Zusduri™
(mitomycin) for intravesical solution

Access and Reimbursement Guide

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 see Important Safety Information throughout and click here for Full Prescribing Information.

UroGen is committed to helping appropriate patients access ZUSDURI by providing support at every step

This guide is a comprehensive resource to help ensure proper billing, coding, and reimbursement for ZUSDURI.

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PA, prior authorization.

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Please see Important Safety Information throughout and click here for Full Prescribing Information.

Basic coverage information

Billing and coding requirements for ZUSDURI will vary based on many factors, including the administration site of the drug, the patient's type of insurance, and the benefit type under which ZUSDURI is covered.

Site of care

ZUSDURI may be administered at a physician office or HOPD. This guide provides information on coverage, coding, and billing at both sites of care.

Benefit category

Most payers cover physician-administered products such as ZUSDURI under the medical benefit rather than the pharmacy benefit. In the case of Medicare, ZUSDURI will typically be covered under Part B.

Payer type

Coverage for ZUSDURI spans across payer channels.

Most likely coverage scenario at launch:

Medicare Part B FFS	ZUSDURI is covered through Medicare's medical necessity definition.
Medicare Advantage	ZUSDURI is covered through Medicare or health plan's medical necessity definition and is anticipated to require prior authorization.
Commercial	ZUSDURI is covered via prior authorization aligned to label or the health plan's medical necessity definition; coverage policies vary based on the patient's specific plan.

For Medicaid Managed Care, Medicare Advantage, and commercial plans: It is essential that providers verify their specific contract fee schedules before administering buy-and-bill medications. Although benefit investigations may confirm coverage, reimbursement can vary significantly based on the provider's contracted rates. UroGen is not able to confirm or access site-specific contracted rates—providers are responsible for validating reimbursement adequacy for their place of service.

FFS, Fee-for-Service; HOPD, hospital outpatient department.

Zusduri™ (mitomycin) for intravesical solution

Key product information[1,2]

Product name

ZUSDURI™ (mitomycin) for intravesical solution

FDA approval date

June 12, 2025

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).

How supplied

ZUSDURI is supplied in a single-dose carton containing the following:

- Two 40 mg (each) single-dose vials of sterile, lyophilized, grey to greyish-purple, cake or powder of mitomycin for intravesical solution
- One single-dose vial of 60 mL of sterile, clear, colorless gel with or without bubbles at room temperature or clear, colorless liquid at 2°C to 8°C (36°F to 46°F), to be used as a vehicle for reconstitution

Dispensing pack

1 single-dose carton containing two 40-mg vials of mitomycin and 1 vial of 60-mL hydrogel

NDC

10-digit: 72493-106-03

11-digit: 72493-0106-03

Dosage and administration

ZUSDURI is intended for administration in adult patients with LG-IR-NMIBC by urinary catheter once a week for a total of 6 instillations. ZUSDURI for intravesical solution contains mitomycin 75 mg in 56 mL of hydrogel. ZUSDURI can be administered in a physician office or hospital outpatient department by a trained healthcare professional.

FDA, US Food and Drug Administration; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

Clinical trials

The efficacy and safety of ZUSDURI was investigated in ENVISION, a phase 3, open label, single arm, multicenter study of 240 patients with a history of low-grade non-muscle invasive bladder cancer (LG-NMIBC), of whom 223 were evaluable for response. Patients were required to have a previous occurrence of LG-NMIBC (Ta) treated by TURBT.[1]

Patients had recurrent LG-IR-NMIBC. LG-IR-NMIBC was defined as Ta disease, histologically confirmed by biopsy, having 1 or 2 of the following: the presence of multiple tumors, a solitary tumor >3 cm, and/or early or frequent recurrence (1 occurrence of LG-NMIBC within 1 year of the current diagnosis). The trial excluded patients with T1 tumors, or history of high-grade NMIBC within the previous 2 years, and/or those with prior intravesical chemotherapy within the prior 2 years (except for a single dose of intravesical chemotherapy immediately after any previous TURBT) and/or BCG treatment within the previous year.[1]

Efficacy

Primary endpoint: Complete response (CR)

78% of patients achieved **CR* at 3 months with ZUSDURI** (n=173/223 [95% CI: 72, 83]).[1,†]

Key secondary endpoint: Duration of response (DoR)

79% of patients who achieved CR at 3 months **remained in CR 12 months later** (15 months from initiation).[1,‡]

Safety

Most adverse reactions (ARs) were mild to moderate[2]

- 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[2]
- Serious ARs occurred in 12% of patients, including urinary retention (0.8%) and urethral stenosis (0.4%)[1]
- 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[2,§]

For more information on the ENVISION phase 3 trial, including study design, efficacy, and safety, please see the Full Prescribing Information.

*CR was assessed by cystoscopy, urine cytology, and for-cause biopsy at 3 months.[2]
†Based on observed duration of response for 173 patients who had a CR.[1]
‡All patients were followed for a minimum of 15 months. Study is ongoing and further results will follow.[1]
§Lower urinary tract symptoms (2 patients) and 1 event each of dysuria, urinary incontinence, urinary retention, urosepsis, acute cardiac failure, metastatic lung cancer, and hypersensitivity. In total 7 patients had 9 events.[2]

BCG, Bacillus Calmette-Guérin; CI, confidence interval; TURBT, transurethral resection of bladder tumor.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

Zusduri™ (mitomycin) for intravesical solution

Site of care: Physician's office

Using the appropriate codes on claim forms will help ensure timely and accurate reimbursement. For customized assistance, please contact the UroGen Support™ Program.

HCPCS codes[3]

Drugs and biologics are typically reported with permanent, product-specific HCPCS codes assigned by the CMS. Miscellaneous or unclassified codes allow providers to start billing for a service or item as soon as it receives FDA marketing approval and until a permanent code is assigned.[4] The precise reporting of these miscellaneous drug codes can differ based on the site of care, payer, and timing following FDA approval.

Site of care	Miscellaneous product codes
Physician's office	J9999 – Not otherwise classified, antineoplastic drugs J3490* – Unclassified drugs J3590* – Unclassified biologics

*Code used where applicable.

NDCs[1]

NDC	Code	Description
10-digit	72493-106-03	Single-dose kit containing two 40-mg mitomycin vials (80 mg total) and one 60-mL hydrogel vial
11-digit*	72493-0106-03	Single-dose kit containing two 40-mg mitomycin vials (80 mg total) and one 60-mL hydrogel vial

*Note: The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets HIPAA standards. An 11-digit NDC may be required by certain payers when submitting a reimbursement claim form. Please contact the payer for the required format.[5]

CPT® code[6]

Code	Description
51720	Bladder instillation of an anticarcinogenic agent

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

Appropriate ICD-10-CM codes[7]

Code	Description
C67	**Malignant neoplasm of bladder**
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
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; HIPAA, Health Insurance Portability and Accountability Act; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

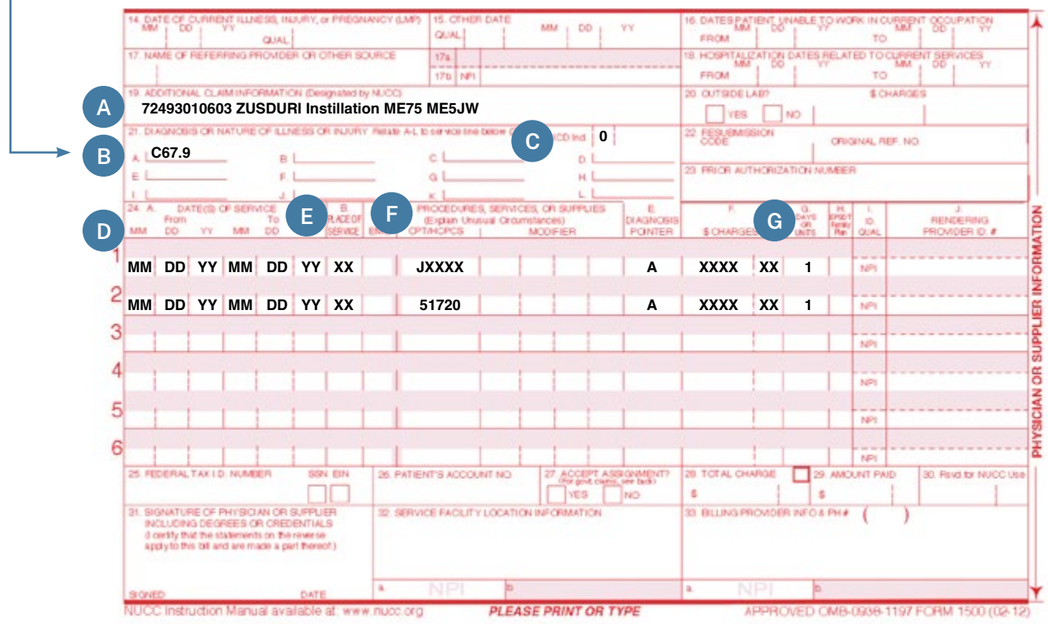
Zusduri™ (mitomycin) for intravesical solution

