Permanent J-Code for ZUSDURI™ (mitomycin) for intravesical solution

Zusduri (mitomycin) for intravesical solution

J9282

The permanent J-Code for ZUSDURI—J9282 mitomycin intravesical instillation, 1 mg—is approved for dates of service beginning January 1, 2026.[1,*]

For the full CMS coding decision, visit:

https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-3-2025-drugs-biologicals.pdf

ZUSDURI is indicated for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

How Supplied[2]	
Dispensing Pack	1 single-dose kit for reconstitution
NDCs	72493-106-03 or 72493-0106-03
Description	2 vials of mitomycin (40 mg each), 1 vial of hydrogel (60 mL)

*Providers are responsible for the selection of appropriate codes for claims forms. This document contains possible coding options relating to the use of Company products, which may vary by health insurance or healthcare provider. The Company cannot guarantee that the billing codes listed in this document will result in coverage or payment. Please verify all codes with private and public plan sponsors prior to submitting claims. Since final coding is at the discretion of the health plan or healthcare provider, the codes in this document should be used for reference purposes only.

NDC, National Drug Code.

INDICATIONS AND USAGE

ZUSDURI™ is indicated for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

IMPORTANT SAFETY INFORMATION

Contraindications

ZUSDURI is contraindicated in patients with perforation of the bladder or in patients with prior hypersensitivity reactions to mitomycin or any component of the product.

Please click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

Clinical highlights[2]

- In the ENVISION trial, 240 patients were screened and enrolled, 223 were evaluated for efficacy, and 240 were evaluated for safety

78% of patients in the ENVISION trial achieved CR* at 3 months (n=173/223 [95% CI: 72, 83])†

79% of patients who achieved CR at 3 months remained in CR 12 months later (15 months from treatment initiation)‡; range in months: 0.0, 25.0+

+ Denotes ongoing response.

Most common adverse reactions (ARs)[2]

	ZUSDURI (N=240)	
ARs	**All Grades (%)**	**Grade 3 or 4§ (%)**
Dysuria	23	0.4
Hematuria¶	10	0
Urinary tract infection¶	12	0.8

- Most ARs were mild to moderate
- Serious ARs occurred in 12% of patients who received ZUSDURI, including urinary retention (0.8%) and urethral stenosis (0.4%)[2]
- Permanent discontinuation of ZUSDURI due to an AR occurred in 2.9% of patients, including 1.7% who discontinued due to a renal or urinary disorder[3,‖]

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ZUSDURI may cause fetal harm.

CI, confidence interval; CR, complete response.

*CR was assessed by cystoscopy, urine cytology, and for-cause biopsy at 3 months.[3]

†Based on observed duration of response for 173 patients who had a CR.[2]

‡All patients were followed for a minimum of 15 months. Study is ongoing and further results will follow.[2]

§Only includes grade 3 ARs.

¶Includes multiple related terms.

‖Lower urinary tract symptoms (2 patients), and 1 event each of dysuria, urge incontinence, urinary retention, urosepsis, acute cardiac failure, metastatic lung cancer, and hypersensitivity. In total, 7 patients had 9 events.

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Warnings and Precautions

Risks in Patients with Perforated Bladder

ZUSDURI may lead to systemic exposure to mitomycin and 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 instillation of ZUSDURI and do not administer to patients with a perforated bladder or mucosal compromise until bladder integrity has been restored.

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, ZUSDURI can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with ZUSDURI and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ZUSDURI and for 3 months following the last dose.

Adverse Reactions

Common Adverse Reactions

The most common (≥10%) adverse reactions, including laboratory abnormalities, that occurred in patients treated with ZUSDURI were increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

Additional Adverse Reactions Information

Clinically relevant adverse reactions occurring in <10% of patients who received ZUSDURI included increased urinary frequency, fatigue, urinary incontinence, urinary retention, urethral stenosis, genital pain, urinary urgency, genital edema, genital pruritus, genital rash, urethritis, acute kidney injury, balanoposthitis, and nocturia.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ZUSDURI and for 1 week following the last dose.

Preparation and Administration Information

ZUSDURI is to be administered by intravesical instillation only. Do not administer ZUSDURI by pyelocalyceal instillation or by any other route.

ZUSDURI must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the ZUSDURI Instructions for Pharmacy and administration instructions found in the ZUSDURI Instructions for Administration.

ZUSDURI may discolor urine to a violet to blue color following the instillation procedure. Advise patients for at least 24 hours post-instillation to avoid urine contact with skin, to void urine sitting on a toilet, and to flush the toilet several times after use. Advise patients to wash hands, perineum or glans with soap and water after each instillation procedure.

ZUSDURI is a hazardous drug. Follow applicable special handling and disposal procedures.

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(mitomycin) for intravesical solution

How can I learn more or get help?

Contact your UroGen Field Reimbursement Manager, who can answer your questions about utilizing this code.

UroGen Support™

Reimbursement and Patient Support
To learn more about ZUSDURI, please visit UROGENSUPPORT.com or call 833-UROGEN1 (833-876-4361).

Please click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

References: 1. Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations. Third Quarter, 2025 HCPCS Coding Cycle. U.S. Department of Health & Human Services; 2025. Accessed November 4, 2025. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-3-2025-drugs-biologicals.pdf **2.** ZUSDURI. Prescribing information. UroGen Pharma, Ltd. **3.** Prasad SM, Shishkov D, Mihaylov NV, et al. Primary chemoablation of recurrent low-grade intermediate-risk nonmuscle-invasive bladder cancer with UGN-102: a single-arm, open-label, phase 3 trial (ENVISION). *J Urol*. 2025;213(2):205-216.

UroGen Pharma

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