Anktiva®
(nogapendekin alfa inbakicept-pmln)

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).

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Overview

Anktiva®
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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:

- **Navigating payer restrictions**
- **Ordering**
- **Billing**
- **Claims filing**
- **The appeals process**
- **Patient support**

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.

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

Contact us for support

Anktiva®
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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 as little as $25 per vial*
- Patient Assistance Program (PAP)
- Treatment is available free of charge to eligible patients who are uninsured or underinsured.†

Prior authorization support and tracking

Coding and billing assistance

Claim denial guidance 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.

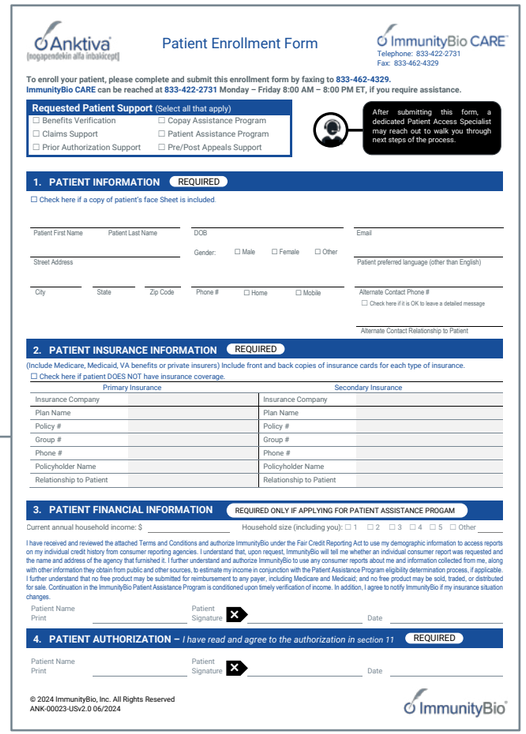
ImmunityBio CARE™

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 (nogapendekin alfa inbakicept)

Patient Enrollment Form

ImmunityBio CARE
Telephone: 833-422-2731
Fax: 833-462-4329

To enroll your patient, please complete and submit this enrollment form by faxing to **833-462-4329.**
ImmunityBio CARE can be reached at **833-422-2731** Monday – Friday 8:00 AM – 8:00 PM ET, if you require assistance.

Requested Patient Support (Select all that apply)
☐ Benefits Verification ☐ Copay Assistance Program
☐ Claims Support ☐ Patient Assistance Program
☐ Prior Authorization Support ☐ Pre/Post Appeals Support

After submitting this form, a dedicated Patient Access Specialist may reach out to walk you through next steps of the process.

1. PATIENT INFORMATION REQUIRED

☐ Check here if a copy of patient's face Sheet is included

Patient First Name | Patient Last Name | DOB | Email
Gender: ☐ Male ☐ Female ☐ Other
Street Address | Patient preferred language (other than English)
City | State | Zip Code | Phone # ☐ Home ☐ Mobile | Alternate Contact Phone #
☐ Check here if it is OK to leave a detailed message
Alternate Contact Relationship to Patient

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.

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. PATIENT FINANCIAL INFORMATION REQUIRED ONLY IF APPLYING FOR PATIENT ASSISTANCE PROGAM

Current annual household income: $ _____ Household size (including you): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Other _____

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 tell 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 _____

4. PATIENT AUTHORIZATION – *I have read and agree to the authorization in section 11* REQUIRED

Patient Name Print _____ Patient Signature ✕ _____ Date _____

ImmunityBio®

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

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

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

Ordering ANKTIVA®

Anktiva®
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ANKTIVA is available directly through specialty distributors for buy and bill

If you prefer, ANKTIVA can also be dispensed through our specialty pharmacy. Please call 1-877-ANKTIVA (1-877-265-8482) to determine if your patient is eligible for specialty pharmacy services and how to enroll.

