



Illustrative depiction.  
Not actual size.

## Your guide to ordering **INLEXZO™**

**Disclaimer:** 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.

### 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 additional [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



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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™.

### 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 the full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



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

J&J

withMe

## Access and affordability resources plus personalized support for your patients

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

- **Access support**—to help navigate payer processes
- **Affordability resources**—to help patients discover ways to afford INLEXZO™
- **Dedicated, free 1-on-1 support for your patients throughout their treatment journey**— Each patient's INLEXZO™ treatment journey is unique. We're here to help by providing personalized 1-on-1 support from oncology-trained nurses\*



### Complete the J&J withMe Patient Enrollment Form

J&J withMe provides your office with access and affordability support, including benefits investigation support, prior authorization support and status monitoring, information on the exceptions and appeals process, coding and billing information, and finding cost support options for eligible patients.



**Click here to complete patient enrollment**

Visit [Portal.JNJwithMe.com](https://Portal.JNJwithMe.com) to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support\*

Visit [JNJwithMe.com/hcp/](https://JNJwithMe.com/hcp/) for access and affordability information for the J&J medicine you prescribed

**Bookmark these links** for quick and easy access!



**Questions? Call 833-JNJ-wMe1 (833-565-9631)**

Monday – Friday, 8:00 AM – 8:00 PM ET

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 INLEXZO™.

\*Care Navigators do not provide medical advice.

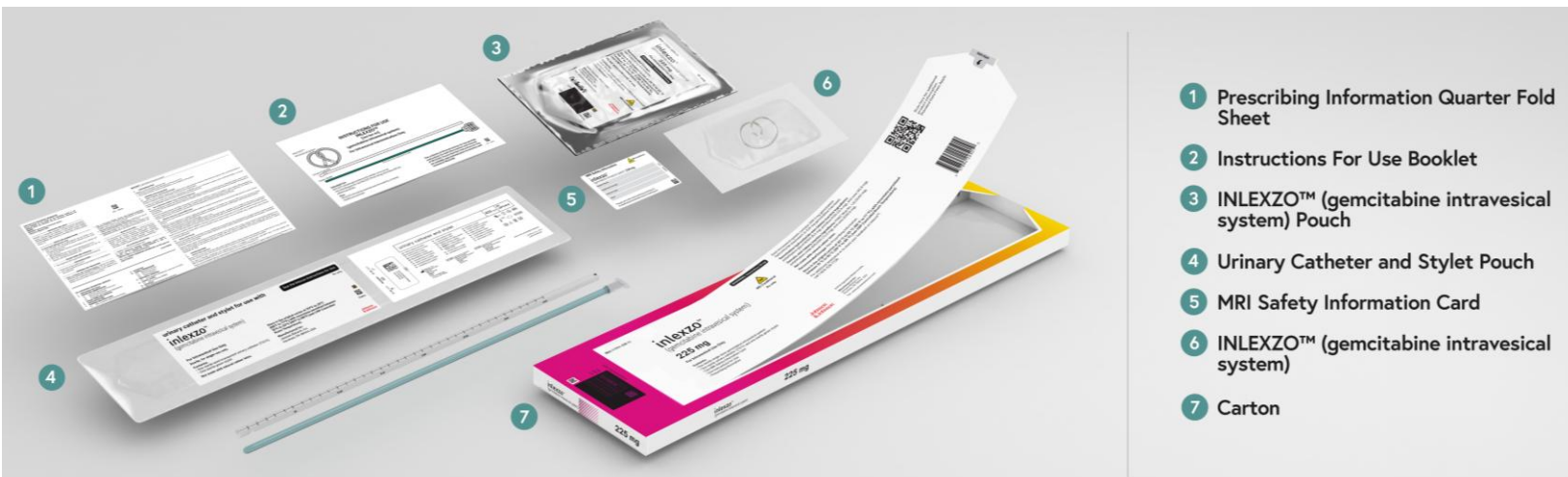
Please read [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





## What's included with INLEXZO™ & storage considerations

One carton includes one sterile single dose of INLEXZO™ co-packaged with one sterile urinary catheter and one sterile stylet



*Carton does not include lubricant or syringes. Consider ordering prefilled lubrication syringes.*

**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.<sup>1-6†</sup>

### Storage

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

### Handling During Insertion and Removal

INLEXZO™ contains a hazardous drug. Follow applicable special handling and disposal procedures while handling INLEXZO™ and during the insertion and removal.

