Reference number(s)
7038-A

Standard Medicare Part B 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[1]

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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Bladder Cancer[1]

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:

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- 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.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Zusduri.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zusduri are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

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

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