J9183

Permanent J-code
EFFECTIVE APRIL 1, 2026[1]

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.

INLEXZO™ Coding Information	
HCPCS J-Code[1]	J9183
HCPCS J-Code Descriptor[1]	Gemcitabine intravesical system, 225 mg
NDCs[2]	10-digit: 57894-225-01
	11-digit: 57894-0225-01
Billing Units	1 intravesical system = 1 billing unit
Procedure Coding Information	
CPT® Category I[3]	**Insertion:** 51720 – Bladder instillation of anticarcinogenic agent (including retention time) **Removal:** 52310 – Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder separate procedure); simple

Physician Office Sample Claim Form (CMS-1500): Gemcitabine intravesical system, 225 mg[4]

If NDC is required, it will be entered in the shaded portion of Item 24A.

	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	N457894022501 UN1 MM/DD/YY	MM/DD/YY	11		J9183				1		NPI	123 456 7890
2	MM/DD/YY	MM/DD/YY	11		52310				1		NPI	123 456 7890
3	MM/DD/YY	MM/DD/YY	11		51720				1		NPI	123 456 7890

UPPLIER INFORMATION

HOPD/ASC Sample Claim Form (CMS-1450/UB-04): Gemcitabine intravesical system, 225 mg[5]

If NDC is required, it will be entered in the unshaded portion of Locator Box 43.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0360	Operating room services, general	52310	MM/DD/YYYY	1				1
2									2
3	0360	Operating room services, general	51720	MM/DD/YYYY	1				3
4									4
5	0636	N457894022501UN1	J9183	MM/DD/YYYY	1				5
6									6

Please check with individual payers for specific documentation and guidance when billing with J9183.

ASC=ambulatory surgical center; CMS=Centers for Medicare and Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; HOPD=hospital outpatient department; NDC=National Drug Code.

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 the next page and full Prescribing Information and Instructions for Use for INLEXZO™.

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

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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

cp-520096v1

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

References: 1. Centers for Medicare & Medicaid Services. Accessed January 21, 2026. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-4-2025-drugs-biologicals.pdf **2.** INLEXZO (gemcitabine intravesical system) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **3.** American Medical Association. *Current Procedural Terminology: CPT® 2026: Professional Edition.* Chicago, IL: AMA Press; 2025. **4.** Centers for Medicare & Medicaid Services. Accessed January 13, 2026. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **5.** Centers for Medicare & Medicaid Services. Accessed January 13, 2026. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf

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