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.<sup>1</sup>

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

#### 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.

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How to obtain INLEXZO™

## steps to ordering

Your practice can obtain INLEXZO™ via 2 options



Through a  
**specialty distributor**  
(buy-and-bill)



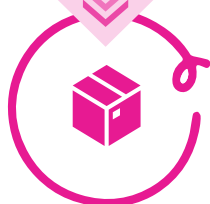
Step 1  
**Conduct benefits  
investigation**



Step 2  
**Obtain prior  
authorization (PA)**



Step 3  
**Schedule the patient**



Step 4  
**Order INLEXZO™**



Click here to begin



Through a  
**specialty pharmacy**  
(Accredo® or your hospital or  
practice-owned pharmacy)



Step 1  
**Submit prescription  
and PA paperwork to  
Accredo® or your  
hospital or practice-  
owned pharmacy**



Step 2  
**Coordinate delivery  
of INLEXZO™ with  
specialty pharmacy**



Step 3  
**Schedule the patient**



Click here to begin





## How to obtain INLEXZO™ through a **specialty distributor** (buy-and-bill)

Step  
**1**

### Conduct benefits investigation



Complete a benefits investigation request in the Provider Portal at [Portal.JNJwithMe.com](https://Portal.JNJwithMe.com)



or download and complete the Patient Enrollment Form, and fax to 1-855-998-4422

#### **J&J withMe will conduct a benefits investigation.**

Upon completion, you will receive a benefits investigation summary, which will include details regarding the patient's coverage and prior authorization requirements.

### **and enroll commercially insured patients in the J&J withMe Savings Program**



Commercial or private insurance?  
(Insurance issued by an employer)

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

- Treatment Cost Support for the cost of INLEXZO™ treatment
- Treatment Administration Cost Support for costs related to each insertion and removal of the treatment delivery system

Maximum program benefit per calendar year shall apply. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medicines. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply. See program requirements at [INLEXZO.JNJwithMeSavings.com](https://INLEXZO.JNJwithMeSavings.com).

Go to Step 2





## How to obtain INLEXZO™ through a **specialty distributor** (buy-and-bill)

### Step 2

## Obtain prior authorization (if required)



### Prior authorization (PA) form

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

*It may be beneficial to provide the diagnosis, product, and procedure codes for products/services to be provided/performed if not part of the prior authorization form.*

***See next page for more information.***



### Letter of medical necessity

Typically includes the rationale for treatment, and a summary of the patient's diagnosis and history.

A sample letter of medical necessity is available at [JNJwithMe.com/hcp/](http://JNJwithMe.com/hcp/)



### Supporting documents, including:

- ☐ Patient Authorization and Notice of Release of Information
- ☐ Patient's health plan or prescription card (front and back)
- ☐ FDA Approval Letter
- ☐ Prescribing Information



## How to obtain INLEXZO™ through a specialty distributor (buy-and-bill)

Step

2

### Obtain prior authorization (continued)

It may be beneficial to provide the diagnosis, product, and procedure codes for products/services to be provided/performed if not part of the prior authorization form.

**Code type****Code and Descriptor**

Office



HOPD



ASC

Diagnosis  
**ICD-10-CM<sup>7\*</sup>**

**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 (internal urethral orifice)  
**C67.6** – Malignant neoplasm of ureteric orifice  
**C67.8** – Malignant neoplasm of overlapping sites of bladder  
**C67.9** – Malignant neoplasm of bladder, unspecified  
**D09.0** – Carcinoma *in situ* of bladder  
**Z85.51** – Personal history of malignant neoplasm of bladder

INLEXZO™  
**NDC**

11-digit (5-4-2 format): **57894-0225-01<sup>1,8†</sup>**  
INLEXZO™ (gemcitabine intravesical system) contains the equivalent to 225 mg gemcitabine (present as 256.3 mg gemcitabine hydrochloride), co-packaged with a urinary catheter and stylet

