VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Intravesical) – Zusduri Utilization Management Medical Policy
- Zusduri™ (mitomycin intravesical – UroGen Pharma)

REVIEW DATE: 06/25/2025

OVERVIEW

Zusduri, an alkylating agent, is indicated for the treatment of recurrent low-grade intermediate-risk non-muscle invasive bladder cancer in adults.[1]

Dosing Information

The recommended dose of Zusduri is 75 mg (56 mL) instilled once weekly for six weeks into the bladder via a urinary catheter.[1] Zusduri is administered by intravesical instillation only.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on bladder cancer (version 1.2025 – March 25, 2025) does not address Zusduri yet.[2] The guidelines recommend transurethral resection of bladder tumor (TURBT) for non-muscle invasive bladder cancer. Intravesical chemotherapy is recommended as immediate postoperative therapy, which is comprised of a single instillation of chemotherapy given 24 hours after surgery (ideally within 6 hours). In this setting, gemcitabine is "Preferred" and mitomycin is also recommended (both category 1). Induction (adjuvant) therapy is initiated 3-4 weeks after TURBT with or without maintenance. Induction (adjuvant) therapy includes intravesical chemotherapy (e.g. mitomycin or gemcitabine) or intravesical Bacillus Calmette-Guerin (BCG). Weekly instillations during induction are given for approximately 6 weeks. Intravesical BCG can be used as maintenance therapy and ideally maintenance therapy should be given for 1 year for intermediate-risk disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Zusduri. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zusduri as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Zusduri to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zusduri is recommended in those who meet the following criteria:

FDA-Approved Indication

---

1. **Non-Muscle Invasive Bladder Cancer.** Approve for 2 months if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has low-grade intermediate-risk disease; AND
   - **C)** Patient has recurrent disease; AND
   - **D)** The medication is prescribed by or in consultation with an urologist or oncologist.

   Dosing. Approve 75 mg (56 mL) instilled once weekly for six weeks intravesically.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zusduri is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zusduri™ intravesical solution [prescribing information]. Princeton, NJ: UroGen Pharma; June 2025
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – March 25, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 18, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/25/2025