# Clinical Policy: Mitomycin for Pyelocalyceal Solution (Jelmyto)

Reference Number: LA.PHAR.495
Effective Date:
Last Review Date: 05.01.23
Line of Business: Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Please note: This policy is for medical benefit**

**Description**
Mitomycin for pyelocalyceal solution (Jelmyto®) is an alkylating drug.

**FDA Approved Indication(s)**
Jelmyto is indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC).

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections® that Jelmyto is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Low-Grade Upper Tract Urothelial Cancer** (must meet all)**:**

1. Newly diagnosed or recurrent LG-UTUC above the ureteropelvic junction;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Lesion(s) measure ≤ 15 mm;
5. For the affected kidney(s), member does not have a recent history (with the last year) of carcinoma in situ in the urinary tract, invasive urothelial carcinoma, or high-grade papillary urothelial carcinoma;
6. Member is not a candidate for or is not seeking nephroureterectomy as definitive treatment;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 60 mg once weekly for 6 instillations per kidney;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:** 3 months (6 instillations per kidney)

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Low-Grade Upper Tract Urothelial Cancer** (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Jelmyto for a covered indication and has received this medication for at least 30 days;
2. If member has received 6 instillations, complete response (CR) has been achieved at 3 months after initiation of therapy as evidenced by complete absence of tumor lesions on urine cytology and ureteroscopy;
3. Member has not received more than 17 instillations;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. If member has completed < 6 weekly instillations: New dose does not exceed 60 mg once weekly for up to 6 instillations per kidney;
   b. If member has completed ≥ 6 weekly instillations: New dose does not exceed 60 mg once monthly for up to 11 instillations per kidney;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:** 12 months (up to 17 total instillations per kidney)

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
LG-UTUC: low-grade upper tract urothelial cancer

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): perforation of the bladder or upper urinary tract
- Boxed warning(s): none reported

*Appendix D: General Information*
- NCCN Compendium currently recommend Jelmyto with a Category 2A recommendation for primary treatment for a non-metastatic, residual, low-grade, low volume (5-15 mm), solitary tumor in the upper urinary tract for a patient who is not a candidate for or not seeking nephroureterectomy as a definitive treatment. Complete or near complete endoscopic resection or ablation is recommended prior to mitomycin ureteral gel application.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| LG-UTUC | Jelmyto is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration.<br><br>The dose of Jelmyto to be instilled is 4 mg/mL via ureteral catheter or nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin).<br><br>Instill Jelmyto once weekly for six weeks. For patients with a complete response 3 months after Jelmyto initiation, Jelmyto instillations may be administered once a month for a maximum of 11 additional instillations. | 60 mg; 17 instillations |

## VI. Product Availability
For pyelocalyceal solution – carton containing the following:
- Two 40 mg (each) single-dose vials of mitomycin for pyelocalyceal solution
- One vial of 20 mL sterile hydrogel for reconstitution

## VII. References
1. Jelmyto Prescribing Information. Princeton, NJ: UroGen Pharma, Inc.; January 2021. Available at https://www.jelmyto.com/hcp. Accessed April 25, 2022.
2. Kleinmann N, Matin S, Pierorazio P, et al. Primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel

(OLYMPUS): an open-label, single-arm, phase 3 trial. Lancet Oncol 2020. Published online April 29, 2020. Available at https://doi.org/10.1016/S1470-2045(20)30147-9.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 25, 2022.
4. National Comprehensive Cancer Network. Bladder Cancer Version 1.2022. Available at nccn.org. Accessed April 25, 2022.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9281 | Mitomycin pyelocalyceal instillation, 1 mg |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Policy created | 05.01.23 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the

requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.