Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Mitomycin (Zusduri)	MP-RX-FP-176-25	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Mitomycin (ZUSDURI) , a drug approved by the Food and Drug Administration (FDA) for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

Background Information

The efficacy of ZUSDURI was evaluated in ENVISION (NCT05243550), a single-arm, multicenter trial in 240 adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IRNMIBC), of whom 223 were evaluable for response.

LG-IR-NMIBC was defined as Ta disease, histologically confirmed by biopsy, having one or two 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). Patients were required to have a previous occurrence of LG-NMIBC (Ta) treated by TURBT. The trial excluded patients with T1 tumors, or history of high-grade NMIBC within the previous two years, and/or those with prior intravesical chemotherapy within the prior two years (except for a single dose of intravesical chemotherapy immediately after any previous TURBT) and/or Bacillus Calmette-Guerin treatment within the previous year.

Patients received 75 mg ZUSDURI via urinary catheter once a week for 6 weeks.

Assessment of tumor status was performed every 3 months by cystoscopy, for-cause biopsy, and urine cytology. The major efficacy outcome measures were complete response rate (CR) at 3 months (defined as no detectable disease in the bladder by cystoscopy, biopsy [if indicated], and urine cytology) and duration of response.

The median age of patients was 70 years (range, 30-92 years); 62% were male; race was White (97.8%), Black (0.9%), Asian (0.9%), or not reported (0.4%); 1.3% were Hispanic/Latino. Multiple tumors were present in 84% of patients, 6% had a tumor > 3 cm, 55% had a previous LG-NMIBC occurrence within 1 year of the current diagnosis, and all patients had a prior TURBT for LG-NMIBC.

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9999	Not otherwise classified, antineoplastic drugs
C9399	Unclassified drugs or biologicals

ICD-10	Description
C67.0–C67.9	Malignant neoplasm of bladder (site-specific: trigone, lateral wall, etc.)

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Mitomycin (ZUSDURI)

A. Criteria For Initial Approval

i. Individual is diagnosed with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IRNMIBC); **AND**

ii. Individual has had a previous occurrence of LG-NMIBC (Ta) treated by TURBT (Prasad et al., 2025).

B. Criteria For Continuation of Therapy

i. MMM considers continuation of ***Mitomycin (ZUSDURI)***therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:

a. *A. A current oncology note documenting the patient's response to treatment showing no progression of disease.*
B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

a. Initial Approval Duration: Approval per cycle

b. Reauthorization Approval Duration: Approval per cycle

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Any other uses not described in the above section (Section A); **OR**

ii. Individual has documented perforation of the bladder.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
ZUSDURI (mitomycin) for intravesical solution	Maximum quantity of 6 kits per 6-week cycle
Intravesical solution kit	
• Two 40 mg (each) single-dose vials of mitomycin for intravesical solution. • One vial of 60 mL sterile hydrogel for reconstitution.	

Reference Information

1. Prasad, S. M., Shishkov, D., Mihaylov, N. V., Khuskivadze, A., Genov, P., Terzi, V., … Schoenberg, M. (2025). Primary Chemoablation of Recurrent Low-Grade Intermediate-Risk Nonmuscle-Invasive Bladder Cancer With UGN-102: A Single-Arm, Open-Label, Phase 3 Trial (ENVISION). Journal of Urology, 213(2), 205–216. https://doi.org/10.1097/JU.0000000000004296 (Original work published February 1, 2025)
2. ZUSDURI™ FDA Label.
3. DailyMed – zusduri- mitomycin kit (no date) U.S. National Library of Medicine. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8dc68793-bca8-4e3d-b672-622961b58255 (Accessed: 11 July 2025).

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception 7/11/2025	MMM developed Medical Policy.	7/21/2025	8/8/2025