Clinical Policy: Mitomycin for Pyelocalyceal Solution (Jelmyto)

Reference Number: PA.CP.PHAR.495
Effective Date: 07/2020
Last Review Date: 07/2023

Revision Log

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 PA Health & Wellness® 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 that is both (a and b):
   a. Above the ureteropelvic junction;
   b. Non-metastatic;
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 not seeking nephroureterectomy as definitive treatment;
7. One of the following (a or b):
   a. Member has had complete or near complete endoscopic resection or ablation;
   b. Member is not a candidate for endoscopic/surgical intervention;
8. 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*).

Approval duration: 3 months (6 instillations per kidney)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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*).

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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
LG-UTUC: low-grade upper tract urothelial cancer
NCCN: National Comprehensive Cancer Network

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. 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). 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.; September 2022. Available at https://www.jelmyto.com/hcp. Accessed April 13, 2023.
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 May 2, 2023.
4. National Comprehensive Cancer Network. Bladder Cancer Version 2.2023. Available at nccn.org. Accessed May 2, 2023.

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	P&T Approval Date
Policy created	07/2020	
3Q 2021 annual review: no significant changes; added HCPCS codes; references reviewed and updated.	07/2021	
3Q 2022 annual review: updated initial approval criteria to include "member is not candidate for or seeking nephroureterectomy as definitive treatment" to mirror NCCN bladder cancer guidelines, added Appendix D for additional information from NCCN Compendium to support this addition; references reviewed and updated.	07/2022	
3Q 2023 annual review: added criteria that LG-UTUC be non-metastatic; added requirement for endoscopic resection or ablation if member is a candidate per NCCN; references reviewed and updated.	07/2023	