Physician's office: Sample CMS-1500 claim form

Prescribers use this form when billing insurers for their professional services and medication administered in the physician's office.

The CMS-1500 form is used to bill for ZUSDURI in a urology practice setting. Refer to the notes below when populating the fields, which are essential information required by plans for reimbursement. You are required to code to the highest level of specificity. Contact the third-party payer if you have questions about their specific procedures. The image shown is not a complete depiction of the CMS-1500 form; portions of the full form are not shown.

Use the appropriate ICD-10-CM code based on the patient's diagnosis



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IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

A Box 19

Comment field

This area may be used to list the drug name, NDC number, the route of administration, and the amount administered. When billing with a miscellaneous code, wastage is recorded here. Example: If a patient receives 75 mg from an 80-mg vial of medication, the wastage of 5 mg is recorded as "ME5JW."

B Box 21

Diagnosis code(s)

Enter the appropriate ICD-10-CM diagnosis code(s) based on the patient's clinical history and diagnosis.

ICD-10-CM codes for bladder cancer may include:

- C67 Malignant neoplasm of bladder
- 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
- C67.6 Malignant neoplasm of ureteric orifice
- C67.7 Malignant neoplasm of urachus
- C67.8 Malignant neoplasm of overlapping sites of bladder
- C67.9 Malignant neoplasm of bladder, unspecified

C Box 21

ICD indicator

Enter the ICD indicator as a single digit between the vertical, dotted lines:
0 – ICD-10-CM diagnosis.

D Box 24A

Dates of service

In the non-shaded area, list the date of service. In the shaded area, give a detailed drug description. List the N4 indicator first, then the 11-digit NDC number. Third is the unit of measurement qualifier; the unit quantity is listed at the end.
(Note: Some payers may ask for the NDC number in Box 19.)

E Box 24B

Place of service

Enter the appropriate site of service code.

F Box 24D

HCPCS and CPT® codes

Product: The following HCPCS codes may be appropriate for use when billing for ZUSDURI:

J9999 – Not otherwise classified, antineoplastic drugs
J3490* – Unclassified drugs
J3590* – Unclassified biologics

Administration procedure: Enter the CPT® code that accurately describes the administration service performed. Use CPT® code 51720 for bladder instillation of an anticarcinogenic agent.

G Box 24G

Days or service units

Enter the appropriate number of units instilled for ZUSDURI. When using the miscellaneous J-Code, the unit amount is 1.

*Code used where applicable.

CPT, Common Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION (cont'd)

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™ (mitomycin) for intravesical solution

Site of care: Hospital outpatient department

Using the appropriate codes on claim forms will help ensure timely and accurate reimbursement. For customized assistance, please contact the UroGen Support™ Program.

HCPCS codes[3]

Drugs and biologics are typically reported with permanent, product-specific HCPCS codes assigned by CMS. Miscellaneous or unclassified codes allow providers to start billing for a service or item as soon as it receives FDA marketing approval and until a permanent code is assigned.[4] The precise reporting of these miscellaneous drug codes can differ based on the site of care, payer, and timing following FDA approval.

Site of care	Miscellaneous product codes
Hospital outpatient department	C9399 – Unclassified drugs or biologics
	J9999 – Not otherwise classified, antineoplastic drugs
	J3490* – Unclassified drugs
	J3590* – Unclassified biologics

*Code used where applicable.

