Mitomycin (Zusduri™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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

Compendial Use
Non-muscle invasive bladder cancer (NMIBC)

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

COVERAGE CRITERIA

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:

- The requested drug will be given via intravesical instillation.
- The requested drug will be administered once weekly for six weeks.
- The member will not receive surgery as part of the current course of treatment.

CONTINUATION OF THERAPY

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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-

label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Zusduri [package insert]. Princeton, NJ: UroGen Pharma, Inc.; June 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed August 10, 2026.

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