Clinical Policy: Mitomycin for Pyelocalyceal Solution (Jelmyto)

Reference Number: ERX.SPA.397
Effective Date: 09.01.20
Last Review Date: 08.21
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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 since 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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	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.; January 2021 Available at https://www.jelmyto.com/hcp/. Accessed March 17, 2021.
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 March 16, 2021.
4. National Comprehensive Cancer Network. Bladder Cancer Version 3.2021. Available at nccn.org. Accessed May 3, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.26.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	03.17.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.