NDCs[1]

NDC	Code	Description
10-digit	72493-106-03	Single-dose kit containing two 40-mg mitomycin vials (80 mg total) and 1 60-mL hydrogel vial
11-digit*	72493-0106-03	Single-dose kit containing two 40-mg mitomycin vials (80 mg total) and 1 60-mL hydrogel vial

*Note: The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets HIPAA standards. An 11-digit NDC may be required by certain payers when submitting a reimbursement claim form. Please contact the payer for the required format.[5]

CPT® code[6]

Code	Description
51720	Bladder instillation of an anticarcinogenic agent

IMPORTANT SAFETY INFORMATION (cont'd)

Preparation and Administration Information (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

Revenue codes[8]

Code	Description
0636	Drugs requiring detailed coding
0510	Non-surgical outpatient clinical service

ICD-10-CM codes[7]

Code	Description
C67	**Malignant neoplasm of bladder**
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
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
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C67.9	Malignant neoplasm of bladder, unspecified

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IMPORTANT SAFETY INFORMATION (cont'd)

Preparation and Administration Information (cont'd)

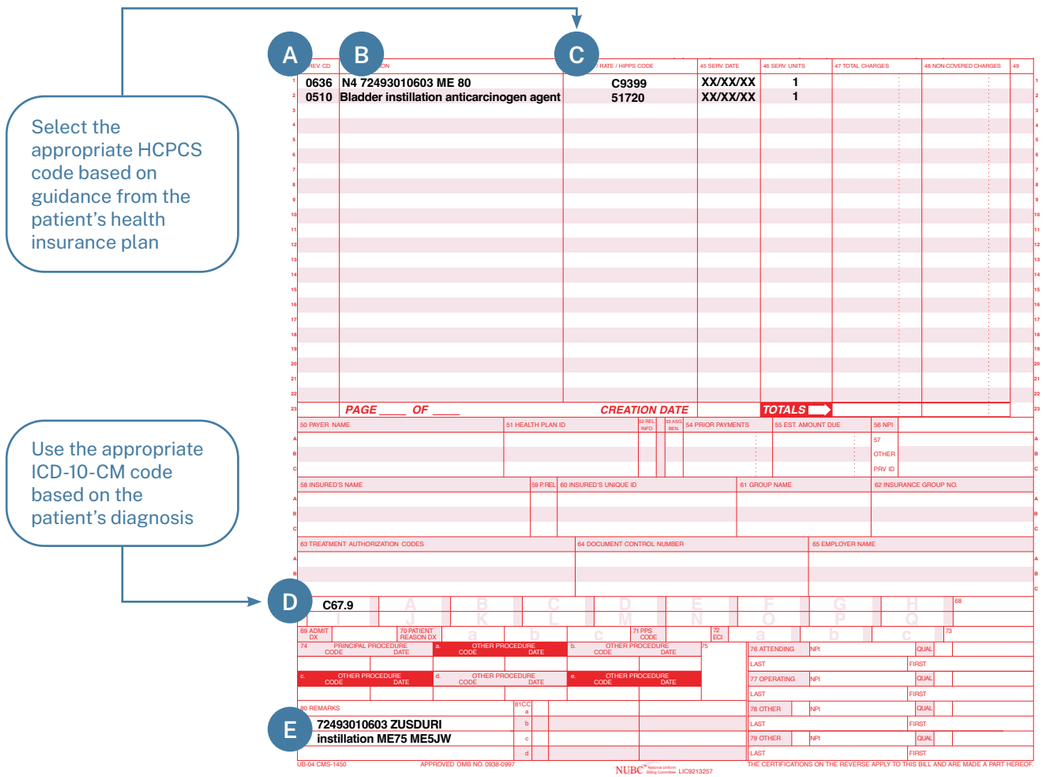
ZUSDURI is a hazardous drug. Follow applicable special handling and disposal procedures.

Zusduri™ (mitomycin) for intravesical solution

Hospital outpatient department: Sample UB-04 (CMS-1450) claim form

Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Make sure to include the appropriate revenue codes when billing in the outpatient setting.

The UB-04 (CMS-1450) form is used for billing prescribed medications such as ZUSDURI administered in a hospital outpatient department setting. Refer to the notes below when populating the fields, which contain essential information the plans require for reimbursement. You are required to code to the highest level of specificity. Contact the third-party payer if you have questions about their specific procedures.



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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 see Important Safety Information throughout and click here for Full Prescribing Information.

A Form Locator (FL) 42

Enter the 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.

B FL 43

Enter a detailed description of the drug for the payer. List the N4 indicator first and the 11-digit NDC number second. Third, add the unit of measurement qualifier, then the unit quantity at the end.

