

Clinical Policy: Mitomycin for Pyelocalyceal Solution (Jelmyto)

Reference Number: CP.PHAR.495

Effective Date: 09.01.20

Last Review Date: 08.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder at the end of this policy for important regulatory and legal information.](#)

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 health plans affiliated with Centene Corporation® 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 \geq 18 years;
4. Lesion(s) measure \leq 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. 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

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
LG-UTUC	<p>Jelmyto is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration.</p> <p>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).</p> <p>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.</p>	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. Available at <https://www.jelmyto.com/hcp/>. Accessed April 20, 2020.
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](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 May 26, 2010.
4. National Comprehensive Cancer Network. Bladder Cancer Version 5.2020. Available at [nccn.org](http://www.nccn.org). Accessed May 26, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.26.20	08.20

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. The Health Plan makes no representations and

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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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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