

Zusduri™ (mitomycin) (Intravesical)

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Dates Reviewed: 07/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided for a total of 6 doses (6 weeks).
- Renewal: Prior authorization validity cannot be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 80 mg (two 40 mg vials) per week for 6 weeks

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Will not be used concurrently with other mitomycin formulations (i.e., Jelmyto®); **AND**
- Patient does not have a neurogenic bladder, active urinary retention or any other condition that would prohibit normal voiding of urine; **AND**
- Patient does not have a perforation of the bladder or mucosal compromise until bladder integrity has been restored; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**
- Patient is not a candidate for generically available mitomycin [J9280] instilled intravesically; **AND**

Bladder Cancer † ¹⁻³

- Patient has low-grade non-muscle invasive bladder cancer (NMIBC); **AND**
- Patient has recurrent intermediate-risk disease defined as having one or two of the following:
 - Presence of multiple tumors
 - Solitary tumor > 3 cm.
 - Early or frequent recurrence (≥ 1 occurrence of low-grade NMIBC within 1 year of the current diagnosis; **AND**
- Patient has not received treatment with Bacillus Calmette-Guerin (BCG) or intravesical chemotherapy (except for a single-dose post-TURBT) for high-grade NMIBC

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
Bladder Cancer	The recommended dose of Zusduri is 75 mg (56 mL) instilled once weekly for six weeks into the bladder via a urinary catheter.
<i>– Zusduri should NOT be administered by pyelocaliceal (or by any other route) instillation.</i> <i>– Zusduri must be chilled at -3°C to 5°C (27°F to 41°F) to convert to a viscous liquid prior to instillation. When instilling, each syringe must be emptied within thirty (30) seconds to avoid gelation.</i> <i>– Instillation of Zusduri requires syringes and a urinary catheter.</i> <i>– 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, to wash hands and genital area with water and soap after each urination, and to flush the toilet several times after use.</i>	

VI. Billing Code/Availability Information

HCP Code:

- J9999 – Not otherwise classified, antineoplastic drugs

NDC(s):

- Zusduri single-dose kit: 72493-0106-xx
 - Two 40 mg (each) single-dose vials of lyophilized mitomycin: 72493-0104-xx
 - One 60 mL single dose-vial of hydrogel vehicle for reconstitution: 72493-0105-xx

VII. References

1. Zusduri [package insert]. Princeton, NJ; UroGen Pharm, Inc.; June 2025. Accessed June 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for mitomycin. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2025.

4. 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 Feb;213(2):205-216. doi: 10.1097/JU.0000000000004296. Epub 2024 Oct 24.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC