

**POLICY:** Oncology – Jelmyto™ (mitomycin solution for pyelocalyceal administration – UroGen Pharma)

**EFFECTIVE DATE:** 1/1/2021

**LAST REVISION DATE:** 05/10/2023

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

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## **OVERVIEW**

Jelmyto, an alkylating agent, is indicated for the treatment of low-grade upper tract **urothelial cancer** in adults.<sup>1</sup>

## **Dosing Information**

Jelmyto is for pyelocalyceal use only.<sup>1</sup> The recommended dose is 4 mg/mL of mitomycin administered by ureteral catheter or a nephrostomy tube, with total instillation volume determined on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin). The dose is instilled once weekly for 6 weeks. In patients with a complete response 3 months after initiating Jelmyto, therapy can continue once a month for an additional 11 instillations.

## **Guidelines**

The National Comprehensive Cancer Network (NCCN) guidelines for **bladder cancer** (version 2.2023 – April 25, 2023) recommend Jelmyto as a primary treatment for upper urinary tract tumors (category 2A).<sup>2,3</sup> Jelmyto is recommended following complete or near complete endoscopic resection or ablation of a non-metastatic, residual, low-grade, low volume, solitary tumor in patients not a candidate for or seeking definitive treatment with nephroureterectomy.

## **POLICY STATEMENT**

Prior Authorization is recommended for medical benefit coverage of Jelmyto. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. 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 listed below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Jelmyto as well as the monitoring required for adverse events and long-term efficacy, approval requires Jelmyto to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## **RECOMMENDED AUTHORIZATION CRITERIA**

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

### **FDA-Approved Indication**

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- 1. Upper Tract Urothelial Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
- A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has non-metastatic disease; AND
  - C) Patient has low-grade disease; AND
  - D) Patient has undergone endoscopic resection or ablation; AND
  - E) Jelmyto is prescribed by or in consultation with an oncologist or urologist.

**Dosing.** Each dose must not exceed 15 mL instilled into the pyelocalyceal system once weekly for 6 doses, then no more frequently than once a month.

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jelmyto 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. Jelmyto® for pyelocalyceal solution [prescribing information]. Princeton, NJ: UroGen Pharma; September 2022.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 5, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 5, 2023. Search term: Jelmyto.

### HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Upper Tract Urothelial Cancer.</b> Removed “low-grade” from the condition of approval and added requirement that the patient has low-grade disease.	05/11/2022
Annual Revision	No criteria changes.	05/10/2023