

DRUG POLICY

Zusduri™ (mitomycin)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

POLICY

Criteria for Initial Approval

Bladder Cancer

Authorization of 3 months (6 doses) may be granted for treatment of recurrent low-grade intermediate-risk (e.g., presence of multiple tumors, solitary tumor greater than 3 cm, and/or early or frequent recurrence) non-muscle invasive bladder cancer (LG-IR-NMIBC) when all of the following criteria are met:

1. The requested drug will be given via intravesical instillation
2. The requested drug will be administered once weekly for six weeks

Continuation of Therapy

Bladder Cancer

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Other

Zusduri (mitomycin) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Zusduri (mitomycin) 75 mg (56 mL) supplied as one kit containing two 40 mg single-dose vials of mitomycin for intravesical solution and one vial of 60 mL sterile hydrogel for reconstitution	1 kit per week for total 6 weeks	Administer 75 mg (56 mL) by intravesical instillation once weekly for six weeks.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9282 – Mitomycin, intravesical instillation, 1 mg (effective 1/1/26)
- J9999 – Not otherwise classified, antineoplastic drugs
- J3490 – Unclassified drugs
- J3590 – Unclassified biologics
- C9399 – Unclassified drug or biologicals (Hospital outpatient)

REFERENCES

Zusduri [package insert]. Princeton, NJ: UroGen Pharma, Inc.; June 2025.

POLICY HISTORY

Policy #: 05.05.97

Original Effective Date: September 27, 2025

Reviewed: August 2026

Revised:

Current Effective Date: September 27, 2025