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	**Cencora (AmerisourceBergen)** Oncology Supply: 800-633-7555 ASD: 800-746-6273 Besse Medical: 800-543-2111 **McKesson** McKesson Plasma & Biologics: 877-625-2566 McKesson Specialty Health: 800-482-6700 **Cardinal Health** 855-855-0708 **CuraScript** 877-599-7748
Specialty Pharmacy	**Accredo** 866-828-1129 www.accredo.com/prescribers/manage-referrals

Intravesical Instillation Schedule of ANKTIVA®

FIRST INDUCTION

Month 1 2 3

- **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

Month 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40

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 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

Month 1 2 3 4 5

- **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

Month 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40

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 7, 10, 13 and 19. 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.

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Coverage & Payment for ANKTIVA®

Anktiva®
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Appropriate Coding

Healthcare providers should include appropriate codes on claim forms to ensure timely and accurate claims processing. Important codes include:

- The product-specific HCPCS code
- The Current Procedural Terminology (CPT) code(s) for the procedure
- *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)* codes for the patient's diagnosis

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.** 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.

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

Submitting Claims for ANKTIVA®

Anktiva®
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Best Practices

Accurate completion of the CMS-1500 or CMS-1450 (UB-04) claim form is important for timely and appropriate claims processing and to avoid claim denials. To accurately complete the claim form for patients receiving ANKTIVA, the following steps should be considered:

1. Initiate a patient-specific insurance benefits verification through ImmunityBio CARE™ or conduct one with the patient's health insurance payer(s).
2. Determine whether prior authorization is required. Follow steps to obtain the authorization (if required) and provide the prior authorization reference number when submitting a claim to the payer.
3. Review coding on the claim form before submitting to the payer.
4. Along with the claim form, submit any payer-requested documentation that supports medical necessity.
5. Track claim submission and provider reimbursement.

Additional Documentation

Healthcare providers who prescribe ANKTIVA should prepare to submit additional documentation with the CMS-1500 or CMS-1450 (UB-04) claim form to ensure appropriate claims processing and to avoid claims denials. The following documentation may be requested by payers when processing a claim for ANKTIVA:

- Patient medical history
- Physician clinical notes on the patient's condition
- Letter of medical necessity (see example on page 13)
  - This sample letter of medical necessity can be used as a guide to provide the reasons, in your clinical judgment, ANKTIVA is necessary for your patient. The letter should explain why ANKTIVA is being requested and give health plans additional information that can be used to assess whether the medication can be approved. Please note that providing such a letter does not guarantee the health plan will offer reimbursement for ANKTIVA, and the information is not intended to substitute for or influence the physician/provider's independent medical judgment. The sample letter is provided for guidance purposes only
- Invoice for ANKTIVA
- National Drug Code (NDC) for ANKTIVA (Medicaid and/or commercial payers)
- ANKTIVA Prescribing Information
- FDA approval letter for ANKTIVA

Sample Letter of Medical Necessity

[Use Provider's Letterhead]

[Date]

[Health Plan Contact Name]
[Title]
[Health Plan Organization Name]
[Address]
[City, State ZIP]

Re: [Patient Name]
Insurance Policy ID Number: [Insurance Policy ID Number]
Group Number: [Group Number]

Dear [Health Plan Contact Name],

I am writing on behalf of my patient, [Patient Full Name], to document the medical necessity of ANKTIVA® (nogapendekin alfa inbakicept-pmln). Included below is additional information about the patient's medical history and diagnosis, as well as a statement summarizing my treatment rationale.

[Patient First Name] is [age] years old and has been under treatment for [diagnosis description] since [date]. [Include a detailed overview of the patient's condition and specific diagnosis. Include the patient's history related to the condition and the length of time you think the patient will need to take the medication.]