C FL 44-46

Bill for ZUSDURI with the following HCPCS codes:

C9399 – Unclassified drugs or biologicals
J9999 – Not otherwise classified, antineoplastic drugs
J3490* – Unclassified drugs
J3590* – Unclassified biologics

To report the administration procedure, enter the appropriate CPT® code 51720 and corresponding service units.

D FL 66

ICD-10-CM diagnosis codes for bladder cancer may include:

- C67 Malignant neoplasm of bladder
- 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
- C67.6 Malignant neoplasm of ureteric orifice
- C67.7 Malignant neoplasm of urachus
- C67.8 Malignant neoplasm of overlapping sites of bladder
- C67.9 Malignant neoplasm of bladder, unspecified

E FL 80

Enter the NDC number, drug name, route of administration, and the quantity of drug administered and wasted in the remarks section as needed. This information is required when billing with a miscellaneous HCPCS code.

When billing with a miscellaneous code, wastage is recorded here. For example, if a patient receives 75 mg from an 80-mg vial of medication, the dose administered is recorded as "ME75 ME5JW."

*Code used where applicable.

CPT, Common Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Zusduri™ (mitomycin) for intravesical solution

Prior authorization checklist

Prior Authorization Checklist

Zusduri (mitomycin) for intravesical solution

These considerations are intended to clarify the prior authorization (PA) process for patients who have been prescribed ZUSDURI™ (mitomycin) for intravesical solution.

PA Checklist

PA requirements vary by health plan. In order for us to better assist you, please be prepared to include the following information when you submit the PA. After the benefits investigation is completed, UroGen Support will provide you with a list of specific PA requirements and appropriate forms.

1. Most PA forms will require the following information:
   - ☐ Patient information, including date of birth and insurance policy number
   - ☐ Provider and facility information, including name, NPI number, and tax ID number
   - ☐ Date of service
   - ☐ Relevant procedure codes for services/products to be performed/provided
   - ☐ Setting of care
2. Some PA forms may require a letter of medical necessity. Please visit UroGenSupport.com for a sample letter you can use to advocate for your patients.
3. PA approval for ZUSDURI may require specific information, such as:
   - ☐ ZUSDURI indication statement
   - ☐ ZUSDURI Prescribing Information
   - ☐ Documentation of LG-IR-NMIBC diagnosis
   - ☐ Documentation of previous therapy(ies), including length of therapy and reason for discontinuation
   - ☐ FDA approval letter

PA requirements vary by health plan. Please contact the patient's health plan for specific PA requirements to ensure efficient and timely review. Failure to obtain a PA can result in nonpayment by the plan. Please check your contract for any policy exclusions.

Prior to submission, please keep track of dates and methods of communication (verbal and written), record the names of insurance contacts and reviewers with whom you speak, and summarize conversations and written documents issued by the insurer.

UroGen Support™ **If you have any questions, or need guidance, please call 833-UROGEN1 (833-876-4361) or visit UROGENSUPPORT.com.**

FDA, US Food and Drug Administration; LG-IR-NMIBC, low-grade intermediate-risk non-muscle invasive bladder cancer; NPI, National Provider Identifier.

For Medicaid Managed Care, Medicare Advantage, and commercial plans: It is essential that providers verify their specific contract fee schedules before administering buy-and-bill medications. Although benefit investigations may confirm coverage, reimbursement can vary significantly based on the provider's contracted rates. UroGen is not able to confirm or access site-specific contracted rates—providers are responsible for validating reimbursement adequacy for their place of service.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

Claims submission checklist

Claims Submission Checklist

Zusduri (mitomycin) for intravesical solution

Use this checklist to help simplify the claims submission process for ZUSDURI™ (mitomycin) for intravesical solution and ensure prompt payment by filing completely, accurately, and on time.

