Jelmyto®
(mitomycin) for pyelocalyceal solution

Enhanced Media Kit 2.0

Indications and Usage

JELMYTO® (mitomycin) for pyelocalyceal solution is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

Contraindications

JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract.

Welcome

Congratulations on offering JELMYTO® (mitomycin) for pyelocalyceal solution at your facility. By doing so, you are giving patients with low-grade upper tract urothelial carcinoma (UTUC) the opportunity to potentially benefit from a kidney-sparing treatment option.[1]*

Low-grade UTUC is a rare and challenging disease to treat.[2] Historical treatment options have been endoscopic management and/or kidney removal.[2,3] These options, however, aren't suited for all patients and may even pose serious risks.[3-5] The advent of JELMYTO is therefore a critical one and represents a significant shift in the treatment of this disease.

Enhanced Media Kit Contents

- **Overview of JELMYTO and the JELMYTO Enhanced Media Kit**
- **Resources for Urologists**
- **Public Relations Guidance and Overview**
- **Important Safety Information**

Overview of JELMYTO Key Points

- The only FDA-approved primary treatment for low-grade UTUC[1,6]
- Spares the patient's kidney for tomorrow[1]*
- Offers the versatility to treat low-grade UTUC across diverse presentations[3]
- Efficacy[1,3]:
    - Complete response (CR) in 58% of patients in OLYMPUS, the phase 3 study
    - 56% of the patients who achieved CR remained in CR at the 12-month time point for assessment of durability
        - See study design below
- The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria, and vomiting[1]
- JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract[1]
- Once-weekly instillation for 6 weeks with the flexibility of[1,3]
    - Antegrade or retrograde administration
    - Instillation at a clinic, ambulatory surgery center, or hospital
- Accessibility across all payer channels with a comprehensive suite of offerings and financial assistance for eligible patients

*JELMYTO is instilled via the pyelocalyceal system in a procedure that spares the kidney.[1]

OLYMPUS Study design: The efficacy of JELMYTO was investigated in the OLYMPUS Study (N=71), a phase 3, open-label, single-arm, multicenter trial in patients with treatment-naïve or recurrent low-grade upper tract urothelial carcinoma (UTUC) with ≥ 1 measurable papillary tumor 5 to ≤ 15 mm located above the ureteropelvic junction (partial tumor resection/debulking was permitted if > 15 mm). Patients received JELMYTO once weekly for 6 weeks. Complete response (CR) was defined as complete absence of tumor lesions in the ipsilateral pyelocalyceal system at 3 months after initiation of JELMYTO by urine cytology, ureteroscopy, and biopsy (if warranted). The primary endpoint was CR and the secondary efficacy endpoint was duration of response at 12 months.[1,3]

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For more information on JELMYTO, please see pages 6-7 for Full Important Safety Information and refer to the Full Prescribing information, which is available as a download here.

References: 1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2022. **2.** Coleman JA, Clark PE, Bixler BR, et al. Diagnosis and management of non-metastatic upper tract urothelial carcinoma: AUA/SUO guideline. *J Urol.* 2023;209(6):1071-1081. **3.** Kleinmann N, Matin SF, Pierorazio PM, 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;21(6):776-785. **4.** Lane BR, Smith AK, Larson BT, et al. Chronic kidney disease after nephroureterectomy for upper tract urothelial carcinoma and implications for the administration of perioperative chemotherapy. *Cancer.* 2010;116(12):2967-2973. **5.** Raman JD, Lin Y-K, Kaag M, et al. High rates of advanced disease, complications, and decline of renal function after radical nephroureterectomy. *Urol Oncol.* 2014;32(1):47e9-47e14. **6.** FDA approves first therapy for treatment of low- grade upper tract urothelial cancer. News release. US Food & Drug Administration; April 15, 2020. Accessed April 28, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapy-treatment-low-grade-upper-tract-urothelial-cancer

Purpose of the JELMYTO Enhanced Media Kit

This Enhanced Media Kit provides key resources that will enable you to share information about JELMYTO and its use at your facility. It includes both Resources for Urologists as well as PR Guidance and Overview. These resources can be customized at your discretion to meet your requirements and then sent to local urologists as a part of your own independent community education plan. They may also be used within your facility for the purpose of informing and educating both healthcare providers and patients.

We hope the Enhanced Media Kit supports your endeavors to inform the community and to continue to offer JELMYTO to patients with low-grade UTUC. If you have any questions, please contact us through your local JELMYTO representative.

Preserving Your Independence

The decision to use or not use content provided in this Enhanced Media Kit rests exclusively with your institution. Your institution is the sole owner of all education materials developed and has exclusive responsibility for all education materials that incorporate content taken from this Enhanced Media Kit. However, UroGen strongly encourages your institution to include the JELMYTO Important Safety Information and the FDA-approved labeling for JELMYTO (or identify where such labeling may be accessed at Jelmyto.com) with all educational materials relating to JELMYTO. Consult as necessary with your institution's legal department about your educational materials.

UroGen's provision of the JELMYTO Enhanced Media Kit is intended for educational purposes and to facilitate patient access to appropriate treatment with JELMYTO. UroGen's provision of the Enhanced Media Kit is not intended to induce your institution to purchase, prescribe, or recommend JELMYTO or to reward your institution for any past purchase, prescription, or recommendation. UroGen's provision of this Enhanced Media Kit is not contingent upon your institution's decision to use or prescribe JELMYTO.