In summary, ANKTIVA is medically necessary for this patient's medical condition, and [Health Plan Name] should cover this product for my patient without delay. Please contact me at [phone number] if additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician/Provider's Name, degree(s), and signature]

Enclosures: [Attach any additional documentation, as appropriate]

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

Submitting Claims for ANKTIVA® (cont'd)

Anktiva®
(nogapendekin alfa inbakicept-pmln)

Addressing a Claim Denial

Common Reasons for Denial of an ANKTIVA Claim

Typically payers deny claims for one or more of the following:

- Incomplete form
- Inaccurate coding
- Missing information or supporting documentation
- Processing error by the payer
- Coverage for ANKTIVA is not available through the patient's health insurance plan

Appealing a Denied Claim

In the event that the claim form was filled out incorrectly or was incomplete, the healthcare provider may resend a claim form that is accurate and complete, and label it "resubmit" to avoid double-billing. If the payer made an error in processing the claim, the provider's office should contact the payer to discuss the processing issue.

When appealing a denied claim, payers may request additional documentation (beyond what was submitted with the original claim), including:

- Letter of appeal (see sample letter on page 15)
- Copy of physician's order
- Copy of the original claim
- ANKTIVA Prescribing Information
- Copy of denial notification from payer
- FDA approval letter
- Copy of invoice

Sample Letter of Appeal

[Use Provider's Letterhead]

[Date]

[Contact Name]
[Site Name]
[Address Line 1]
[Address Line 2]
[City, State Zip]

Re: [Patient First Name] [Patient Last Name]
[Policy Number]
[Group Number]
[Diagnosis Code 1]

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 Lash Name], on [Denial Date]. [Patient First Name] [Patient Lash Name], has been under treatment for [Diagnosis Description 1]. [Insurance Company Name] has stated that ANKTIVA is not covered because [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].

[Insert all relevant patient information here.]

Patient History and Diagnosis
[Patient First Name] is a [Age]-year-old [male/female] who has been under treatment for [Diagnosis Description 1] since [Date]. During this time, [he/she] has been treated with other therapies including [discuss previous therapies and patient's response to therapy]. [Continue with patient history and clinical support for medical necessity...]

Sincerely,

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

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

Coding & Billing

Anktiva®
(nogapendekin alfa inbakicept-pmln)

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 for both. 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) Codes[2]

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
	A9589	Instillation, hexaminolevulinate hydrochloride, 100 mg
	C9738	Adjunctive blue light cystoscopy with fluorescent imaging agent

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 OPPS for some biologic drugs. This information can be found in the OPPS Addendum D1 with status indicator (G).

Administration and Other Procedures

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

Current Procedural Terminology (CPT) Codes[3]

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
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 or laser surgery, and/or resection of medium bladder tumor(s) (2.0 to 5.0 cm)
52240	Cystourethroscopy, with fulguration, including cryosurgery or laser surgery, and/or resection of large bladder tumor(s) (>5.0 cm)
88104	Cytopath nongyn smear
88108	Cytopath concentrate tech
88112	Cytopath cell enhance tech

AMA: American Medical Association; CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; FARS: Federal Acquisition Regulation Supplement; HHSARS: Health and Human Services Acquisition Regulation; ICD: International Classification of Diseases; NDC: National Drug Code.

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

Coding & Billing (cont'd)

CPT Evaluation and Management (E/M) Codes[3]

In some instances, you may provide an evaluation and management (E/M) service in addition to ANKTIVA® administration. The following codes may be used to report such services in the office or an outpatient facility.

Code	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, 30-39 minutes

AHA Revenue Codes[4]

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

Documentation of Drug Wastage[5]

Healthcare providers must use the JW modifier to report the amount of unused drug from a single-use vial that is discarded and must document the amount of discarded drug in the patient's medical record. 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
JW	Drugs amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

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.

