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For Immediate Release

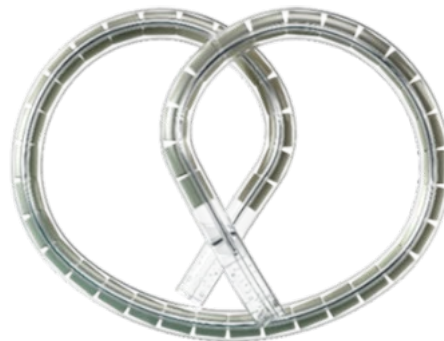
INLEXZO™ (gemcitabine intravesical system) Assigned Permanent Billing Code, Supporting Access for Patients with Certain Bladder Cancers

- *INLEXZO permanent J-code (J9183) effective April 1*

RARITAN, N.J., April 1, 2026 — Johnson & Johnson (NYSE:JNJ) today announced the permanent Healthcare Common Procedure Coding System (HCPCS) J-code for INLEXZO™ (gemcitabine intravesical system) is now in effect. Adult patients living with certain types of Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS) with or without papillary tumors who have historically had limited options before possible bladder removal may benefit from a more standardized billing pathway for this therapy. The unique identifier, J9183, assigned by the Centers for Medicare & Medicaid Services (CMS), can be used by U.S. government and commercial payers, as well as physicians and their office staff, in the billing and reimbursement process for INLEXZO.

“Navigating reimbursement complexity shouldn’t stand between patients and a therapy that could change their disease trajectory,” said Scott White, Chief Operating Officer, North America, Johnson & Johnson. “This permanent code allows healthcare providers to focus on delivering innovative care by helping reduce administrative complexity associated with billing.”

INLEXZO was approved by the Food and Drug Administration (FDA) in September 2025 for the treatment of adult patients with BCG-unresponsive, NMIBC with carcinoma *in situ* (CIS), with or without papillary tumors.¹ It is the first and only FDA-approved intravesical drug-releasing system (iDRS) to provide extended local delivery of a cancer medication into the bladder. This potentially practice-changing approach for treating patients with certain types of bladder cancer addresses a significant unmet need in patients who have failed BCG therapy and for patients refusing or ineligible for bladder removal surgery (radical cystectomy).¹



“Patients often experience fear and frustration when treatments are available but inaccessible due to reimbursement delays,” said Aleksandar Alchev*, DMD, MBA, Director, Business Development, Minnesota Urology. “INLEXZO’s permanent J-code may help support more consistent billing processes and may help facilitate the treatment process for patients over time.”

“For two decades, BCAN has been guided by the voices and experiences of people impacted by bladder cancer. New treatment options, including those with permanent billing codes, are welcome news for patients and their loved ones. They deserve access to therapies without unnecessary delays due to administrative steps,” said Meri-Margaret Deoudes**, CEO, Bladder Cancer Advocacy Network (BCAN).

As of April 1, 2026, physicians and treatment centers can utilize J9183 for INLEXZO when submitting claims for eligible patients, subject to individual payer coverage policies.

Johnson & Johnson is committed to helping patients access our treatments. Once a patient and their doctor have decided that INLEXZO is right for the patient, [J&J withMe](#) provides a simple, comprehensive patient support program offering cost support, a dedicated Care Navigator, and educational resources, at no cost to the patient.†

About INLEXZO™

INLEXZO is approved by the U.S. Food and Drug Administration (FDA) 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 is an intravesical system enabling extended release of gemcitabine into the bladder. It is placed in a few minutes without general anesthesia or further monitoring immediately post-insertion within the healthcare provider’s office.

The safety and efficacy of INLEXZO are being evaluated in clinical trials in patients with MIBC in [SunRISe-4](#), and NMIBC in [SunRISe-1](#), [SunRISe-3](#), and [SunRISe-5](#).

For more information, visit www.INLEXZO.com.

INLEXZO™ INDICATION AND IMPORTANT SAFETY INFORMATION

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.

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

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About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at <https://www.inj.com/> or at www.innovativemedicine.inj.com. Follow us at [@JNJInnovMed](#).

Cautions Concerning Forward-Looking Statements

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of INLEXZO™ (gemcitabine intravesical system). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson’s most recent Annual Report on Form 10-K, including in the sections captioned “Cautionary Note Regarding Forward-Looking

Statements” and “Item 1A. Risk Factors,” and in Johnson & Johnson’s subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Footnotes:

**Aleksandar Alchev has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.*

***Meri-Margaret Deoudes has not been paid for any media work.*

†The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient’s healthcare provider, offer services that would normally be performed by the provider’s office, or serve as a reason to prescribe a Johnson & Johnson medicine.

1. INLEXZO™ U.S. Prescribing Information