

# Specialty Guideline Management

## Zusduri

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zusduri	mitomycin

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indication<sup>1</sup>

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

All other indications are considered experimental/investigational and not medically necessary.

### Coverage Criteria

#### Bladder Cancer<sup>1</sup>

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:

Reference number(s)
7037-A

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

## Continuation of Therapy

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

## References

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