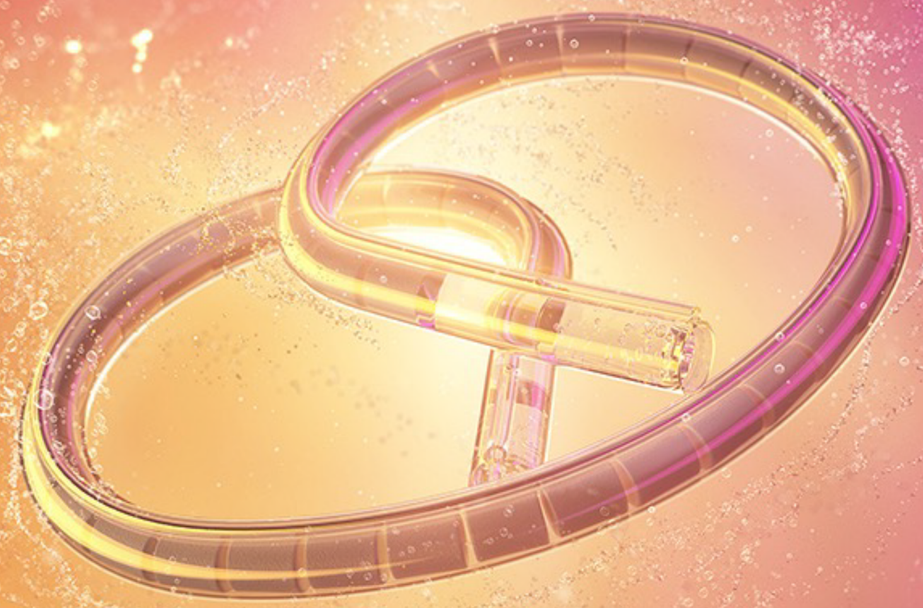

Access & Reimbursement Guide

Navigating coverage, coding, and procurement to support patient access to INLEXZO™

inlexzo™
gemcitabine intravesical system | 225 mg

INDICATION

INLEXZO™ (gemcitabine intravesical system) is indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INLEXZO™ is contraindicated in patients with:

- Perforation of the bladder.
- Prior hypersensitivity reactions to gemcitabine or any component of the product.

WARNINGS AND PRECAUTIONS

Risks in Patients with Perforated Bladder

INLEXZO™ may lead to systemic exposure to gemcitabine and to severe adverse reactions if administered to patients with a perforated bladder or to those in whom the integrity of the bladder mucosa has been compromised.

Evaluate the bladder before the intravesical administration of INLEXZO™ and do not administer to patients with a perforated bladder or mucosal compromise until bladder integrity has been restored.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

Important Safety Information

CONTRAINDICATIONS

INLEXZO™ is contraindicated in patients with:

- Perforation of the bladder.
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Risks in Patients with Perforated Bladder

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Evaluate the bladder before the intravesical administration of INLEXZO™ and do not administer to patients with a perforated bladder or mucosal compromise until bladder integrity has been restored.

Risk of Metastatic Bladder Cancer with Delayed Cystectomy

Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. The risk of developing muscle invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of persisting CIS.

Of the 83 evaluable patients with BCG-unresponsive CIS treated with INLEXZO™ in Cohort 2 of SunRISe-1, 7 patients (8%) progressed to muscle invasive (T2 or greater) bladder cancer. Three patients (3.5%) had progression determined at the time of cystectomy. The median time between determination of persistent or recurrent CIS or T1 and progression to muscle invasive disease was 94 days.

Magnetic Resonance Imaging (MRI) Safety

INLEXZO™ can only be safely scanned with MRI under certain conditions. Refer to section 5.3 of the USPI for details on conditions.

Embryo-Fetal Toxicity

Based on animal data and its mechanism of action, INLEXZO™ can cause fetal harm when administered to a pregnant woman if systemic exposure occurs. In animal reproduction studies, systemic administration of gemcitabine was teratogenic, embryotoxic, and fetotoxic in mice and rabbits.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months after final removal of INLEXZO™. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after final removal of INLEXZO™.

Please read full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™
gemcitabine intravesical system | 225 mg

Important Safety Information (cont'd)

ADVERSE REACTIONS

Serious adverse reactions occurred in 24% of patients receiving INLEXZO™. Serious adverse reactions that occurred in >2% of patients included urinary tract infection, hematuria, pneumonia, and urinary tract pain. Fatal adverse reactions occurred in 1.2% of patients who received INLEXZO™, including cognitive disorder.

The most common (>15%) adverse reactions, including laboratory abnormalities, were urinary frequency, urinary tract infection, dysuria, micturition urgency, decreased hemoglobin, increased lipase, urinary tract pain, decreased lymphocytes, hematuria, increased creatinine, increased potassium, increased AST, decreased sodium, bladder irritation, and increased ALT.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on the use of INLEXZO™ in pregnant women to inform a drug-associated risk.

Please see Embryo-Fetal Toxicity for risk information related to pregnancy.

Lactation

Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment and for 1 week after final removal of INLEXZO™.

Females and Males of Reproductive Potential

Pregnancy Testing - Verify pregnancy status in females of reproductive potential prior to initiating INLEXZO™.

Contraception - Please see Embryo-Fetal Toxicity for information regarding contraception.

Infertility (Males) - Based on animal studies, INLEXZO™ may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

Geriatric Use

Of the patients given INLEXZO™ monotherapy in Cohort 2 of SunRISe-1, 72% were 65 years of age or older and 34% were 75 years or older. There were insufficient numbers of patients <65 years of age to determine if these patients respond differently to patients 65 years of age and older.

Please read full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™
gemcitabine intravesical system | 225 mg

HELPING YOUR PATIENTS ACCESS INLEXZO™ EVERY STEP OF THE WAY

Click the images to download the applicable form

1

Complete a benefits investigation

and connect your patients to a J&J withMe Care Connector.

Patient Enrollment Form

2

Submit prior authorization or medical exception request

If request is denied, review the reason for denial and consider submitting an appeal.

Prior Authorization Checklist

Exception Considerations Checklist

Sample Letter of Medical Necessity and Exception Template

3

Acquire INLEXZO™ via Buy-and-Bill or specialty pharmacy

Determine whether to acquire INLEXZO™ through Buy-and-Bill or a specialty pharmacy based on payer coverage.

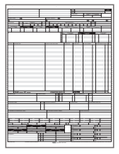
"How to order" guide

4

Submit a reimbursement claim for INLEXZO™ and procedure and track progress

Track claim status and initiate appeals process, if denied.

CMS-1500



CMS-1450

Appeal Process Consideration Checklist

5

Schedule the patient's next appointment

Confirm the patient's health insurance has not changed, and arrange the next appointment.

*Patients can also initiate enrollment themselves by visiting INLEXZOwithMe.com/signup OR calling 833-JNJ-wMe1 (833-565-9631), Monday through Friday, 8:00 AM–8:00 PM ET.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™
gemcitabine intravesical system | 225 mg

TABLE OF CONTENTS

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™
gemcitabine intravesical system | 225 mg

INTRODUCTION

Reimbursement Support

Johnson & Johnson is committed to providing you with reimbursement information for INLEXZO™. This Access and Reimbursement Guide has been developed to provide you with:

- Important Product Information
- Coverage and Coding Considerations
- Sample Claim Forms
- Reimbursement Support Resources

J&J withMe

INLEXZO™ access and reimbursement support resources are available through J&J withMe.

For information and assistance, please contact: **833-JNJ-wMe1** (833-565-9631) or visit JNJwithMe.com

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Johnson & Johnson that these codes will be appropriate or that reimbursement will be made. This document is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe a J&J medicine.

CPT®=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

INTRODUCTION

Site of Care Coding Summary for INLEXZO™

INDICATION

INLEXZO™ (gemcitabine intravesical system) is indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors.