When you submit a claim:

- ☐ Ensure all patient information (ie, name, address, date of birth, insurance ID) is accurate
- ☐ Verify the name of the healthcare provider and NPI
- ☐ Provide ZUSDURI information (as required by the payer)
  - CPT code(s), unit(s), drug name, drug description, dose, route of administration, NDC
  - Additional information in box 19 of the CMS-1500 form or field 80 of the CMS-1450 (UB-04) form
- ☐ Include diagnosis code(s) (as required by the payer)
  - Primary diagnosis code required for Medicare (as applicable for other payers)
  - Ensure correct numbers and punctuation of codes
- ☐ Use the correct HCPCS codes and modifiers where appropriate
- ☐ Include additional documentation supporting medical necessity with the claim form (if requested by the payer)
  - Most Medicare carriers do not require additional documentation upon initial claim submission. However, upon processing, additional documents may be requested
- ☐ Specify the setting or POS codes where the service was provided (services billed with incorrect POS codes could result in a claim denial/rejection)
- ☐ Provide the PA approval number
  - Failure to include the PA approval number on the form may result in a denied claim
- ☐ Verify claim submitted within the required time frame (as required by the payer)
- ☐ Track claim submission and provider reimbursement

Claims for ZUSDURI may require additional submission information, such as:

- ☐ Patient medical history
- ☐ Physician's clinical notes on the patient's condition and prior treatment for the condition
- ☐ Letter of medical necessity
- ☐ Prescribing Information
- ☐ FDA approval letter
- ☐ Drug purchase invoice
- ☐ Lab tests with support for diagnosis

UroGen Support™ **If you have any questions, or need guidance, please call 833-UROGEN1 (833-876-4361) or visit UROGENSUPPORT.com.**

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The suggestions contained in this resource are for example only. UroGen makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. The use of this information does not guarantee payment or that any payment received will cover your costs.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

Zusduri™ (mitomycin) for intravesical solution

Letter of Appeal/Denial

Instructions:

This appeal letter template is provided as a resource for healthcare providers when responding to an insurance company's denial of coverage of a prescription for ZUSDURI™ (mitomycin) for intravesical solution. Please include the required attachments with the letter of appeal, including insurer forms, Prescribing Information, a copy of the denial or explanation of benefits, and any other additional supporting documents. If you need additional references, please contact UroGen Support at 1-833-UROGEN1 (833-876-4361).

When determining if treatment with ZUSDURI is medically appropriate for a patient, please refer to the full Prescribing Information.

Use of this sample letter does not guarantee that the insurance company will provide reimbursement for the medicine requested and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider.

Sample Letter of Appeal
(Healthcare Provider Letterhead)

Date: [Date]
Payer Name: [Payer Name]
Payer Address: [Payer Address]
City, State, ZIP Code: [City, State, ZIP Code]
Payer Phone and Fax Number: [Payer Phone and Fax Number]

Re: Coverage of ZUSDURI
Patient Name: [Patient Name]
Patient Date of Birth: [Patient Date of Birth]
Policy Number: [Policy Number]
Group Number: [Group Number]

Dear [Name of Medical Director at Health Insurance Company],

I am writing on behalf of my patient, [Name of Patient], to appeal [Name of Health Insurance Company]'s decision to deny coverage of ZUSDURI™ (mitomycin) for intravesical solution, [insert approved indication].

[Patient name] has been diagnosed with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) and has previously received [list all relevant treatments inclusive of therapeutics and/or procedures]. It is my understanding that based on your letter of denial dated [date], coverage has been denied for the following reason(s): [List the specific reason(s) for the denial as stated in the letter of denial].

Letter of Medical Necessity

Instructions:

This template is provided as a resource for healthcare providers when responding to a request from a patient's health insurance company to provide a letter of medical necessity for ZUSDURI™ (mitomycin) for intravesical solution. Please include the required attachments with the letter of medical necessity, including insurance forms, Prescribing Information, and any additional supporting documents. If you need additional references, please contact UroGen Support at 1-833-UROGEN1 (833-876-4361).

When determining if treatment with ZUSDURI is medically appropriate for a patient, please refer to the full Prescribing Information.

Use of this sample letter does not guarantee that the insurance company will provide reimbursement for the medicine requested and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider.

Sample Letter of Medical Necessity
(Healthcare Provider Letterhead)

Date: [Date]
Payer Name: [Payer Name]
Payer Address: [Payer Address]
City, State, ZIP Code: [City, State, ZIP Code]
Payer Phone and Fax Number: [Payer Phone and Fax Number]

Re: Coverage of ZUSDURI
Patient Name: [Patient Name]
Patient Date of Birth: [Patient Date of Birth]
Policy Number: [Policy Number]
Group Number: [Group Number]

To whom it may concern,

I am writing on behalf of my patient, [Patient Name], to document the medical necessity of ZUSDURI™ (mitomycin) for intravesical solution, [insert approved indication].

