CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 06/24/2026

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

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on bladder cancer (version 1.2026 – March 16, 2026) recommend transurethral resection of bladder tumor (TURBT) for non-muscle invasive bladder cancer.[2-3] Intravesical chemotherapy is recommended as immediate postoperative therapy, which is comprised of a single instillation of chemotherapy given 24 hours after surgery.[2-3] In this setting, gemcitabine is "Preferred" and mitomycin/Zusduri is also recommended (both category 1). Induction (adjuvant) therapy is initiated 3 to4 weeks after TURBT with or without maintenance. Induction (adjuvant) therapy includes intravesical chemotherapy (e.g., mitomycin/Zusduri 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 and 3 years for high-risk disease. The guidelines recommend Zusduri as subsequent treatment for muscle invasive Stage II or Stage IIIA disease in combination with TURBT for carcinoma in situ, Ta, or T1 disease.

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] NCCN guidelines also recommend a single instillation of Zusduri given 24 hours after TURBT as immediate postoperative therapy. Zusduri is administered by intravesical instillation only.

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 6 months if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has intermediate-risk disease or high-risk disease; AND
   - **C)** The medication is prescribed by or in consultation with a urologist or oncologist.

   Dosing. Approve BOTH of the following dosing regimens (A and B):
   - **A)** Initial dosing: Approve 75 mg (56 mL) intravesically once; AND
   - **B)** Subsequent dosing: Approve 75 mg (56 mL) intravesically once weekly for six weeks, initiated 3 to 4 weeks following the initial dose.

Other Uses with Supportive Evidence

2. **Muscle Invasive Bladder Cancer.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Stage II or Stage IIIA disease; AND
   - **C)** Patient has carcinoma in situ (CIS), Ta, or T1 disease; AND
   - **D)** The medication will be used in combination with transurethral resection of bladder tumor (TURBT); AND
   - **E)** The medication is prescribed by or in consultation with a urologist or oncologist.

   Dosing. Approve BOTH of the following dosing regimens (A and B):
   - **A)** Initial dosing: Approve 75 mg (56 mL) intravesically once; AND
   - **B)** Subsequent dosing: Approve 75 mg (56 mL) intravesically once weekly for six weeks, initiated 3 to 4 weeks following the initial dose.

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 1.2026 – March 16, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 19, 2026.
3. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 16, 2026. Search term: Zusduri.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/25/2025
Annual Revision	**Non-Muscle Invasive Bladder Cancer:** The duration of approval was extended to 6 months. The requirements of low-grade disease and recurrent disease were removed. An option for approval was added for a patient with high-risk disease. Initial dosing requirements of 75 mg (56 mL) intravesically once were added. The following dosing requirement "75 mg (56 mL) intravesically once weekly for six weeks" was moved to subsequent dosing and the following wording was added "initiated 3 to 4 weeks following the initial dose." **Muscle Invasive Bladder Cancer:** Condition of approval, criteria, and dosing were added to Other Uses with Supportive Evidence.	06/24/2026