Information	Code Type	Code and Descriptor	Physician Office	Hospital Outpatient	Ambulatory Surgical Center
Diagnosis	ICD-10-CM*	**C67.0** – Malignant neoplasm of trigone of bladder[1] **C67.1** – Malignant neoplasm of dome of bladder[1] **C67.2** – Malignant neoplasm of lateral wall of bladder[1] **C67.3** – Malignant neoplasm of anterior wall of bladder[1] **C67.4** – Malignant neoplasm of posterior wall of bladder[1] **C67.5** – Malignant neoplasm of bladder neck (internal urethral orifice)[1] **C67.6** – Malignant neoplasm of ureteric orifice[1] **C67.8** – Malignant neoplasm of overlapping sites of bladder[1] **C67.9** – Malignant neoplasm of bladder, unspecified[1]	✓	✓	✓
		D09.0 – Carcinoma in situ of the bladder[1] **Z85.51** – Personal history of malignant neoplasm of bladder[1]	✓	✓	✓

***These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive, and additional codes may apply. Please consult your ICD-10-CM codebook for more information.**

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

INTRODUCTION

Site of Care Coding Summary for INLEXZO™

Information	Code Type	Code and Descriptor	Physician Office	Hospital Outpatient	Ambulatory Surgical Center
INLEXZO™	11-Digit NDC (5-4-2 Format)*	**57894-0225-01** – INLEXZO™ (gemcitabine intravesical system) contains the equivalent of 225 mg of gemcitabine (present as 256.3 mg of gemcitabine hydrochloride), co-packaged with one urinary catheter and one stylet[2]	✓	✓	✓
	Revenue Code	**0636** – Pharmacy, drugs requiring detailed coding[3]		✓	
	HCPCS Level II†‡	**C9399** – Unclassified drug or biological[4,5]		Required by Medicare	Required by Medicare
		J3490 – Unclassified drugs[6] **J3590** – Unclassified biologics[6] **J9999** – Not otherwise classified, antineoplastic drugs[6]	Required by Medicare	As required by payer	As required by payer

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

*Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.
†C9399 is required by Medicare when INLEXZO™ is administered in an outpatient hospital or ambulatory surgical center.
‡A miscellaneous J-code is required by Medicare when INLEXZO™ is administered in a physician's office. Because requirements may vary, it is advisable to check with your payer prior to submitting claims reporting miscellaneous codes.
HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

INTRODUCTION

Site of Care Coding Summary for INLEXZO™

Information	Code Type	Code and Descriptor	Physician Office	Hospital Outpatient	Ambulatory Surgical Center
Procedure	Revenue Code	**0360 –** Operating room services, general[3]		✓	
	CPT® Category I	**51720 –** Bladder instillation of anticarcinogenic agent (including retention time)[7]			
		52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]	✓	✓	✓

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024.

STORAGE AND HANDLING

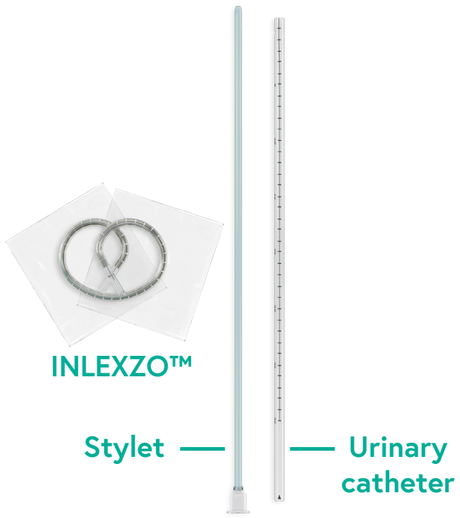
The only off-the-shelf FDA-approved intravesical product for BCG-UR NMIBC CIS*: INLEXZO™ can be stored at room temperature and does not require special preparation prior to use[2,8-12†]

Storage[2]

Store in the original carton at 20°-25°C (68°-77°F)

Handling[2]

- INLEXZO™ is a hazardous drug. Follow applicable special handling and disposal procedures while handling INLEXZO™ and during the insertion and removal
- Carton includes one sterile single dose of INLEXZO™ co-packaged with one sterile urinary catheter and one sterile stylet



Please read full Prescribing Information and Instructions for Use for complete information on how to prepare and administer INLEXZO™.

*As of 09/25.
†INLEXZO™ does not require freezing, refrigeration, reconstitution, or use of a hood for preparation.[2]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Risk of Metastatic Bladder Cancer with Delayed Cystectomy

Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. The risk of developing muscle invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of persisting CIS.

Of the 83 evaluable patients with BCG-unresponsive CIS treated with INLEXZO™ in Cohort 2 of SunRISe-1, 7 patients (8%) progressed to muscle invasive (T2 or greater) bladder cancer. Three patients (3.5%) had progression determined at the time of cystectomy. The median time between determination of persistent or recurrent CIS or T1 and progression to muscle invasive disease was 94 days.

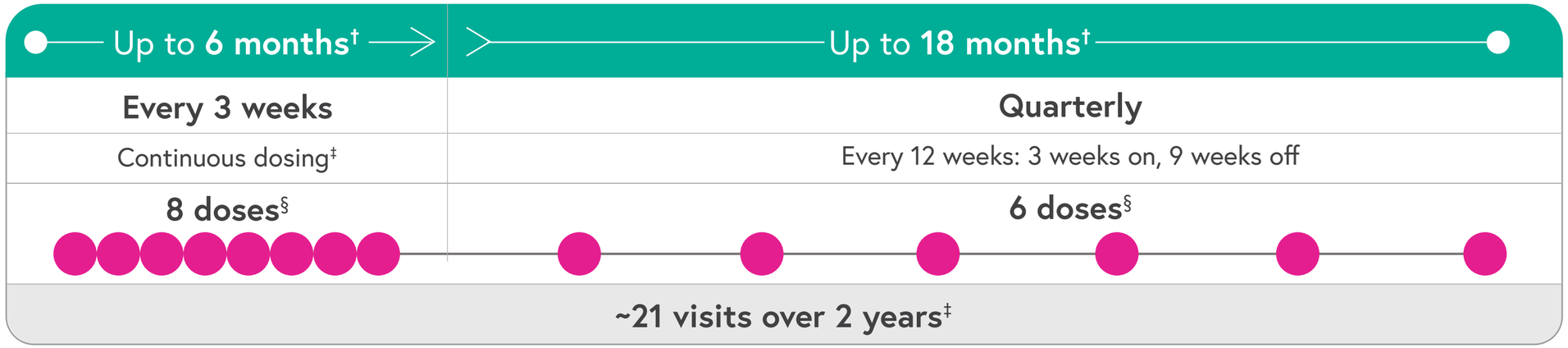
Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

DOSING & ADMINISTRATION

INLEXZO™ is administered in a familiar,* in-office procedure in 14 doses over 2 years[2]

Remove INLEXZO™ after each 3-week indwelling period



*Uses catheterization and cystoscopy.[13]
†Or until unacceptable toxicity or disease persistence, recurrence, or progression.[2]
‡Assumes same-day removal and new insertion during first 6 months.[2]
§One dose=insertion and removal 3 weeks later.[2]

Administration[13]

- Administer INLEXZO™ intravesically only using the co-packaged urinary catheter and stylet
- INLEXZO™ should be inserted and removed by a trained healthcare provider thoroughly familiar with the insertion and removal instructions

Missed Dose[2]

- If a dose is missed, it should be administered as closely as possible to the original treatment schedule

Prophylactic Antibiotics[2]

- Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each INLEXZO™ insertion and removal

MRI Scans[2,13]

- INLEXZO™ contains a metal wire. When INLEXZO™ is indwelling in the bladder, the patient can only be safely scanned with MRI under certain conditions.
  Please read full Prescribing Information for INLEXZO™ for specific MRI scanning conditions.

MRI=magnetic resonance imaging.

View administration video

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Magnetic Resonance Imaging (MRI) Safety

INLEXZO™ can only be safely scanned with MRI under certain conditions. Refer to section 5.3 of the USPI for details on conditions.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

Once you have made the clinical decision to prescribe INLEXZO™ (gemcitabine intravesical system), Johnson & Johnson has resources to help you support your patients.

J&J withMe

Comprehensive Support Throughout Your Patients' Treatment Journey

J&J withMe is your single source for access, affordability, and treatment support programs from J&J. Your patients will be connected to INLEXZO withMe.

Access support to help navigate payer processes

- Insurance coverage verification
- Benefits investigation support
- Prior authorization support
- Exceptions and appeals process information
- Reimbursement information

Affordability resources for your patients

Help patients discover ways to afford INLEXZO™—regardless of their insurance type or even if they have no insurance at all.

Dedicated, free 1-on-1 support for your patients throughout their treatment journey

Patients will partner with their Care Navigator, an oncology-trained nurse*, to schedule phone calls during key milestones in their treatment.

*Care Navigators do not provide medical advice.

Get started with J&J withMe

Enroll your patients in J&J withMe at **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631)

The patient support and resources provided by J&J withMe and INLEXZO withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe INLEXZO™.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

Once you have made the clinical decision to prescribe INLEXZO™ (gemcitabine intravesical system), Johnson & Johnson has resources to help you support your patients.

Cost support options are available regardless of insurance type

Commercially Insured Patients

J&J withMe Savings Program

Eligible patients pay **$5 per treatment** for INLEXZO™ out-of-pocket treatment costs and pay **$0** for certain treatment administration costs.

Maximum program benefit per calendar year shall apply. Offer subject to change or end without notice. See program requirements at **Inlexzo.JNJwithMeSavings.com**

Government coverage (Medicare, Medicaid, Military)

Foundation Support and Advocacy

J&J withMe can provide information about resources that may help your patients with their out-of-pocket treatment costs:

- State Pharmaceutical Assistance Programs (SPAPs)
- State Health Insurance Programs (SHIPs)
- Medicare Savings Program
- Independent Sources of Support

No insurance

Affordability support for patients without insurance coverage

J&J withMe can help identify other resources that may help your patients with out-of-pocket treatment costs.

Call us at **833-JNJ-wMe1** (833-565-9631) or visit **JNJwithMe.com** for information on affordability programs that may be available.

Additional Affordability Support from Johnson & Johnson

Patient assistance is available if your patient is uninsured or has commercial, employer-sponsored, or government coverage that does not fully meet their needs. Your patient may be eligible to receive their medicine from J&J at no cost for up to one year if they meet the eligibility and income requirements for the Johnson & Johnson Patient Assistance Program. See terms and conditions at **PatientAssistanceInfo.com** or en español at **PatientAssistanceInfo.com/ES**, or call 833-742-0791.