INLEXZO™  
**Revenue  
code**

**0636** – Pharmacy, drugs requiring detailed coding<sup>9</sup>

INLEXZO™  
**HCPCS  
Level II<sup>‡§</sup>**

**C9399** – Unclassified drug or biological<sup>10</sup>  
**J3490** – Unclassified drugs<sup>11</sup>  
**J3590** – Unclassified biologics<sup>11</sup>  
**J9999** – Not otherwise classified antineoplastic drugs<sup>11</sup>

Required  
by  
Medicare

Required by Medicare

As required by  
payerProcedure  
**Revenue  
code**

**0360** – Operating room services, general<sup>9</sup>

Procedure  
**CPT®  
Category I**

**51720** – Bladder instillation of anticarcinogenic agent  
(including retention time)<sup>12</sup>  
**52310** – Cystourethroscopy, with removal of foreign body, calculus, or  
ureteral stent from urethra or bladder (separate procedure); simple<sup>12</sup>



Go to Step 3



The fact that a drug, device, procedure or service is assigned an 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.

**\*These codes are not intended to be promotional or suggest a use of 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.**

<sup>†</sup>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.

<sup>‡</sup>C9399 is required by Medicare when INLEXZO™ is administered in an outpatient hospital or ambulatory surgical center.

<sup>§</sup>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.

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; OPPTS=Outpatient Prospective Payment System.

Please read [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





# How to obtain INLEXZO™ through a specialty distributor (buy-and-bill)

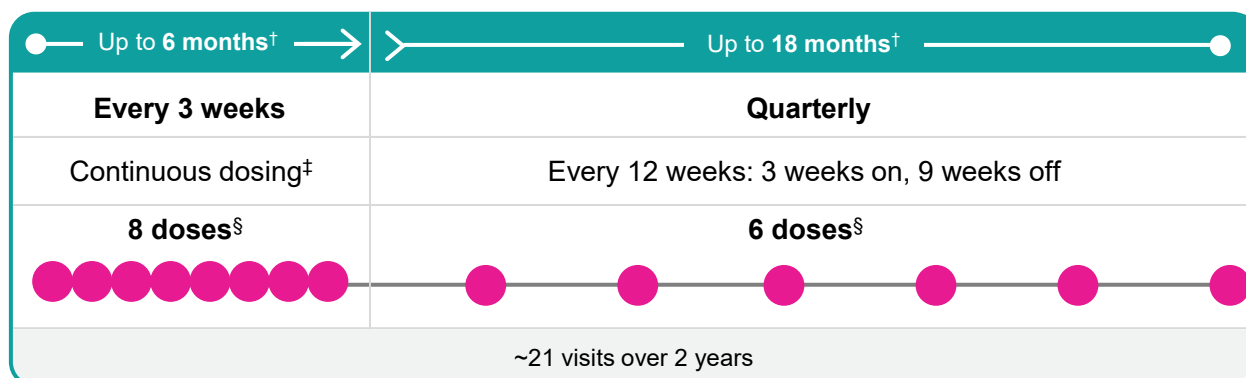
Step  
3

## Schedule the patient

INLEXZO™ is administered in a familiar,\* in-office procedure in 14 doses over 2 years<sup>1</sup>



Remove INLEXZO™ after each 3-week indwelling period<sup>1</sup>



\*Uses catheterization and cystoscopy. †Or until unacceptable toxicity or disease persistence, recurrence, or progression.<sup>1</sup>

<sup>‡</sup>Assumes same-day removal and new insertion during first 6 months.<sup>1</sup> <sup>§</sup>One dose=insertion and removal 3 weeks later.<sup>1</sup>

- Administer **INLEXZO™** intravesically only using the co-packaged urinary catheter and stylet<sup>1</sup>
- **INLEXZO™** should be inserted and removed by a trained healthcare provider thoroughly familiar with the insertion and removal instructions<sup>1</sup>
- Removal of **INLEXZO™** by cystoscopy provides the opportunity for simultaneous assessment of disease response<sup>1,13</sup>
- If a dose is missed, it should be administered as closely as possible to the original treatment schedule<sup>1</sup>
- Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each **INLEXZO™** insertion and removal<sup>1</sup>
- **INLEXZO™** contains a metal wire. When **INLEXZO™** is indwelling in the bladder, the patient can only be safely scanned with MRI under certain conditions<sup>14</sup>

Please read full [Prescribing Information](#) for specific MRI scanning conditions.

