Miscellaneous and Unclassified Billing Codes for ZUSDURI™ (mitomycin) for Intravesical Solution

Zusduri™ (mitomycin) for intravesical solution

Newly approved drugs or biologics do not have unique HCPCS codes. However, once the FDA allows a service or item to be marketed, providers may use miscellaneous or unclassified codes until the assignment of a permanent code.[1]

Coding information for ZUSDURI[2]

Site of care	Coding following FDA approval up to the assignment of a permanent HCPCS code
Physician's office	J9999 – Not otherwise classified, antineoplastic drugs
	J3490* – Unclassified drugs
	J3590* – Unclassified biologics

Site of care	Coding immediately following FDA approval
Hospital outpatient department	C9399 – Unclassified drugs or biologics
	J9999 – Not otherwise classified, antineoplastic drugs
	J3490* – Unclassified drugs
	J3590* – Unclassified biologics

Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment. The provider is solely responsible for determining appropriate treatment for the patient based on the unique medical needs of each patient and the independent judgment of the provider. It is also the responsibility of the provider to determine payer-appropriate coding, medical necessity, site of service, documentation requirements, and payment levels and to submit appropriate codes, modifiers, and charges for services rendered. Although we have made every effort to provide information that is current at the time of its issue, it is recommended you consult your legal counsel, reimbursement/compliance advisor, and/or payer organization(s) for interpretation of payer-specific coding, coverage, and payment expectations.

UroGen Support™

For assistance, call 1-833-UROGEN1 (1-833-876-4361) or visit UROGENSUPPORT.com

*Code used where applicable.

FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System.

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.

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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.

Please click here for Full Prescribing Information.

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References: 1. Centers for Medicare & Medicaid Services. Billing and Coding: Hospital Outpatient Drugs and Biologicals Under the Outpatient Prospective Payment System (OPPS). Accessed October 10, 2024. https://www.cms.gov/medicare-coveragedatabase/view/article.aspx?articleId=55913 **2.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Accessed October 10, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update

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