The patient support and resources provided by J&J withMe and INLEXZO withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe INLEXZO™.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

SITE OF CARE

Coverage and Coding for INLEXZO™

Third-party payers (eg, commercial insurers, Medicare) are expected to cover INLEXZO™ for its approved U.S. Food and Drug Administration (FDA) indication, under a medical benefit, when delivered in an authorized site of care.

Coding for INLEXZO™ and its administration depends on the site of care, as well as individual payer policies. This section includes code sets and guidelines for physician offices, hospital outpatient departments, and ambulatory surgical centers.

Coverage and coding may vary depending on the payer and the specific plan in which a patient is enrolled. Please refer to specific payer requirements when submitting claims for INLEXZO™.

Physician Office

Hospital Outpatient

Ambulatory Surgical Center

Click on your site of care to view coverage and coding information for INLEXZO™.

PHYSICIAN OFFICE

Coverage and Coding for INLEXZO™

- **Coverage for Medicare Part B and Commercial Payers/Medicare Advantage**
- **Diagnosis Codes**
  - ICD-10-CM
- **INLEXZO™ Codes**
  - NDCs
  - HCPCS Level II
- **Billing Considerations**
  - NDC Units
  - Miscellaneous HCPCS Codes
- **Procedure Code**
  - CPT®: Category I
- **Place of Service (POS) Code**
- **Modifiers**
- **Sample CMS-1500 Claim Form**

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

PHYSICIAN OFFICE
Coverage Summary

Medicare Part B	Commercial Payers/Medicare Advantage*
• Physician fee schedule • Drug and procedures covered separately	• Prior authorization may be required • Drug and procedure are typically covered separately • Payer policies may vary

*Medicare Advantage provides all Medicare Parts A and B benefits through Medicare-approved private payers that must follow rules set by Medicare.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

PHYSICIAN OFFICE

Diagnosis and Product Codes for INLEXZO™

INDICATION

INLEXZO™ (gemcitabine intravesical system) is indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors.

Information	Code Type	Code and Descriptor
Diagnosis*	ICD-10-CM	**C67.0** – Malignant neoplasm of trigone of bladder[1] **C67.1** – Malignant neoplasm of dome of bladder[1] **C67.2** – Malignant neoplasm of lateral wall of bladder[1] **C67.3** – Malignant neoplasm of anterior wall of bladder[1] **C67.4** – Malignant neoplasm of posterior wall of bladder[1] **C67.5** – Malignant neoplasm of bladder neck (internal urethral orifice)[1] **C67.6** – Malignant neoplasm of ureteric orifice[1] **C67.8** – Malignant neoplasm of overlapping sites of bladder[1] **C67.9** – Malignant neoplasm of bladder, unspecified[1]
		D09.0 – Carcinoma in situ of the bladder[1] **Z85.51** – Personal history of malignant neoplasm of bladder[1]
INLEXZO™	NDCs†	**10-digit:** 57894-225-01[2] **11-digit:** 57894-0225-01
	HCPCS Level II	**J3490** – Unclassified drugs[6] **J3590** – Unclassified biologics[6] **J9999** – Not otherwise classified, antineoplastic drugs[6]

What are ICD-10-CM codes?

What are NDCs?

***These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive, and additional codes may apply. Please consult your ICD-10-CM codebook for more information.**

†Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

PHYSICIAN OFFICE

Billing With NDC Units

Coding with the NDC on professional claims requires similar information and formats. The NDC unit of measure is determined by how the drug is supplied. The INLEXZO™ intravesical system is 1 unit. The NDC quantity reported is based on the NDC quantity dispensed. One INLEXZO™ intravesical system inserted in the bladder is a dose of 1 unit.

Dose to Be Billed	11-Digit NDC* (5-4-2 Format)	Packaging	NDC Unit of Measure	NDC Units
1 intravesical system	**57894-0225-01**	INLEXZO™ is a sterile, non-resorbable intravesical system containing the equivalent of 225 mg of gemcitabine (present as 256.3 mg of gemcitabine hydrochloride)	UN	1

INLEXZO™ is an intravesical system. Each intravesical system equates to 1 NDC unit. Accurate NDC coding typically requires reporting the following components in this order:

- N4 qualifier[15]
- 11-digit NDC followed by a space[15]
- 2-character NDC unit of measure[15]
- Quantity dispensed[15]

Using the INLEXZO™ example above, here is how NDC coding would appear on professional claims:
N457894022501 UN1[15]

*Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.
NDC=National Drug Code.

PHYSICIAN OFFICE

Billing With Miscellaneous HCPCS Codes

Drugs and biologics are typically reported with permanent, product-specific HCPCS codes assigned by the Centers for Medicare and Medicaid Services (CMS). As a newly approved drug, INLEXZO™ does not yet have a unique HCPCS code. Miscellaneous/not otherwise classified codes allow providers to begin billing immediately for a service or item as soon as the FDA allows it to be marketed while awaiting assignment of a permanent code. Required reporting of miscellaneous drug codes can vary by site of care, payer, and timing after FDA approval.[16]

Under the PFS, Medicare requires new FDA-approved drugs and biologicals that have not yet been assigned a specific HCPCS code to be billed with one of the unclassified HCPCS codes. These J-codes are also generally accepted by non-Medicare payers.

- J3490 – Unclassified drugs[6]
- J3590 – Unclassified biologics[6]
- J9999 – Not otherwise classified, antineoplastic drugs[6]

Transition to Permanent Drug Code for Physician Offices

Payer	Coding Immediately Following FDA Approval Up to the Assignment of a Permanent HCPCS Code	Permanent HCPCS Code
All payers	As required by payer	Anticipated 6-9 months after FDA approval

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.
HCPCS=Healthcare Common Procedure Coding System; PFS=physician fee schedule.

PHYSICIAN OFFICE

Billing With Miscellaneous HCPCS Codes (cont'd)

Unclassified codes are not drug or dose specific and therefore require additional information to assure correct claims processing.

Medicare

When reporting a miscellaneous drug code (ie, J9999, J3590, or J3490) on the CMS-1500, record a unit of "1" in Item 24G, regardless of the actual dose, then report additional detail in Item 19. At a minimum, Medicare requires the drug name and dosage,[15] but requirements can vary with the individual Medicare Administrative Contractor (MAC).[17]

Non-Medicare Payers

Other payers commonly accept claims with unclassified drug codes, but requirements can vary widely. It is important to follow payer policy for correct coding and claims submission. Requirements may include reporting the NDC, submitting the drug purchase invoice, sharing the INLEXZO™ Prescribing Information, documenting medical necessity, and others.

Because requirements may vary, it is advisable to check with your payer prior to submitting claims reporting miscellaneous codes.

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

PHYSICIAN OFFICE

Procedure Codes, Place of Service Code, and Modifiers

Information	Code Type	Code and Descriptor
Procedure	CPT® Category I	**Insertion 51720** – Bladder instillation of anticarcinogenic agent (including retention time)[7] **Removal 52310** – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]
Location	Place of Service (POS)	**11** – Office[18]
Modifiers	CPT® Modifier	**25** – Significant, separately identifiable E/M service by the same physician or other qualified HCP on the same day of the procedure or other service[7]
	HCPCS Modifier	**JZ** – Zero drug amount discarded/not administered to any patient[20] Providers and suppliers are required to report the JZ modifier 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[19]

What are CPT® Category I codes?

What is a POS code?

What are modifiers?

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; E/M=evaluation and management; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