Please read full [Instructions for Use](#) for complete information on preparation, intravesical administration, and removal.

Go to Step 4

MRI=magnetic resonance imaging.

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

#### 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 additional [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



## How to obtain INLEXZO™ through a **specialty distributor** (buy-and-bill)

### Step 4

### Ordering INLEXZO™

INLEXZO™ can be ordered through one of the following specialty distributors

Specialty distributor	Phone	Fax
<b>Besse Medical</b> besse.com	800-543-2111	800-543-8695
<b>CuraScript SD</b> curascriptsd.com	877-599-7748	800-862-6208
<b>Cencora (AmerisourceBergen)</b> asdhealthcare.com	800-746-6273	800-547-9413
<b>Cencora Oncology Supply (AmerisourceBergen Oncology Supply)</b> oncologysupply.com	800-633-7555	800-248-8205
<b>Cardinal Health Specialty Pharmaceutical Distribution</b> specialtyonline.cardinalhealth.com orderexpress.cardinalhealth.com	Physician's offices: 877-453-3972 Hospitals/all others: 855-855-0708	614-652-7043
<b>Cardinal P.R. 120 (Puerto Rico)</b> cardinalhealth.pr	787-625-4200	787-625-4398
<b>McKesson Plasma and Biologics</b> biologics.mckesson.com	877-625-2566	888-752-7626
<b>McKesson Specialty Health</b> mscs.mckesson.com	Oncology: 800-482-6700 All other specialties: 855-477-9800	855-824-9489

<b>Brand name<sup>1</sup></b>	INLEXZO™
<b>Generic name<sup>1</sup></b>	gemcitabine intravesical system
<b>Package presentation</b>	1 intravesical system (1 NDC unit)
<b>National Drug Code (NDC)</b>	11-digit: <b>57894-0225-01</b>

Accurate NDC coding typically requires reporting the following components in this order: N4 qualifier, 11-digit NDC number, 2-character NDC unit of measure, and quantity dispensed. Using the INLEXZO™ example above, here is how NDC coding would appear on professional claims: **N457894022501UN1<sup>8</sup>**



## How to obtain INLEXZO™ through a **specialty pharmacy**

Step  
**1**

**Submit prescription to Accredo® or your hospital or practice-owned pharmacy** (specialty pharmacy will conduct the benefits investigation for the prescription)



### **Accredo Health Group, Inc.**

accredo.com

1-877-732-3431

1-888-302-1028

**ePrescribe info:**  
Accredo Health Group  
1620 Century Center Pkwy  
Memphis, TN 38134  
NPI#: 1275740474

or



**Your hospital or  
practice-owned  
pharmacy**

## **and enroll commercially insured patients in the J&J withMe Savings Program**

Commercial or private insurance?  
(Insurance issued by an employer)

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

- Treatment Cost Support for the cost of INLEXZO™ treatment
- Treatment Administration Cost Support for costs related to each insertion and removal of the treatment delivery system

Maximum program benefit per calendar year shall apply. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medicines. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply. See program requirements at [INLEXZO.JNJwithMeSavings.com](https://www.inlexzo.com/JNJwithMeSavings.com).





## How to obtain INLEXZO™ through a **specialty pharmacy**

Step

1

continued

### Obtain prior authorization (if required)



#### Prior authorization (PA) form

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

*It may be beneficial to provide the diagnosis, product, and procedure codes for products/services to be provided/performed if not part of the prior authorization form.*

***See next page for more information.***



#### Letter of medical necessity

Typically includes the rationale for treatment, and a summary of the patient's diagnosis and history.

A sample letter of medical necessity is available at [JNJwithMe.com/hcp/](https://JNJwithMe.com/hcp/)



#### Supporting documents, including:

- ☐ Patient Authorization and Notice of Release of Information
- ☐ Patient's health plan or prescription card (front and back)
- ☐ FDA Approval Letter
- ☐ Prescribing Information





# How to obtain INLEXZO™ through a specialty pharmacy

Step

1

continued

## Obtain prior authorization (continued)

It may be beneficial to provide the diagnosis, product, and procedure codes for products/ services to be provided/performed if not part of the prior authorization form.

