PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Other) – Jelmyto Prior Authorization Policy
- Jelmyto™ (mitomycin solution for pyelocalyceal administration – UroGen)

REVIEW DATE: 05/11/2022

OVERVIEW
Jelmyto, an alkylating agent, is indicated for the treatment of adults with low-grade upper tract **urothelial cancer**.[1]

Dosing Information
Jelmyto is for pyelocalyceal use only.[1] 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 and 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 1.2022 – February 11, 2022) recommend Jelmyto as a primary treatment for upper urinary tract tumors (category 2A).[2,3] 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 prescription benefit coverage of Jelmyto. All approvals are provided for the duration noted 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

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 ≥ 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.

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; January 2021.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 3, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 3, 2022. Search term: Jelmyto.