Medicaid. Accessed on December 4, 2025. <https://www.medicare.gov/basics/costs/help/medicaid>
3. Medicare.gov. Fact Sheet: What's the Medicare Prescription Payment Plan? Accessed on December 3, 2025. <https://www.medicare.gov/publications/12211-whats-the-medicare-prescription-payment-plan.pdf>
4. National Council On Aging (NCOA). Benefits Check Up: Medicare Part D Low Income Subsidy (LIS) - Extra Help. Accessed on December 3, 2025. https://benefitscheckup.org/program/rxgov_fd_medicare_lis
5. Medicare.gov. Help with Drugs. Accessed on December 3, 2025. <https://www.medicare.gov/basics/costs/help/drug-costs>
6. Medicare Rights Center. Charity programs that help pay for prescriptions. Accessed on December 3, 2025. https://www.medicarerights.org/fliers/Help-With-Drug-Costs/copay_charities.pdf?nrd=1
7. Centers for Medicare & Medicaid Services (CMS). January 2026 Alpha-numeric HCPCS file. Accessed December 4, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>
8. American Medical Association. Current Procedural Terminology: CPT® 2025. Chicago, IL: AMA Press; 2024.
9. Centers for Medicare & Medicaid Services (CMS). ICD-10-CM tabular list of diseases and injuries. Accessed November 26, 2025. https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf
10. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17 - Drugs and biologicals. Issued June 6, 2025. Accessed December 2, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>
11. Noridian Healthcare Solutions. Revenue codes. Updated June 17, 2025. Accessed December 4, 2025. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>
12. Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual. Chapter 26 - Completing and processing form CMS-1500 data set. Issued August 9, 2024. Accessed November 26, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf>
13. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25 - Completing and processing the form CMS-1450 data set. Revised December 20, 2023. Accessed November 26, 2025. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

Please see Important Safety Information on page 2 and **Full Prescribing Information** for ANKTIVA.



ANKTIVA® and its design are registered trademarks of ImmunityBio, Inc. ©2026 ImmunityBio. All rights reserved. US-ANK-250010 v2, Feb 2026.