PHYSICIAN | HOPD | SURGICAL CENTER

CMS-1500

Physician Office

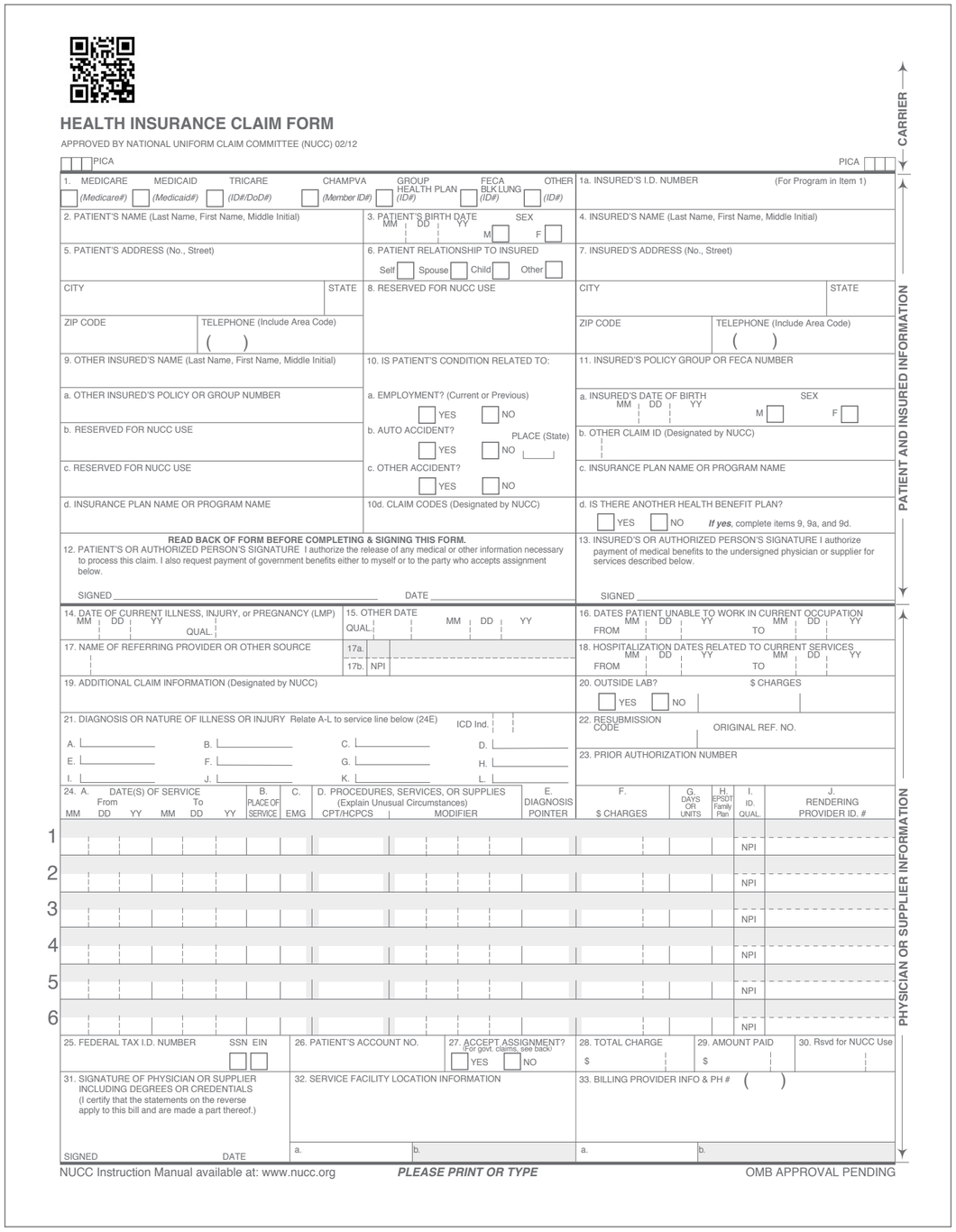
The CMS-1500 Claim Form

The Form CMS-1500 is the basic form prescribed by CMS for Medicare and Medicaid programs for claims from suppliers and noninstitutional providers that qualify for a waiver from the Administrative Simplification Compliance Act requirement for electronic submission of claims. It has also been adopted by the TRICARE program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf

Filing Professional Claims Electronically

The 837P (Professional) is the standard format used by healthcare providers and suppliers to transmit healthcare claims electronically. The ANSI ASC X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that 1 processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites. For more information on electronic claims, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 24, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c24.pdf, or the CMS website at: https://www.cms.gov/medicare/coding-billing/electronic-billing/electronic-healthcare-claims

Download the CMS-1500 Claim Form



HEALTH INSURANCE CLAIM FORM

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

PICA | PICA

1. MEDICARE (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

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)

CITY | STATE

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

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 MM DD YY | SEX M F

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

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 _____ 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 MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

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. 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										NPI	
2										NPI	
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 $

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. b.

33. BILLING PROVIDER INFO & PH # ( )

a. b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* OMB APPROVAL PENDING

CMS=Centers for Medicare & Medicaid Services.

PHYSICIAN | HOPD | SURGICAL CENTER

CMS-1500

Physician Office (cont'd)

INLEXZO™ Removal and Insertion:
Sample CMS-1500 Claim for Physician Office

A **Item 19** – When submitting claims with an unclassified drug code, enter additional detail here. At a minimum, Medicare requires the drug name and dosage, but MAC and non-Medicare payer requirements can vary. Please check with your payer[15]

B **Item 21** – Indicate diagnoses using appropriate ICD-10-CM diagnosis codes. Code to the highest level of specificity for the date of service and enter the diagnoses in priority order

C **Item 24B** – Indicate appropriate Place of Service code
POS 11 – Physician Office[18]

D **Item 24D** – Indicate appropriate CPT® and HCPCS codes, and modifiers (if applicable)
INLEXZO™
- **J3490 or J3590 or J9999** – per payer requirements[6]
- **Modifier: JZ** – zero drug amount discarded[19]

Removal Procedure: 52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]

Insertion Procedure: 51720 – Bladder instillation of anticarcinogenic agent (including retention time)[7]

E **Item 24E** – Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line

F **Item 24G** – Enter the units for items/services provided
INLEXZO™
- **For any unclassified code** – Enter 1 unit and report additional information in Item 19[17]

Removal Procedure: 52310 – Enter 1 unit

Insertion Procedure: 51720 – Enter 1 unit

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

PICA | PICA

1. MEDICARE | MEDICAID | TRICARE | CHAMPVA | GROUP HEALTH PLAN | FECA BLK LUNG | OTHER
(Medicare#) | (Medicaid#) | (ID#/DoD#) | (Member ID#) | (ID#) | (ID#) | (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

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)

CITY | STATE

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

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 MM DD YY SEX M F

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

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 _____ 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 MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

A 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
INLEXZO™ (gemcitabine intravesical system), containing 225 mg gemcitabine

20. OUTSIDE LAB? YES NO $ CHARGES

B 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. C67.2 B. C. D.
E. F. G. H.
I. J. K.

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 MM/DD/YY	MM/DD/YY	11		J9999	JZ	A		1		NPI	
2 MM/DD/YY	MM/DD/YY	11		52310		A		1		NPI	
3 MM/DD/YY	MM/DD/YY	11		51720		A		1		NPI	
4		C		D		E		F		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 $

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. b.

33. BILLING PROVIDER INFO & PH # ( )
a. b.

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* OMB APPROVAL PENDING

HOSPITAL OUTPATIENT DEPARTMENT

Coverage and Coding for INLEXZO™

- **Coverage for Medicare Part B and Commercial Payers/Medicare Advantage**
- **Diagnosis Codes**
  - ICD-10-CM
- **INLEXZO™ Codes**
  - NDCs
  - Revenue
  - HCPCS Level II
- **Billing Considerations**
  - NDC Units
  - Miscellaneous HCPCS Codes
- **Procedure Codes**
  - Current Procedural Terminology (CPT®): Category I
  - Revenue
- **Modifiers**
- **Sample CMS-1450 Claim Form**

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™
gemcitabine intravesical system | 225 mg

HOSPITAL OUTPATIENT DEPARTMENT

Coverage Summary

Medicare Part B	Commercial Payers/Medicare Advantage†
• Outpatient Prospective Payment System • Drug* and procedures covered separately	• Prior authorization may be required • Drug and procedure are typically covered separately • Payer policies may vary

*Drugs with status indicators A or G are separately paid and not included in Comprehensive Ambulatory Payment Classification (C-APC) packaging.
†Medicare Advantage provides all Medicare Parts A and B benefits through Medicare-approved private payers that must follow rules set by Medicare.

HOSPITAL OUTPATIENT DEPARTMENT

Diagnosis and Product Codes for INLEXZO™

INDICATION

INLEXZO™ (gemcitabine intravesical system) is indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors.

Information	Code Type	Code and Descriptor	
Diagnosis	ICD-10-CM*	**C67.0** – Malignant neoplasm of trigone of bladder[1] **C67.1** – Malignant neoplasm of dome of bladder[1] **C67.2** – Malignant neoplasm of lateral wall of bladder[1] **C67.3** – Malignant neoplasm of anterior wall of bladder[1] **C67.4** – Malignant neoplasm of posterior wall of bladder[1] **C67.5** – Malignant neoplasm of bladder neck (internal urethral orifice)[1] **C67.6** – Malignant neoplasm of ureteric orifice[1] **C67.8** – Malignant neoplasm of overlapping sites of bladder[1] **C67.9** – Malignant neoplasm of bladder, unspecified[1]	
		D09.0 – Carcinoma in situ of the bladder[1] **Z85.51** – Personal history of malignant neoplasm of bladder[1]	
INLEXZO™	NDCs†	**10-digit:** 57894-225-01[2] **11-digit:** 57894-0225-01	
	Revenue Code	**0636** – Pharmacy, drugs requiring detailed coding[3]	
	HCPCS Level II	**Non-Medicare**	**Medicare**
		J3490 – Unclassified drugs[6] **J3590** – Unclassified biologics[6] **J9999** – Not otherwise classified, antineoplastic drugs[6]	**C9399** – Unclassified drug or biological[4]

What are ICD-10-CM codes?

What are NDCs?

What are revenue codes?

*These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive, and additional codes may apply. Please consult your ICD-10-CM codebook for more information.

†Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

HOSPITAL OUTPATIENT DEPARTMENT

Billing With NDC Units

Coding with the NDC on institutional claims requires similar information and formats. The NDC unit of measure is determined by how the drug is supplied. The INLEXZO™ intravesical system is 1 unit. The NDC quantity reported is based on the NDC quantity dispensed. One INLEXZO™ intravesical system inserted in the bladder is a dose of 1 unit.