[Patient name] has been diagnosed with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) and has previously received [list all relevant treatments inclusive of therapeutics and/or procedures.]

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

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.

Zusduri™ (mitomycin) for intravesical solution

UroGen Support™ offers resources and services to help eligible patients navigate insurance coverage, financial assistance, and access to ZUSDURI treatment

UroGen Support™ can help identify financial assistance programs for eligible patients prescribed ZUSDURI. The appropriate program will depend on the patient's coverage.

Commercial Copay Program

Commercially insured patients are enrolled in the UroGen Support™ Copay Program, which allows them to pay as little as $50 for a dose of ZUSDURI. The annual maximum benefit is up to $14,000 per year. Eligibility criteria and terms and conditions apply.

Patient Assistance Program

Qualifying patients without insurance or who are under insured may benefit from the UroGen Support™ Patient Assistance Program.

Full eligibility criteria and terms and conditions for UroGen financial programs are available through UroGen Support™.

Independent charitable organizations

Charitable organizations may help cover treatment costs for eligible patients with Medicare or Medicaid. These programs are not affiliated with UroGen Pharma. Each foundation sets their own eligibility requirements and support determinations, and UroGen cannot guarantee that they will be able to help.

UroGen Support™ can help identify financial assistance programs for eligible patients prescribed ZUSDURI. The appropriate program will depend on the patient's coverage.

Access and support

- Insurance coverage determination and support
- Financial assistance program

Order management

- Coordinate ZUSDURI pharmacy preparation/mixing, shipment, and delivery
- Handling returns and replacement requests

Contact your dedicated Support Specialist at UroGen Support™

UroGen Support™

Call: 833-UROGEN1 (833-876-4361)

Email: contact@UroGenSupport.com

Fax: 833-664-7216

Hours of operation: Monday-Friday, 8 AM-8 PM ET

Visit our resource library for forms, templates, and samples to support your practice.

Support resources
These resources include information on:

- How to utilize our UroGen Support™ offerings
- Our Return Goods Policy
- How to bill for ZUSDURI

Practice forms and documents
Here, you'll find:

- Forms for patient enrollment
- Claims submission information
- Appeal and denial sample letters

Visit UROGENSUPPORT.COM to view the full suite of available resources.

UroGen Support™ does not guarantee access or cost savings.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout and click here for Full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

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™ (mitomycin) for intravesical solution

Appendix

For informational purposes only

POS codes[9]

Code	Location	Description
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
22	Hospital Outpatient Department	Designates a hospital's outpatient department where services are offered to patients who do not require hospitalization

POS, place of service.

IMPORTANT SAFETY INFORMATION (cont'd)

Preparation and Administration Information (cont'd)

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.

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.

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.

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

Please click here for full Prescribing Information.

Zusduri™ (mitomycin) for intravesical solution

Billing, coding, or reimbursement questions?

Contact your UroGen Field Reimbursement Manager
or UroGen Support™ for assistance.

UroGen Support™ 833-UROGEN1 (833-876-4361) | UROGENSUPPORT.com

Please see Important Safety Information throughout and click here for Full Prescribing Information.

References: 1. ZUSDURI. Prescribing information. UroGen Pharma, Ltd. **2.** 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. **3.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed April 29, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **4.** Centers for Medicare & Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). Updated December 17, 2024. Accessed April 29, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913 **5.** Park SJ. The National Drug Code (NDC) rules for assigning and changing NDCs. Accessed October 10, 2024. https://www.fda.gov/media/154502/download **6.** Pohrte J. Billing CPT 51720 with bladder tumor resections. Medic Management Blog. June 4, 2023. Accessed April 15, 2025. https://blog.medicmgmt.com/billing-cpt-51720-with-bladder-tumor-resections **7.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification. Updated April 1, 2025. Accessed April 29, 2025. https://icd10cmtool.cdc.gov **8.** Noridian Healthcare Solutions. Revenue codes. Updated March 18, 2024. Accessed October 11, 2024. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **9.** Centers for Medicare & Medicaid Services. Place of service codes for professional claims. Updated May 2, 2024. Accessed October 11, 2024. https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/downloads/website-pos-database.pdf

UroGen® Pharma

Zusduri™ (mitomycin) for intravesical solution