Diagnosis and Findings

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes[6]

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
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
D09.0	Carcinoma in situ of bladder
R82.7	Abnormal findings on microbiological examination of urine
R82.8	Abnormal findings of cytological and histological examination of urine
R82.9	Other and unspecified abnormal findings of urine
Z80.52	Family history of malignant neoplasm of bladder
Z85.51	Personal history of malignant neoplasm of bladder

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

Coding & Billing (cont'd)

A **Item 19:** Payer requirements vary. Payer may ask providers to specify dosage, NDC, name, strength, and method of administration.

B **Item 21:** Indicate appropriate ICD-10 diagnosis code.

C **Item 24D:** Indicate appropriate CPT and HCPCS codes and modifiers, if required. Be sure to enter the correct CPT codes by payer. Use the JW modifier to identify unused drugs from a single use vial. This modifier, billed on a separate line, will provide payment for the amount of discarded drug. When no drug is discarded or unused, the JZ modifier should be applied.

D **Item 24E:** Refer to the diagnosis for this service (see Box 21).

E **Item 24F:** Indicate $ charges.

F **Item 24G:** Indicate the appropriate billing units. **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

PICA

1. MEDICARE (X) (Medicare#)	1a. INSURED'S I.D. NUMBER: 000-00-1234
2. PATIENT'S NAME: Doe, Jane A.	3. PATIENT'S BIRTH DATE: 01 06 48; SEX: M F X
4. INSURED'S NAME: Doe, Jane A.	
5. PATIENT'S ADDRESS: 1024 Maple Street	6. PATIENT RELATIONSHIP TO INSURED: Self X Spouse Child Other
7. INSURED'S ADDRESS: 1024 Walnut Street	
CITY: Anytown; STATE: AS	8. RESERVED FOR NUCC USE
CITY: Anytown; STATE: AS	
ZIP CODE: 01010; TELEPHONE: (301) 123-4567	
ZIP CODE: 01010; TELEPHONE: (301) 123-4567	
9. OTHER INSURED'S NAME	10. IS PATIENT'S CONDITION RELATED TO:
11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) YES NO
a. INSURED'S DATE OF BIRTH; SEX	
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES NO PLACE (State)
b. OTHER CLAIM ID (Designated by NUCC)	
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES NO
c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare	10d. CLAIM CODES (Designated by NUCC)
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.	

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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. SIGNED: On File DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE: I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL	15. OTHER DATE QUAL MM DD YY
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. Dr. Smith; 17b. NPI 123 456 7890
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): 400 mcg ANKTIVA intravesical injection, NDC: 81481-803-01, Carton	20. OUTSIDE LAB? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.: A C67.0 B C D E F G H I J K L	22. RESUBMISSION CODE ORIGINAL REF. NO.
	23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1	01 01 25	01 01 25	11		J9028	JZ	A	XXX XX	400		NPI	123 456 7890
2	01 01 25	01 01 25	11		J9030	JZ	A	XXX XX	1		NPI	123 456 7890
3											NPI	
4											NPI	
5											NPI	
6											NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN	26. PATIENT'S ACCOUNT NO.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO
28. TOTAL CHARGE $ 0.00	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.) SIGNED DATE	32. SERVICE FACILITY LOCATION INFORMATION a. NPI b.	33. BILLING PROVIDER INFO & PH # (301) 987-6543 Dr. Smith 1028 William Road Anytown, AS 01010 a. 123 456 7890 b.

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

Clear Form

CARRIER — PATIENT AND INSURED INFORMATION — PHYSICIAN OR SUPPLIER INFORMATION

A B C D E F

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

Coding & Billing (cont'd)

Anktiva®
(nogapendekin alfa inbakicept-pmln)

A **Item 42:** Indicate revenue codes.

B **Item 43:** Describe procedure.

C **Item 44:** Indicate appropriate CPT and HCPCS codes and modifiers, if required. Be sure to enter the correct CPT codes by payer. Consult payer for coding policy.

D Use the JW modifier to identify unused drugs or biologics from a single use vial. This modifier, billed on a separate line, will provide payment for the amount of discarded drug. When no drug is discarded or unused, the JZ modifier should be applied.