Dose to Be Billed	11-Digit NDC* (5-4-2 Format)	Packaging	NDC Unit of Measure	NDC Units
1 intravesical system	**57894-0225-01**	INLEXZO™ is a sterile, non-resorbable intravesical system containing the equivalent of 225 mg of gemcitabine (present as 256.3 mg of gemcitabine hydrochloride)	UN	1

INLEXZO™ is an intravesical system. Each intravesical system equates to 1 NDC unit. Accurate NDC coding typically requires reporting the following components in this order:

- N4 qualifier[20]
- 11-digit NDC[20]
- 2-character NDC unit of measure[20]
- Quantity dispensed[20]

Using the INLEXZO™ example above, here is how NDC coding would appear on facility claims:
N457894022501UN1[20]

*Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.
NDC=National Drug Code.

HOSPITAL OUTPATIENT DEPARTMENT

Billing With Miscellaneous HCPCS Codes

Drugs and biologics are typically reported with permanent, product-specific HCPCS codes assigned by the Centers for Medicare and Medicaid Services (CMS). As a newly approved drug, INLEXZO™ does not yet have a unique HCPCS code. Miscellaneous/not otherwise classified codes allow providers to begin billing immediately for a service or item as soon as the FDA allows it to be marketed while awaiting assignment of a permanent code. Required reporting of miscellaneous drug codes can vary by payer and timing after FDA approval.[16]

Under the OPPS, Medicare requires new FDA-approved drugs and biologicals that have not yet been assigned a specific HCPCS code to be billed with the unclassified drug code: C9399.[4]

Transition to Permanent Drug Code for Hospital Outpatient Departments

Payer	Coding Immediately Following FDA Approval	Coding Beginning 1-3 Months After FDA Approval	Permanent HCPCS Code
Medicare	**C9399** – Unclassified drug or biological[4]	Temporary, drug-specific code	Anticipated 6-9 months after FDA approval
Non-Medicare	As required by payer*		

*Non-Medicare payers may require one of the unclassified HCPCS codes: J3490 – Unclassified drugs, J3590 – Unclassified biologics, J9999 – Not otherwise classified, antineoplastic drugs.

HCPCS=Healthcare Common Procedure Coding System; OPPS=Outpatient Prospective Payment System.

HOSPITAL OUTPATIENT DEPARTMENT

Billing With Miscellaneous HCPCS Codes (cont'd)

Unclassified codes are not drug or dose specific and therefore require additional information to assure correct claims processing.

Medicare

Medicare requires reporting new, unclassified drugs and biologicals, after FDA approval but before assignment of a product-specific HCPCS code, with C9399. Record a unit of "1" in Form Locator 46, regardless of the actual dose. Then report additional detail in Form Locator 80. At a minimum, Medicare requires the NDC, quantity administered, and date furnished,[4] but requirements can vary with the individual Medicare Administrative Contractor (MAC).[17]

Non-Medicare Payers

Other payers typically do not require C9399, but commonly accept claims with other unclassified drug codes (ie, J9999, J3590, J3490). It is important to follow payer policy for correct coding and claims submission. Requirements can vary widely and may include additional support such as reporting the NDC, submitting the drug purchase invoice, sharing the INLEXZO™ Prescribing Information, documenting medical necessity, and others.

Because requirements may vary, it is advisable to check with your payer prior to submitting claims reporting miscellaneous codes.

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

HOSPITAL OUTPATIENT DEPARTMENT

Procedure Codes and Modifiers

Information	Code Type	Code and Descriptor
Procedure	Revenue Code	**0360** – Operating room services, general[3]
	CPT® Category I	**Insertion 51720** – Bladder instillation of anticarcinogenic agent (including retention time)[7] **Removal 52310** – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]
Modifiers	CPT® Modifier	**25** – Significant, separately identifiable E/M service by the same physician or other qualified HCP on the same day of the procedure or other service[7]
	HCPCS Modifiers	**JZ** – Zero drug amount discarded/not administered to any patient[19] Providers and suppliers are required to report the JZ modifier 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[19] **TB** – Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes[6] CMS requires all 340B-covered entities that submit claims for separately payable Part B drugs and biologicals to report the TB modifier for drugs acquired through the 340B program[21]

What are CPT® Category I codes?

What are modifiers?

CMS=Centers for Medicare & Medicaid Services; CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; E/M=evaluation and management; HCPCS=Healthcare Common Procedure Coding System.

CMS-1450

Hospital Outpatient Department

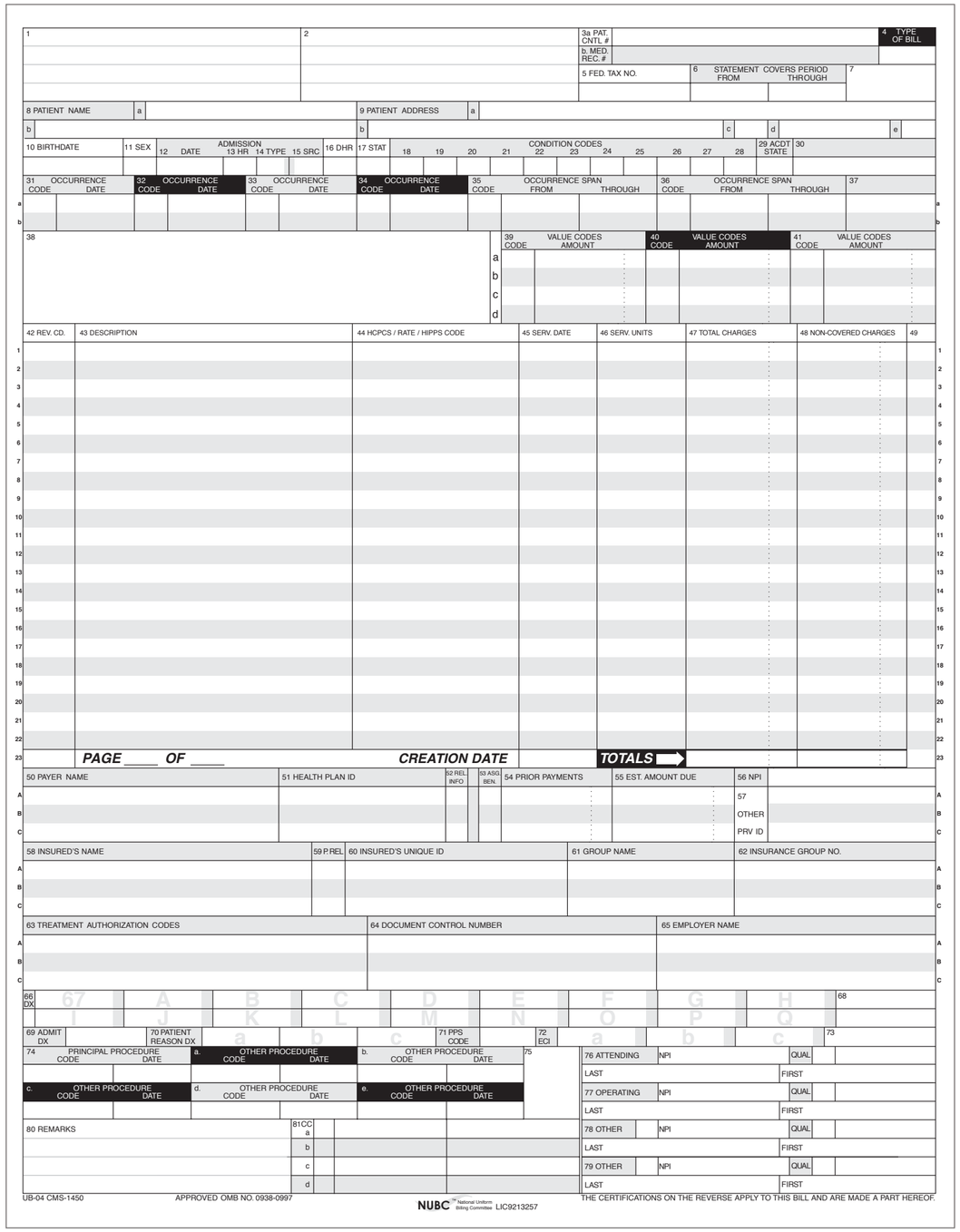
The CMS-1450 (UB-04) Claim Form

The form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf

Filing Institutional Claims Electronically

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The ANSI ASC X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites. For more information on electronic claims, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 24, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c24.pdf, or the CMS website at: https://www.cms.gov/medicare/coding-billing/electronic-billing/electronic-healthcare-claims