Code type	Code and Descriptor	Office	HOPD	ASC
Diagnosis ICD-10-CM <sup>7*</sup>	<b>C67.0</b> – Malignant neoplasm of trigone of bladder	✓	✓	✓
	<b>C67.1</b> – Malignant neoplasm of dome of bladder			
	<b>C67.2</b> – Malignant neoplasm of lateral wall of bladder			
	<b>C67.3</b> – Malignant neoplasm of anterior wall of bladder			
	<b>C67.4</b> – Malignant neoplasm of posterior wall of bladder			
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	<b>C67.9</b> – Malignant neoplasm of bladder, unspecified			
	<b>D09.0</b> – Carcinoma <i>in situ</i> of bladder			
<b>Z85.51</b> – Personal history of malignant neoplasm of bladder				
INLEXZO™ NDC	11-digit (5-4-2 format): <b>57894-0225-01</b> <sup>1,8†</sup> INLEXZO™ (gemcitabine intravesical system) contains the equivalent to 225 mg gemcitabine (present as 256.3 mg gemcitabine hydrochloride), co-packaged with a urinary catheter and stylet	✓	✓	✓
INLEXZO™ Revenue code	<b>0636</b> – Pharmacy, drugs requiring detailed coding <sup>9</sup>		✓	
INLEXZO™ HCPCS Level II <sup>‡§</sup>	<b>C9399</b> – Unclassified drug or biological <sup>10</sup>		Required by Medicare	
	<b>J3490</b> – Unclassified drugs <sup>11</sup>	Required by Medicare	As required by payer	
	<b>J3590</b> – Unclassified biologics <sup>11</sup>			
	<b>J9999</b> – Not otherwise classified antineoplastic drugs <sup>11</sup>			
Procedure Revenue code	<b>0360</b> – Operating room services, general <sup>9</sup>		✓	
Procedure CPT® Category I	<b>51720</b> – Bladder instillation of anticarcinogenic agent (including retention time) <sup>12</sup>	✓	✓	✓
	<b>52310</b> – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple <sup>12</sup>			

Go to Step 2



The fact that a drug, device, procedure or service is assigned an 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.

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†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.

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Please read [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



## How to obtain INLEXZO™ through a specialty pharmacy


Step  
2

### Coordinate delivery of INLEXZO™ from specialty pharmacy

**Accredo Health Group, Inc.**  
accredo.com

 1-877-732-3431

 1-888-302-1028

 **ePrescribe info:**  
Accredo Health Group  
1620 Century Center Pkwy  
Memphis, TN 38134  
NPI#: 1275740474

or



**Your hospital or  
practice-owned  
pharmacy**

<b>Brand name<sup>1</sup></b>	INLEXZO™
<b>Generic name<sup>1</sup></b>	gemcitabine intravesical system
<b>Package presentation</b>	1 intravesical system (1 NDC unit)
<b>National Drug Code (NDC)</b>	11-digit: <b>57894-0225-01</b>

Accurate NDC coding typically requires reporting the following components in this order: N4 qualifier, 11-digit NDC, 2-character NDC unit of measure, and quantity dispensed. Using the INLEXZO™ example above, here is how NDC coding would appear on professional claims:  
**N457894022501UN1<sup>8</sup>**

