



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™](#).



IMPORTANT SAFETY INFORMATION

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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 to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support*

Visit 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.



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



- 1 Prescribing Information Quarter Fold Sheet
- 2 Instructions For Use Booklet
- 3 INLEXZO™ (gemcitabine intravesical system) Pouch
- 4 Urinary Catheter and Stylet Pouch
- 5 MRI Safety Information Card
- 6 INLEXZO™ (gemcitabine intravesical system)
- 7 Carton

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.^{1-6†}

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.¹

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.

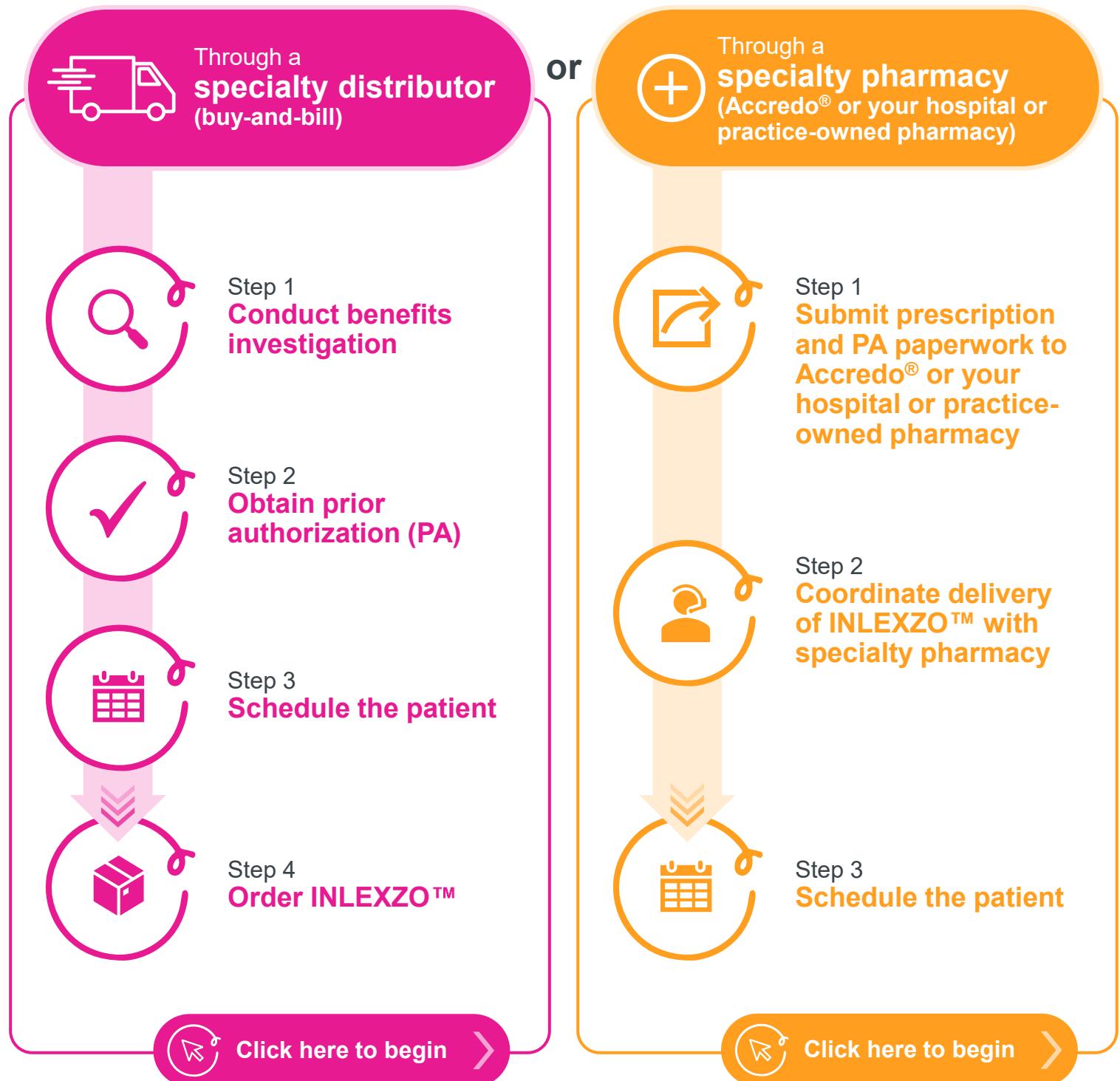
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Please read additional [Important Safety Information](#) on page 2 and see full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



How to obtain INLEXZO™ steps to ordering

Your practice can obtain INLEXZO™ via 2 options





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



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.



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/



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.



Office

HOPD

ASC

Code type	Code and Descriptor	Office	HOPD	ASC
Diagnosis ICD-10-CM ⁷ *	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 <i>in situ</i> of bladder Z85.51 – Personal history of malignant neoplasm of bladder	✓	✓	✓
INLEXZO™ NDC	11-digit (5-4-2 format): 57894-0225-01 ^{1,8†} 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 ⁹	✓		
INLEXZO™ HCPCS Level II ^{‡\$}	C9399 – Unclassified drug or biological ¹⁰ J3490 – Unclassified drugs ¹¹ J3590 – Unclassified biologics ¹¹ J9999 – Not otherwise classified antineoplastic drugs ¹¹		Required by Medicare	As required by payer
Procedure Revenue code	0360 – Operating room services, general ⁹		✓	
Procedure CPT® Category I	51720 – Bladder instillation of anticarcinogenic agent (including retention time) ¹² 52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple ¹²	✓	✓	✓

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.

†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.

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; OPPS=Outpatient Prospective Payment System.