Download the CMS-1450 Claim Form



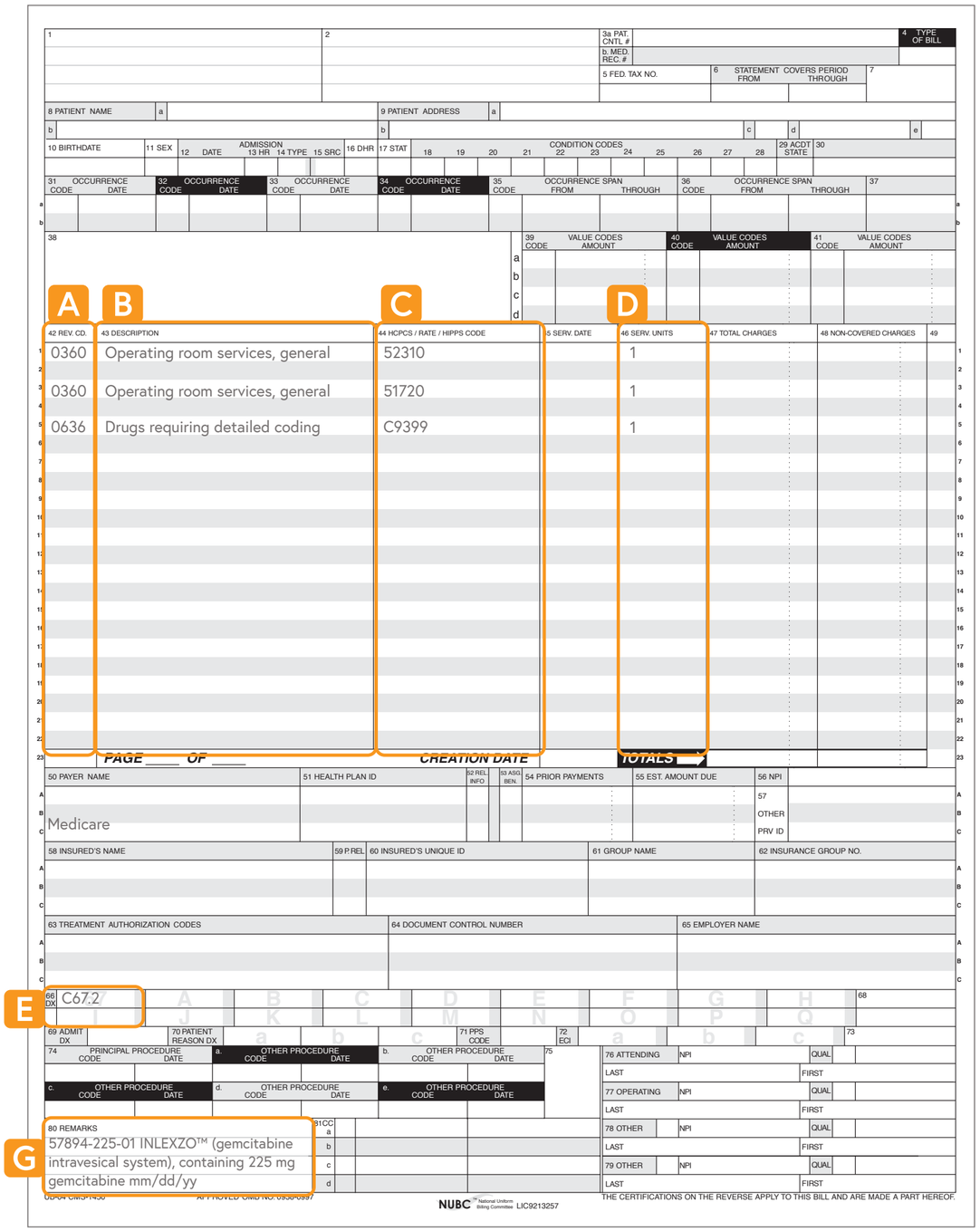
CMS=Centers for Medicare & Medicaid Services; HOPD=hospital outpatient department.

PHYSICIAN | HOPD | SURGICAL CENTER

CMS-1450

Hospital Outpatient Department (cont'd)

INLEXZO™ Removal and Insertion:
Sample CMS-1450 (UB-04) Claim
for Hospital Outpatient Departments



A **FL 42** – List revenue codes in ascending order

B **FL 43** – Enter narrative description for corresponding revenue code

C **FL 44** – Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable)

INLEXZO™

- **Medicare: C9399** – Unclassified drug or biological[4]
- **Non-Medicare: J3490 or J3590 or J9999** as required by payer[6]
- **Modifiers:** The JZ modifier does not apply to C9399; non-Medicare payer requirements may vary[19]

Removal Procedure: 52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]

Insertion Procedure: 51720 – Bladder instillation of anticarcinogenic agent (including retention time)[7]

D **FL 46** – Enter the units for items/services provided

INLEXZO™

- **Medicare: C9399** – Enter 1 unit and report additional information in FL 80 "Remarks"
- **Non-Medicare: J3490 or J3590 or J9999** – Enter 1 unit and report additional information in FL 80 "Remarks"

Insertion Procedure: 51720 – Enter 1 unit

Removal Procedure: 52310 – Enter 1 unit

E **FL 67** – Indicate diagnoses using appropriate ICD-10-CM diagnosis codes. Code to the highest level of specificity for the date of service and enter the diagnoses in priority order

G **FL 80** – When submitting claims with an unclassified drug code, enter additional detail here. At a minimum, Medicare requires the NDC, dose given, and date administered, but MAC and non-Medicare payer requirements can vary. Please check with your payer

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; MAC=Medicare Administrative Contractor; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™
gemcitabine intravesical system | 225 mg

AMBULATORY SURGICAL CENTER

Coverage and Coding for INLEXZO™

Coverage for Medicare Part B and Commercial Payers/Medicare Advantage

Diagnosis Codes

- ICD-10-CM

INLEXZO™ Codes

- NDCs
- HCPCS Level II

Billing Considerations

- NDC Units
- Miscellaneous HCPCS Codes

Procedure Codes

- CPT®: Category I

Modifiers

Sample CMS-1500 Claim Form

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

AMBULATORY SURGICAL CENTER

Coverage Summary

Medicare Part B	Commercial Payers/Medicare Advantage*
• ASC Payment System • ASC-eligible procedures covered • OPPS drugs and biologicals, integral to a surgical procedure, covered separately	• Prior authorization may be required • Payer policies may vary

*Medicare Advantage provides all Medicare Parts A and B benefits through Medicare-approved private payers that must follow rules set by Medicare.
ASC=ambulatory surgical center; OPPS=Outpatient Prospective Payment System.

AMBULATORY SURGICAL CENTER

Diagnosis and Product Codes for INLEXZO™

INDICATION

INLEXZO™ (gemcitabine intravesical system) is indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors.

Information	Code Type	Code and Descriptor	
Diagnosis	ICD-10-CM*	**C67.0** – Malignant neoplasm of trigone of bladder[1] **C67.1** – Malignant neoplasm of dome of bladder[1] **C67.2** – Malignant neoplasm of lateral wall of bladder[1] **C67.3** – Malignant neoplasm of anterior wall of bladder[1] **C67.4** – Malignant neoplasm of posterior wall of bladder[1] **C67.5** – Malignant neoplasm of bladder neck (internal urethral orifice)[1] **C67.6** – Malignant neoplasm of ureteric orifice[1] **C67.8** – Malignant neoplasm of overlapping sites of bladder[1] **C67.9** – Malignant neoplasm of bladder, unspecified[1]	
		D09.0 – Carcinoma in situ of the bladder[1] **Z85.51** – Personal history of malignant neoplasm of bladder[1]	
INLEXZO™	NDCs†	**10-digit:** 57894-225-01[2] **11-digit:** 57894-0225-01	
	HCPCS Level II	**Non-Medicare** **J3490** – Unclassified drugs[6] **J3590** – Unclassified biologics[6] **J9999** – Not otherwise classified, antineoplastic drugs[6]	**Medicare** **C9399** – Unclassified drug or biological[4,5]

What are ICD-10-CM codes?

What are NDCs?

***These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive, and additional codes may apply. Please consult your ICD-10-CM codebook for more information.**

†Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

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AMBULATORY SURGICAL CENTER

Billing With NDC Units

Coding with the NDC on professional claims requires similar information and formats. The NDC unit of measure is determined by how the drug is supplied. The INLEXZO™ intravesical system is 1 unit. The NDC quantity reported is based on the NDC quantity dispensed. One INLEXZO™ intravesical system inserted in the bladder is a dose of 1 unit.

Dose to Be Billed	11-Digit NDC* (5-4-2 Format)	Packaging	NDC Unit of Measure	NDC Units
1 intravesical system	**57894-0225-01**	INLEXZO™ is a sterile, non-resorbable intravesical system containing the equivalent of 225 mg of gemcitabine (present as 256.3 mg of gemcitabine hydrochloride)	UN	1

INLEXZO™ is an intravesical system. Each intravesical system equates to 1 NDC unit. Accurate NDC coding typically requires reporting the following components in this order:

- N4 qualifier[15]
- 11-digit NDC followed by a space[15]
- 2-character NDC unit of measure[15]
- Quantity dispensed[15]

Using the INLEXZO™ example above, here is how NDC coding would appear on ASC claims: **N457894022501 UN1**[5]

*Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.
ASC=ambulatory surgical center; NDC=National Drug Code.

