

Medical Drug Clinical Criteria

Subject: Zusduri (mitomycin intravesical solution)

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Overview

This document addresses the use of Zusduri (mitomycin intravesical solution). Zusduri is a sustained-release formulation of mitomycin C, an alkylating agent that disrupts cancer growth. Incorporation of a reverse thermal gel that solidifies at body temperature enables longer exposure of mitomycin C to the bladder. Zusduri is approved for the treatment of recurrent low-grade intermediate-risk non-muscle invasive bladder cancer and is only approved for intravesical instillation via a urinary catheter.

Clinical Criteria

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.

Zusduri (mitomycin intravesical solution)

Requests for Zusduri (mitomycin intravesical solution) may be approved if the following criteria are met:

- I. Individual has a diagnosis of recurrent low-grade intermediate-risk non-muscle invasive Bladder Cancer (LG-IR-NMIBC); **AND**
- II. Individual is using for intravesical instillation.

Requests for Zusduri (mitomycin intravesical solution) may not be approved for the following:

- I. Individual with perforation of the bladder; **OR**
- II. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Zusduri (mitomycin intravesical solution)]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Zusduri (mitomycin intravesical solution)]

ICD-10 Diagnosis

All diagnosis pend.

Document History

New: 08/15/2025

Document History:

- 08/15/2025 – Annual Review: New clinical criteria for Zusduri. Coding Reviewed: Added HCPCS NOC C9399, J9999, and all diagnosis pend for Zusduri.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 7, 2025.
 - a. Bladder Cancer. V1.2025. Revised March 25, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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