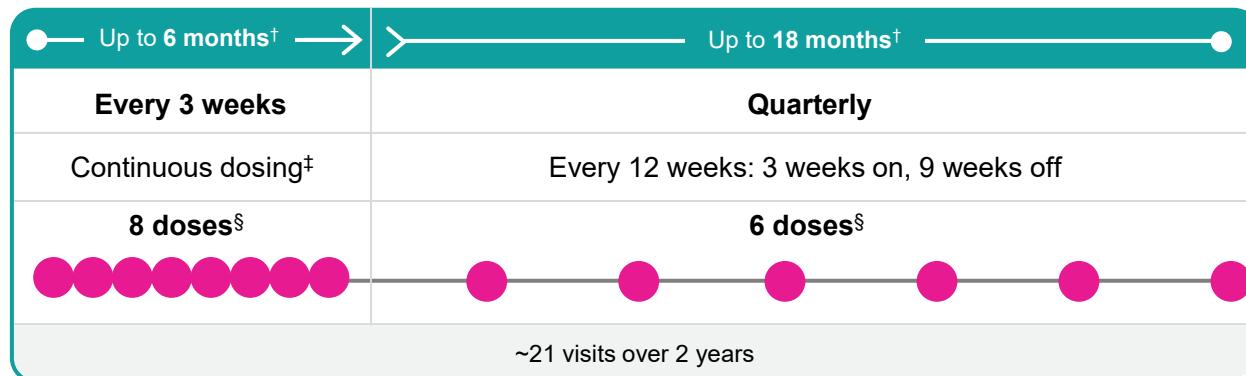
How to obtain INLEXZO™ through a specialty distributor (buy-and-bill)

Step
3

Schedule the patient

INLEXZO™ is administered in a familiar,* in-office procedure in 14 doses over 2 years¹

 Remove INLEXZO™ after each 3-week indwelling period¹



*Uses catheterization and cystoscopy. [†]Or until unacceptable toxicity or disease persistence, recurrence, or progression.¹

[‡]Assumes same-day removal and new insertion during first 6 months.¹ [§]One dose=insertion and removal 3 weeks later.¹

- Administer INLEXZO™ intravesically only using the co-packaged urinary catheter and stylet¹
- INLEXZO™ should be inserted and removed by a trained healthcare provider thoroughly familiar with the insertion and removal instructions¹
- Removal of INLEXZO™ by cystoscopy provides the opportunity for simultaneous assessment of disease response^{1,13}
- If a dose is missed, it should be administered as closely as possible to the original treatment schedule¹
- Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each INLEXZO™ insertion and removal¹
- INLEXZO™ contains a metal wire. When INLEXZO™ is indwelling in the bladder, the patient can only be safely scanned with MRI under certain conditions¹⁴

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.

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

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

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: **N457894022501UN1⁸**



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.





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/



Supporting documents, including:

- Patient Authorization and Notice of Release of Information
- Patient's health plan or prescription card (front and back)
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How to obtain INLEXZO™ through a specialty pharmacy

Step
1
continued

Obtain prior authorization (continued)

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Code type	Code and Descriptor	Office	HOPD	ASC
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INLEXZO™ Revenue code	0636 – Pharmacy, drugs requiring detailed coding ⁹		✓	
INLEXZO™ HCPCS Level II ^{‡\$}	C9399 – Unclassified drug or biological ¹⁰ J3490 – Unclassified drugs ¹¹ J3590 – Unclassified biologics ¹¹ J9999 – Not otherwise classified antineoplastic drugs ¹¹		Required by Medicare	As required by payer
Procedure Revenue code	0360 – Operating room services, general ⁹		✓	
Procedure CPT® Category I	51720 – Bladder instillation of anticarcinogenic agent (including retention time) ¹² 52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple ¹²	✓	✓	✓

Go to Step 2

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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

Brand name ¹	INLEXZO™
Generic name ¹	gemcitabine intravesical system
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National Drug Code (NDC)	11-digit: 57894-0225-01

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N457894022501UN1⁸

Go to Step 3



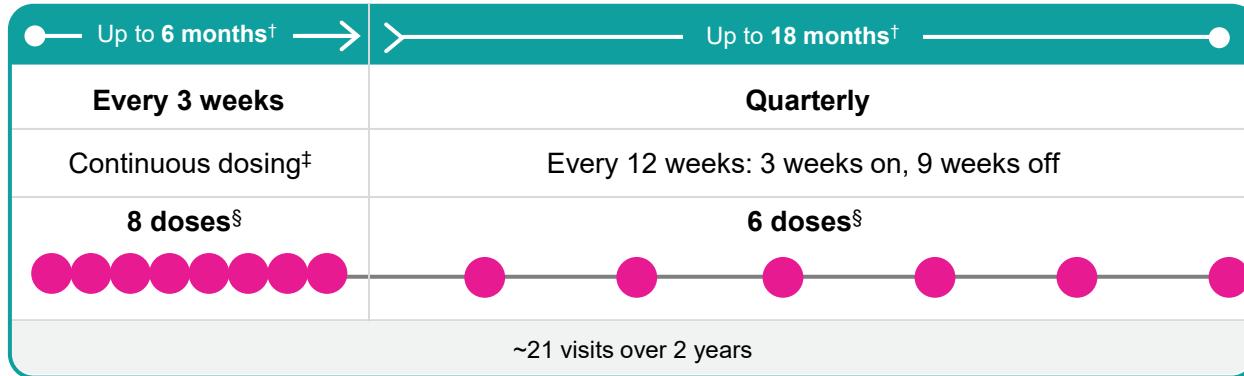
How to obtain INLEXZO™ through a specialty pharmacy

Step
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MRI=magnetic resonance imaging.

IMPORTANT SAFETY INFORMATION (continued)

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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 inbakcept-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.
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