AMBULATORY SURGICAL CENTER

Billing With Miscellaneous HCPCS Codes

Drugs and biologics are typically reported with permanent, product-specific HCPCS codes assigned by the Centers for Medicare and Medicaid Services (CMS). As a newly approved drug, INLEXZO™ does not yet have a unique HCPCS code. Miscellaneous/not otherwise classified codes allow providers to begin billing immediately for a service or item as soon as the FDA allows it to be marketed while awaiting assignment of a permanent code. Required reporting of miscellaneous drug codes can vary by payer and timing after FDA approval.[16]

Under the OPPS and ASC payment systems, Medicare requires new FDA-approved drugs and biologicals that have not yet been assigned a specific HCPCS code to be billed with the unclassified drug code: C9399.[4,5]

Transition to Permanent Drug Code for ASCs

Payer	Coding Immediately Following FDA Approval	Coding Beginning 1-3 Months After FDA Approval	Permanent HCPCS Code
Medicare	**C9399** – Unclassified drug or biological[4,5]	Temporary, drug-specific code	Anticipated 6-9 months after FDA approval
Non-Medicare	As required by payer		

ASC=ambulatory surgical center; HCPCS=Healthcare Common Procedure Coding System; OPPS=Outpatient Prospective Payment System.

AMBULATORY SURGICAL CENTER

Billing With Miscellaneous HCPCS Codes (cont'd)

Unclassified codes are not drug or dose specific and therefore require additional information to assure correct claims processing.

Medicare

Medicare requires reporting new, unclassified drugs and biologicals, after FDA approval but before assignment of a product-specific HCPCS code, with C9399. Record a unit of "1" in Item 24G regardless of the actual dose, then report additional detail in Item 19. At a minimum, Medicare requires the NDC, quantity administered, and date furnished,[4] but requirements may vary with the individual MAC.[17]

Non-Medicare Payers

Other payers typically do not require C9399, but commonly accept claims with other unclassified drug codes (ie, J9999, J3590, J3490). It is important to follow payer policy for correct coding and claims submission. Requirements can vary widely and may include additional support such as reporting the NDC, submitting the drug purchase invoice, sharing the INLEXZO™ Prescribing Information, documenting medical necessity, and others.

Because requirements may vary, it is advisable to check with your payer prior to submitting claims reporting miscellaneous codes.

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

AMBULATORY SURGICAL CENTER

Procedure Codes and Modifiers

Information	Code Type	Code and Descriptor
Procedure	CPT® Category I	**Insertion 51720** – Bladder instillation of anticarcinogenic agent (including retention time)[7] **Removal 52310** – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]
Modifiers	HCPCS Modifier	**JZ** – Zero drug amount discarded/not administered to any patient[19] Providers and suppliers are required to report the JZ modifier 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[19]

What are CPT® Category I codes?

What are modifiers?

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2024; HCPCS=Healthcare Common Procedure Coding System.

CMS-1500

Ambulatory Surgical Center

NOTE: Medicare requires the CMS-1500 claim form for ASC billing. Other payers may require the CMS-1450. Please verify required forms and coding specifications with your payer.

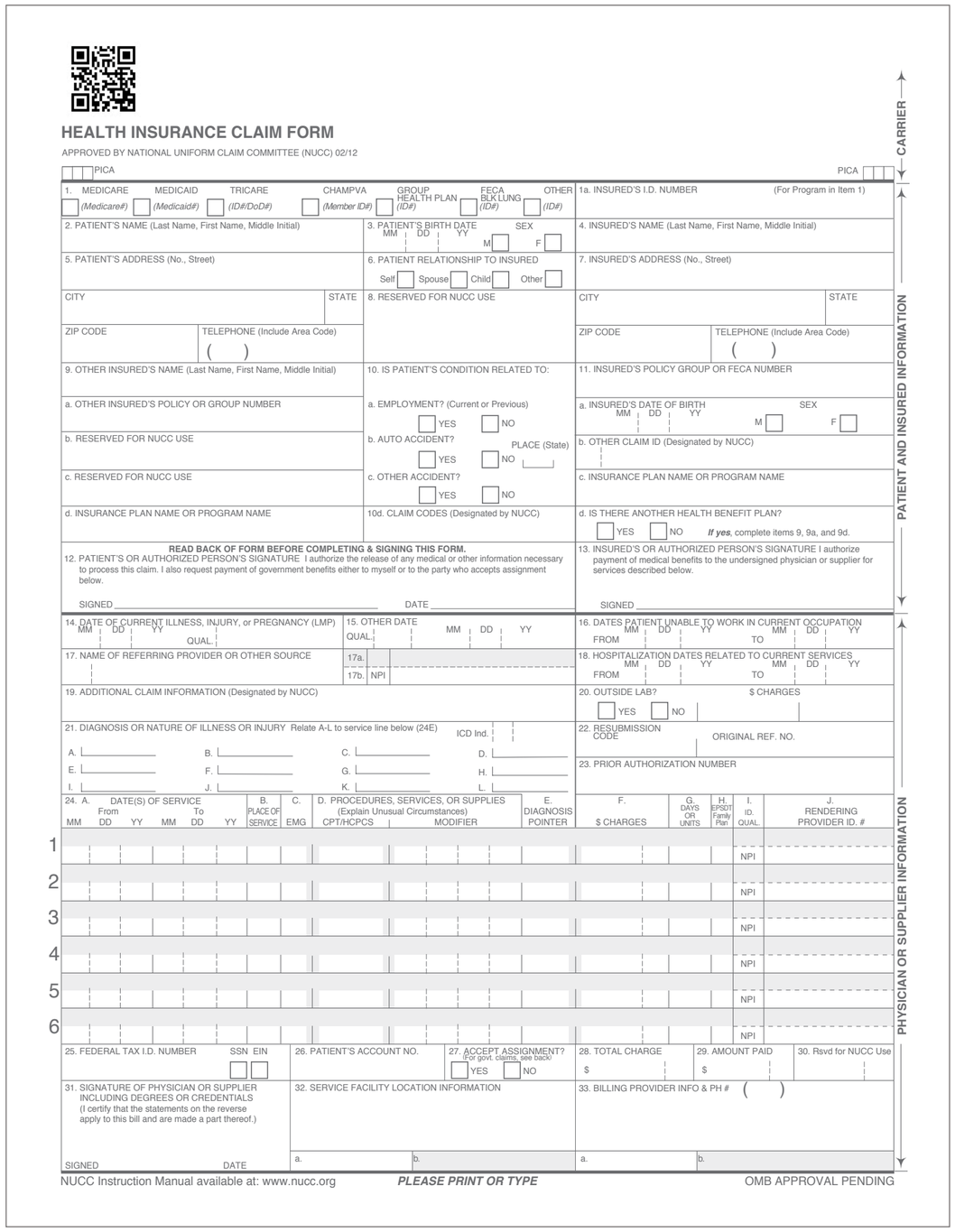
The CMS-1500 Claim Form

The Form CMS-1500 is the basic form prescribed by CMS for Medicare and Medicaid programs for claims from suppliers and noninstitutional providers that qualify for a waiver from the Administrative Simplification Compliance Act requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf

Filing Professional Claims Electronically

The 837P (Professional) is the standard format used by healthcare providers and suppliers to transmit healthcare claims electronically. The ANSI ASC X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that 1 processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites. For more information on electronic claims, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 24, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c24.pdf, or the CMS website at: https://www.cms.gov/medicare/coding-billing/electronic-billing/electronic-healthcare-claims

Download the CMS-1500 Claim Form



HEALTH INSURANCE CLAIM FORM

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

PICA | PICA

CARRIER

1. MEDICARE (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

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)

CITY | STATE

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

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 MM DD YY | SEX M F

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

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 _____ 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 | MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM | MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

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. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

PHYSICIAN OR SUPPLIER INFORMATION

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										NPI	
2										NPI	
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 $

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. b.

33. BILLING PROVIDER INFO & PH # ( )

a. b.

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* OMB APPROVAL PENDING

ASC=ambulatory surgical center; CMS=Centers for Medicare & Medicaid Services.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

CMS-1500

Ambulatory Surgical Center (cont'd)

INLEXZO™ Removal and Insertion:
Sample CMS-1500 Claim for Ambulatory Surgical Centers

A **Item 19** – When submitting claims with unclassified drug code C9399, enter additional detail here. At a minimum, Medicare requires the NDC, dose given, and date administered, but MAC and non-Medicare payer requirements can vary. Please check with your payer.

B **Item 21** – Indicate diagnoses using appropriate ICD-10-CM diagnosis codes. Code to the highest level of specificity for the date of service and enter the diagnoses in priority order

C **Item 24B** – Indicate appropriate Place of Service code

D **Item 24D** – Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable)

INLEXZO™

- **Medicare: C9399** – Unclassified drug or biological[4,5]
- **Non-Medicare: J3490 or J3590 or J9999** as required by payer[6]

Modifiers: The JZ modifier does not apply to C9399; non-Medicare payer requirements may vary[19]

Removal Procedure: 52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple[7]

Insertion Procedure: 51720 – Bladder instillation of anticarcinogenic agent (including retention time)[7]

E **Item 24E** – Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line

F **Item 24G** – Enter the units for items/services provided

INLEXZO™

- **For any unclassified code** – Enter 1 unit and report additional information in Item 19

Removal Procedure: 52310 – Enter 1 unit

Insertion Procedure: 51720 – Enter 1 unit

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

PICA | PICA

1. MEDICARE (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#) — 1a. INSURED'S I.D. NUMBER (For Program in Item 1)
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)
CITY | STATE — 8. RESERVED FOR NUCC USE — CITY | STATE
ZIP CODE | TELEPHONE (Include Area Code) ( ) — ZIP CODE | TELEPHONE (Include Area Code) ( )
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) — 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 MM DD YY SEX M F
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 — 10d. CLAIM CODES (Designated by NUCC) — d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

Medicare

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 ____ 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 MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE — 17a. — 17b. NPI — 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY
A — 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): INLEXZO™ (gemcitabine intravesical system), containing 225 mg gemcitabine — 20. OUTSIDE LAB? YES NO $ CHARGES
B — 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. — A. C67.2 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	MM/DD/YY	MM/DD/YY	24		C9399		A		1		NPI	
2	MM/DD/YY	MM/DD/YY	24		52310		A		1		NPI	
3	MM/DD/YY	MM/DD/YY	24		51720		A		1		NPI	
4			C		D		E		F		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 $ — 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. b. — 33. BILLING PROVIDER INFO & PH # ( ) a. b.

