Utilization Review Policy 236

POLICY: Oncology (Other) – Jelmyto Utilization Management Medical Policy

- Jelmyto® (mitomycin solution for pyelocalyceal administration – UroGen)

EFFECTIVE DATE: 12/1/2020
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Jelmyto, an alkylating agent, is indicated for the treatment of low-grade upper tract **urothelial cancer** in adults.[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. 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 3.2024 – April 16, 2024) 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 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

1. **Upper Tract Urothelial Cancer.** Approve for 1 year 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 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.

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 3.2024 – April 16, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2024. Search term: Jelmyto.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/10/2023
Annual Revision	No criteria changes.	05/08/2024

UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024