Go to Step 3





# How to obtain INLEXZO™ through a specialty pharmacy

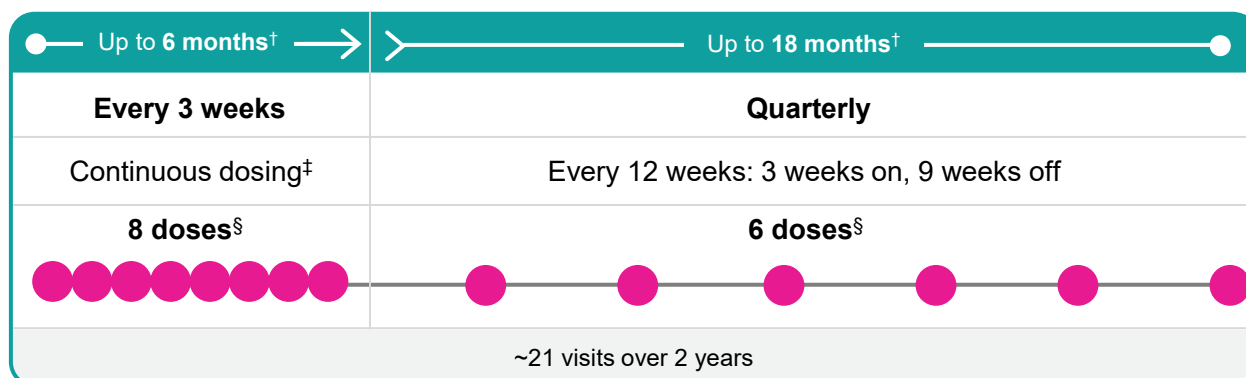
Step  
3

## Schedule the patient

INLEXZO™ is administered in a familiar,\* in-office procedure in 14 doses over 2 years<sup>1</sup>



Remove INLEXZO™ after each 3-week indwelling period<sup>1</sup>



\*Uses catheterization and cystoscopy. <sup>†</sup>Or until unacceptable toxicity or disease persistence, recurrence, or progression.<sup>1</sup>

<sup>‡</sup>Assumes same-day removal and new insertion during first 6 months.<sup>1</sup> <sup>§</sup>One dose=insertion and removal 3 weeks later.<sup>1</sup>

- Administer **INLEXZO™** intravesically only using the co-packaged urinary catheter and stylet<sup>1</sup>
- **INLEXZO™** should be inserted and removed by a trained healthcare provider thoroughly familiar with the insertion and removal instructions<sup>1</sup>
- Removal of **INLEXZO™** by cystoscopy provides the opportunity for simultaneous assessment of disease response<sup>1,13</sup>
- If a dose is missed, it should be administered as closely as possible to the original treatment schedule<sup>1</sup>
- Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each **INLEXZO™** insertion and removal<sup>1</sup>
- **INLEXZO™** contains a metal wire. When **INLEXZO™** is indwelling in the bladder, the patient can only be safely scanned with MRI under certain conditions<sup>14</sup>

Please read full [Prescribing Information](#) for specific MRI scanning conditions.

Please read full [Instructions for Use](#) for complete information on preparation, intravesical administration, and removal.

MRI=magnetic resonance imaging.

## IMPORTANT SAFETY INFORMATION (continued)

### 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.

Please read additional [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



## References:

1. INLEXZO™ (gemcitabine intravesical system) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.
2. Anktiva® (nogapendekin alfa inbakicept-pmln) [Prescribing Information]. Culver City, CA: ImmunityBio, Inc.
3. Adstiladrin® (nadofaragene firadenovec-vncg) [Prescribing Information]. Kastrup, Denmark: Ferring Pharmaceuticals.
4. Jelmyto® (mitomycin) [Prescribing Information]. Princeton, NJ: UroGen Pharma, Inc.
5. Tice® BCG [Prescribing Information]. Durham, NC: Merck Teknika LLC.
6. Valstar® (valrubicin) [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Inc.
7. CMS. ICD-10-CM tabular list of diseases and injuries. Accessed July 31, 2025. [https://www.cms.gov/medicare/coding/icd10/downloads/6\\_i10tab2010.pdf](https://www.cms.gov/medicare/coding/icd10/downloads/6_i10tab2010.pdf)
8. CMS. Medicare Claims Processing Manual, Chapter 26: Completing and processing Form CMS-1500 data set. Revised August 9, 2024. Accessed July 31, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf>
9. Noridian Medicare. Revenue codes. Updated June 17, 2025. Accessed July 31, 2025. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>
10. CMS. Medicare Claims Processing Manual, Chapter 17: Drugs and biologicals. Revised April 11, 2025. Accessed July 31, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>
11. CMS. July 2025 Alpha-numeric HCPCS file. Updated July 9, 2025. Accessed July 31, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>
12. AMA. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: AMA Press; 2024.
13. American Cancer Society. Treatment of bladder cancer, based on the stage and other factors. Accessed July 31, 2025. <https://www.cancer.org/cancer/types/bladder-cancer/treating/by-stage.html>
14. INLEXZO™ [Instructions for Use]. Horsham, PA: Janssen Biotech, Inc.