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CARRIER | PATIENT AND INSURED INFORMATION | PHYSICIAN OR SUPPLIER INFORMATION

NAVIGATING PAYER POLICIES

Medical Necessity

Medical necessity refers to healthcare services or supplies that are needed to diagnose or treat an illness, injury, condition, disease, or its symptoms, and that meet accepted standards. Generally, payers provide coverage only for health-related services they determine to be medically necessary. Payer policies define medical necessity criteria, including indications, required diagnostic test results, and any limitations of coverage that may apply.

When third-party payers consider coverage requests for INLEXZO™, they will first determine if the treatment is covered under their policies. Next, they will look for evidence supporting medical necessity, which may include, but not be limited to:

- Patient diagnosis and alignment with indications for requested therapy
- Summary of patient's current medical condition and history
- Rationale for requested therapy and the expected outcome(s)

Some payers may require the prescribing physician to submit a Letter of Medical Necessity (LMN) summarizing these points.

Click to download a sample Letter of Medical Necessity

NAVIGATING PAYER POLICIES

Prior Authorization (PA)

Prior authorization (also referred to as pre-authorization or “pre-auth”) is a common payer process that requires establishing medical necessity within the framework of specific payer coverage criteria. Many treatments, especially if they are new, are subject to PA; however, the requirements and processes can vary by payer. Some payers may handle oncology treatment requests through their routine PA processes, while others may use a dedicated, specialty-specific approach.

When requesting coverage for INLEXZO™, it is essential to review the payers' policies and adhere to their required steps and timeline. This may include contacting a specific authorization line, submitting dedicated forms, or engaging directly with a payer’s case manager.

The following information may be helpful to organize when preparing to request prior authorization:

- Summary of the patient’s history: timeline and course of the disease; previous treatments and responses; current status
- Rationale for current request: expected result of treatment and anticipated disease course without the treatment
- Patient diagnosis (ICD-10-CM) and alignment with indications for requested treatment
- Supporting data: patient demographics; facility information; product Prescribing Information; National Drug Code (NDC); any applicable nationally recognized clinical practice guidelines (eg, ASCO, NCCN®)

Click to download the Prior Authorization Checklist

ASCO=American Society of Clinical Oncology; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NCCN=National Comprehensive Cancer Network.

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NAVIGATING PAYER POLICIES

Exception Request

An exception is a type of coverage determination that may apply when a drug therapy has been recently approved and a plan has not yet issued a coverage determination (eg, not on formulary, no published policy) or if the patient cannot meet a payer's coverage requirements.

A request for exception asks that the restrictions placed on a specific drug therapy be released because it is medically appropriate and necessary for a patient's treatment. Providers must typically submit a supporting statement with details about the rationale for the request. Payer policies and processes, including the time in which a decision is to be expected, can vary.

Click to download the Exception Considerations Checklist

Appeals

An appeal is any of the procedures used to challenge a payer's denial of benefits that a beneficiary believes they are entitled to receive. If a payer denies an initial request for coverage or an exception request, the decision may be appealed. The payer's notice of denial should include the reason for that decision, as well as instructions for filing an appeal. Most plans have multiple, progressive levels of appeal, allowing beneficiaries to continue advancing their request if initial efforts are not successful.

Appeals may be initiated by the patient or their healthcare provider. No matter the origin, it is generally necessary for prescribers to submit a supporting statement providing details of why the patient is clinically appropriate for the prescribed medication.

To resolve some requests, it may be helpful to schedule a peer-to-peer review between the treating physician and the medical director at the health plan.

Click to download the Appeals Process Consideration Checklist

DUAL PROCUREMENT PATHWAYS

INLEXZO™ is available through 2 procurement pathways

Buy-and-Bill: Choose from a trusted network of Authorized Specialty Distributors according to your practice's specific needs

Authorized Specialty Distributors (SD)			
Name	Phone Number	Fax	Website
Besse Medical	800-543-2111	800-543-8695	besse.com
CuraScript SD	877-599-7748	800-862-6208	curascriptsd.com
Cencora (AmerisourceBergen)	800-746-6273	800-547-9413	asdhealthcare.com
Cencora Oncology Supply (AmerisourceBergen Oncology Supply)	800-633-7555	800-248-8205	oncologysupply.com
Cardinal Health Specialty Pharmaceutical Distribution	Physician's offices: 877-453-3972 Hospitals/all others: 855-855-0708	614-652-7043	specialtyonline.cardinalhealth.com orderexpress.cardinalhealth.com
Cardinal P.R. 120 (Puerto Rico)	787-625-2566	787-625-4398	cardinalhealth.pr
McKesson Plasma & Biologics	877-625-2566	888-752-7626	biologics.mckesson.com
McKesson Specialty Health	Oncology: 800-482-6700 Multispecialty: 855-477-9800	855-824-9489	mscs.mckesson.com

Specialty Pharmacy (SP): As an alternative option, J&J has partnered with a single, independent SP, who will provide white-glove support services for your patients and practice

Authorized Specialty Pharmacy (SP)*				
Name	Phone Number	Fax	Website	ePrescribe
Accredo Health Group, Inc.	1-877-732-3431	1-888-302-1028	accredo.com	Accredo Health Group 1620 Century Center Pkwy Memphis, TN 38134 NPI#: 1184675910

Product Information

NDCs:
10-digit: 57894-225-01[2]
11-digit: 57894-0225-01

Download the INLEXZO™ How to Order Guide

*Hospital or practice-owned pharmacies may be included in the distribution network.
NOTE: Johnson & Johnson does not endorse the use of any specialty distributors or pharmacies.

Please read Important Safety Information and full Prescribing Information and Instructions for Use for INLEXZO™.

inlexzo™ gemcitabine intravesical system | 225 mg

INLEXZO™

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PHYSICIAN OFFICE

Diagnosis and Product Codes for INLEXZO™

Diagnosis Codes: ICD-10-CM

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rin (BCG)-
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What are ICD-10-CM codes?

What are NDCs?

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PHYSICIAN OFFICE

Procedure Codes, Place of Service Code, and Modifiers

Current Procedural Terminology (CPT®) Codes

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What are CPT® Category I codes?

What is a POS code?

What are modifiers?

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PHYSICIAN OFFICE

Procedure Codes, Place of Service Code, and Modifiers

Place of Service (POS) Codes[18]

The POS code set provides setting information necessary to appropriately pay professional service claims. The POS is the location of the provider's face-to-face encounter with the patient. POS codes are required on all claims for professional services (billed on CMS-1500, Item 24B). The physician practice setting is indicated with POS code 11.

Professional services delivered in outpatient hospital settings must specifically include the off-campus or on-campus POS codes on the claim form. Professional services provided in an ASC are coded with POS code 24.

Code	Place of Service	Description[18]
11	**Office**	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	**Off Campus – Outpatient Hospital**	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
22	**On Campus – Outpatient Hospital**	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
24	**Ambulatory Surgical Center**	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis.

ASC=ambulatory surgical center.

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PHYSICIAN OFFICE

Procedure Codes, Place of Service Code, and Modifiers

Modifiers

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Modifier	Description	Indication & Placement
25	Significant, separately identifiable E/M service by the same physician or other qualified HCP on the same day of the procedure or other service	• Patient requires distinct E/M service above and beyond the other service or beyond the usual preoperative and postoperative care associated with a procedure[7] • Must be substantiated with documentation[7] • Append the modifier to the relevant E/M code[7]
JZ	Zero drug amount discarded/ not administered to any patient	• Applies to single-dose containers of drugs when there are no discarded amounts[19] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[19]

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HOSPITAL OUTPATIENT DEPARTMENT

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HOSPITAL OUTPATIENT DEPARTMENT

Diagnosis and Product Codes for INLEXZO™

Revenue Codes

Many payers require use of American Hospital Association revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by 3 other digits and are used on CMS-1450 claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. Generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes, since hospitals' assignment of costs varies. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.

Revenue Code	Descriptor
0360	Operating Room Services, General[3]
0636	Pharmacy, drugs requiring detailed coding[3]

CMS=Centers for Medicare & Medicaid Services.

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TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	• Must be reported by all 340B-covered entities submitting claims for separately payable drugs and biologicals[21] • To be reported on the same claim line as the drug HCPCS code for all 340B-acquired drugs[21]

*NOTE: The JZ modifier does not apply to C9399.[19]
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AMBULATORY SURGICAL CENTER

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