E **Item 46:** Indicate the appropriate billing units. **400 mcg/0.4 mL single dose vial is equivalent to 400 billing units.**

F **Item 47:** Indicates $ charges.

G **Item 66:** Indicate appropriate ICD-10 diagnosis code.

H **Item 80:** Payer requirements vary. Payer may ask providers to specify dosage, NDC, name, strength, and method of administration.

Sample CMS-1450 (UB-04) Form

1 Anytown Hospital 101 Federal Street Anytown, Anystate 01010	2 Pay-to-name Pay-to-address Pay-to-city/state	3a PAT. CNTL # xx-xxxx b. MED. REC. # DOE 1234-97 5 FED. TAX NO. 010001010	4 TYPE OF BILL 6 STATEMENT COVERS PERIOD FROM THROUGH 7
8 PATIENT NAME a Jane A. Doe (ID) b Jane A. Doe	9 PATIENT ADDRESS a 1024 Maple Street b Anytown c AS d 01010 e US		
10 BIRTHDATE 01-06-1948	11 SEX F	12 ADMISSION DATE 13 HR 14 TYPE 15 SRC	16 DHR
17 STAT	18 19 20 21 22 23 24 25 26 27 28 CONDITION CODES	29 ACDT STATE	30
31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE
35 OCCURRENCE SPAN CODE FROM THROUGH	36 OCCURRENCE SPAN CODE FROM THROUGH	37	
38	39 VALUE CODES CODE AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT

A B C E F

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	01-01-25	400	XXX XX		
0636	BCG live intravesical instillation, 1 mg	J9030-JZ	01-01-25	1	XXX XX		

D

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 123 456 7890	57 OTHER PRV ID		
58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME		

G

66 DX	C67.0	67	A	B	C	D	E	F	G	H	68						
		I	J	K	L	M	N	O	P	Q							
69 ADMIT DX		70 PATIENT REASON DX	a	b	c	71 PPS CODE	72 ECI	a	b	c	73						
74 PRINCIPAL PROCEDURE CODE DATE		a. OTHER PROCEDURE CODE DATE		b. OTHER PROCEDURE CODE DATE		75											
XX.XX																	
OTHER PROCEDURE CODE DATE		d. OTHER PROCEDURE CODE DATE		e. OTHER PROCEDURE CODE DATE													

H

76 ATTENDING NPI 123 456 7890	QUAL	LAST	FIRST	
77 OPERATING	NPI	QUAL	LAST	FIRST
78 OTHER	NPI	QUAL	LAST	FIRST
79 OTHER	NPI	QUAL	LAST	FIRST

80 REMARKS 400 mcg ANKTIVA intravesical injection
NDC: 81481-803-01, Carton containing
400 mcg/0.4 mL, single-dose vial

81CC a b c d

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC® National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

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

References

1. ANKTIVA. Prescribing information. ImmunityBio, Inc; 2024.
2. Centers for Medicare & Medicaid Services (CMS). January 2025 Alpha-Numeric HCPCS Files. Open Zip File. Open HCPC2025_JAN_ANWEB_12172024. Accessed December 26, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly update
3. American Medical Association. Current Procedural Terminology: CPT® 2023. Chicago, IL: AMA Press; 2022.
4. Revenue codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Updated March 18, 2024. Accessed January 7, 2025.
5. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17 - Drugs and biologicals. Revised February 15, 2024. Accessed January 6, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
6. Centers for Medicare & Medicaid Services (CMS). ICD-10 Codes. 2025 ICD-10-CM. Downloads. Open 2025 CodeTables, Tabular and Index (ZIP). Open icd10cm_tabular_2025 Adobe Acrobat Document. Accessed December 26, 2024. https://www.cms.gov/medicare/ coding-billing/icd-10-codes/2025-icd-10-cm

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