Resources for Urologists

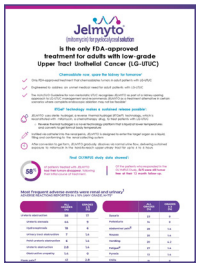
The following resources are available to inform and educate local urologists and community members about JELMYTO.

Introduction Letter Template

It is important to let other urologists know about the treatment benefits of JELMYTO available at your institution. You can copy and paste the content from this templated letter into your letterhead and personalize it for your facility.

- Can be emailed or mailed
- Introduces JELMYTO
- Explains how JELMYTO works
- Identifies your facility as a site of care for JELMYTO treatment to urologists and patients in the local community
- Invites urologists to visit the facility to see JELMYTO treatment in action

Download the JELMYTO Introduction Letter



JELMYTO Backgrounder

The JELMYTO Backgrounder provides an overview of JELMYTO, its novel technology, as well as key data points from the phase 3 OLYMPUS trial. The backgrounder is designed to be distributed as is, but it may also be replicated to conform to your institution's branding. The Backgrounder can complement the JELMYTO Introduction Letter.

Download the JELMYTO Backgrounder

JELMYTO Referral Tracker

Treating complex diseases often calls for a team approach. Some urology practices may not be set up to administer JELMYTO to patients with low-grade UTUC, and referral may be the best option. This downloadable referral tool can help with the referral process and ensure continuity with patients.

Download the JELMYTO Referral Tracker

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Public Relations Guidance and Overview

You have an exciting story to tell as a leading center for urologic care and, in most cases, you are one of very few facilities in your community to offer JELMYTO, the latest advance in the treatment of low-grade UTUC in adult patients. This is a terrific opportunity for you to engage local media to raise awareness of your services.

The following resources may be used within your facility to help create your own communications to educate the healthcare community and local media and/or to respond to potential media inquiries. Please check with your manager and work with your internal communications team for review and approval of this content as needed.

Press Release Template

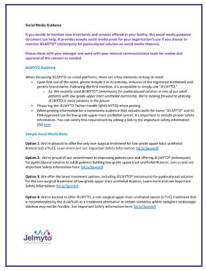
The Press Release can be used to announce your treatment offerings and capabilities, which includes the availability of JELMYTO at your institution and the expert care provided by your staff. You can paste the content from this templated press release into your letterhead and personalize it for your facility should you wish to distribute.

Download the Press Release Template

Internal Communications Template

The Internal Communications can be shared internally at your facility to reinforce your center's commitment to advancing patient care and offering the latest therapies, including JELMYTO. You can paste the content from this templated material into your letterhead and personalize it for your facility should you wish to distribute in print or electronically. The Internal Communications can complement the Press Release.

Download the Internal Communications Template



Social Media Guidance

The Social Media Guidance document provides some basic guidance and sample social media posts to implement across your social media accounts. Please feel free to personalize each post for your facility and secure the necessary approvals prior to distribution.

Download the Social Media Guidance

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Content for Institution's External Communications About JELMYTO

The Content for Institution's External Communications About JELMYTO provides an overview of low-grade UTUC and JELMYTO and can be used to develop external communications and help respond to potential media inquiries. You may use the document as is or paste onto your own letterhead should you wish to distribute internally. Please note this document is for internal use only and should not be distributed externally.

Download the Content for Institution's External Communications About JELMYTO

JELMYTO Healthcare Provider and Patient Testimonials

Positive real-life experiences can be an invaluable way to inform and educate local urologists about JELMYTO and the instillation process. Consider using testimonials from both qualified staff members and patients who have been treated with JELMYTO on your institution's website and other forms of media. Consult with your internal legal department as necessary concerning the appropriate disclosures and consent documents that would be required.

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Ureteric Obstruction

Ureteric obstruction, including ureteral stenosis and hydronephrosis, occurred in patients receiving JELMYTO. Monitor patients for signs and symptoms of ureteric obstruction, including flank pain, and fever, and for changes in renal function. Patients who experience obstruction may require transient or long-term ureteral stents or alternative procedures. Withhold or permanently discontinue JELMYTO based on the severity of ureteric obstruction.

Bone Marrow Suppression

The use of JELMYTO can result in bone marrow suppression, particularly thrombocytopenia and neutropenia. The following tests should be obtained prior to each treatment: Platelet count, white blood cell count differential and hemoglobin. Withhold JELMYTO for Grade 2 thrombocytopenia or neutropenia. Permanently discontinue for Grade 3 or greater thrombocytopenia or neutropenia.

Important Safety Information (continued)

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, JELMYTO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with JELMYTO and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JELMYTO and for 3 months following the last dose.

Common Adverse Reactions

The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria, and vomiting.

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in < 10% and ≥ 2% of patients who received JELMYTO include urinary tract inflammation, bladder spasm, urosepsis, hypersensitivity, and instillation site pain.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with JELMYTO and for 1 week following the last dose.

Preparation and Administration Information

JELMYTO is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration. JELMYTO must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the JELMYTO Instructions for Pharmacy and administration instructions found in the JELMYTO Instructions for Administration.

JELMYTO may discolor urine to a violet to blue color following the instillation procedure. Advise patients to avoid contact with urine for at least six hours post-instillation, to void urine sitting on a toilet, and to flush the toilet several times after use.

JELMYTO is a hazardous drug. Follow applicable special handling and disposal procedures.

For more information on JELMYTO, please click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

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