

JELMYTO Formulary Request: What You Need To Know



The points below outline the most commonly requested information about JELMYTO. Simply copy and paste into your organization's format for a quicker, more complete response.

NOTE TO PC USERS: To copy/paste content, open the document in Google Chrome or click "Edit PDF".

Rationale for Requesting JELMYTO

- JELMYTO is an FDA-approved treatment for adults with low-grade upper tract urothelial carcinoma (LG-UTUC) and is instilled in a kidney-sparing procedure
- JELMYTO uses an innovative reverse-thermal hydrogel (RTGel Technology) that fills and conforms to the complex renal anatomy for 4 to 6 hours of sustained exposure to mitomycin
- Delivers chemoablative therapy directly to the upper tract to complete the primary treatment regimen across diverse presentations, even in endoscopically unreachable areas
- Risks of other commonly used surgical treatments include¹⁻⁴:
 - Endoscopic ablation: anatomical challenges that may limit access and visualization; high recurrence rate
 - Radical nephroureterectomy: post-surgical complications and infections; long-term impact on renal function
- JELMYTO is instilled once-weekly for 6 weeks and can be administered via ureteral catheter or nephrostomy tube. Instillation is an outpatient procedure that does not require an overnight stay

JELMYTO Clinical Highlights

- **58% complete response (CR)** with a comparable response rate in patients with unresectable tumors⁵
- Of the patients who achieved CR in UroGen's Olympus study, 23 (56%) remained at CR at the 12-month time point for assessment of durability⁵
- Patients with ongoing CR were enrolled in the long-term follow-up study (BL007) (N=20)*⁶
- No evidence of recurrence was reported in 75% of participants at their last follow-up⁶
- Median follow-up was 53.3 months⁶
- Most common adverse reactions observed in the Olympus study ($\geq 20\%$) are ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, renal dysfunction, nausea, fatigue, dysuria, and vomiting^{15,7}
- JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract

*A total of 71 patients were enrolled and treated in the parent Olympus study. Of the 71 patients, 41 achieved CR after treatment with 6 weekly instillations of JELMYTO and entered quarterly follow-up for 12 months, after which 20 of those were enrolled in the 5-year rollover trial and were followed for evidence of recurrence, progression, or death by their treating physicians on a semiannual basis.⁶

¹9 participants had early discontinuations in long-term follow-up and 6 ongoing CR in long-term follow-up.⁶

The primary analysis evaluated DOR in the 41 patients who achieved CR.

The statistical methods described above were repeated in the subset of 20 patients who were analyzed for efficacy in the follow-up trial.

Limitations: This is a post hoc analysis. In addition, there is an inherent selection bias for the 20 patients that enrolled in the trial.

National Comprehensive Cancer Network® (NCCN®) recommends mitomycin gel (JELMYTO) following complete or near-complete endoscopic resection as a primary therapy option for patients with upper-tract tumors⁸

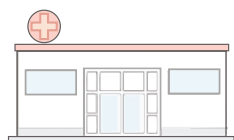
NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

⁸This treatment is most suitably indicated for a 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.⁸

JELMYTO Medication Information

- **Generic Name:** (Mitomycin) for pyelocalyceal solution
- **Brand Name:** JELMYTO®
- **Manufacturer:** UroGen Pharma, Inc.
- **Indication:** Indicated for the treatment of adult patients with LG-UTUC⁵
- **Contraindications:** JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract⁵
- **Approval Date:** April 15, 2020⁹

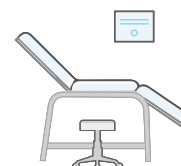
Where Is the Anticipated Site of Care?



**AMBULATORY
SURGICAL CENTER**



HOSPITAL



OFFICE

Projected Annual Use

- You will need to provide the projected annual number of patients who will receive JELMYTO based on your organization's data
- As general background:
 - Between 5% and 10% of primary urothelial cancers originate in the ureter or renal pelvis. They are referred to as upper tract urothelial cancers, or UTUCs¹⁰
 - UTUC is a rare disease affecting ~4500 US patients per year^{11,12}
 - UTUC prevalence is increasing¹
 - Urothelial cancer is the ninth most common cancer globally¹¹
 - Approximately 40% of UTUC disease burden is due to LG-UTUC¹¹⁻¹⁴

Diagnostic and Procedural Coding to Support Patient Identification

Diagnostic ¹⁵	
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C68.9	Malignant neoplasm of urinary organ, unspecified
Procedural ¹⁶	
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic
52354	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion
52355	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor

It is the responsibility of the provider to determine payer appropriate coding, medical necessity, site of service, documentation requirements and payment levels, and to submit appropriate codes, modifiers, and charges for services rendered. Future changes to applicable law and regulations may also have an impact on reimbursement. Although we have made every effort to provide information that is current at the time of its issue, it is recommended you consult your legal counsel, reimbursement/compliance advisor, and/or payer organization(s) for interpretation of payer specific coding, coverage, and payment expectations.

Financial Considerations⁶

Benefit category: Medical (commercial insurance), Medicare Part B

Payer Mix:

- Medicare Part B FFS – **51%**
- Managed Medicare – **24%**
- Commercial – **13%**
- Medicaid, Uninsured, Other – **12%**

Payer Coverage*:

- Medicare Part B FFS – **100%** Benefits Approved
- Managed Medicare – **100%** Benefits Approved
- Commercial – **100%** Benefits Approved

Reimbursement:

- Medicare Part B FFS – **ASP + 6%**
- Commercial plans will reimburse based on the agreement set forth between the plan and your practice

*Based on total JELMYTO patient enrollment from January 1, 2024, to November 1, 2024. Data on file.

Product Information⁵



- Dispensing pack: 1 kit containing:
 - Two 40-mg (each) single-dose vials of mitomycin for pyelocalyceal solution
 - One 20-mL single-dose vial of sterile hydrogel to be used for reconstitution
- NDC: 72493-103-03 or 72493-0103-03
- HCPCS Level II code†: J9281
- WAC‡: \$25,445 per kit
- 340B eligible

†Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment.

‡WAC is subject to change at the election of UroGen.

ASP=average sales price; FFS=Fee-for-Service; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; WAC=wholesale acquisition cost.

Medicare Hospital Outpatient Payments for Select LG-UTUC Procedures

Please contact your UroGen Field Team for more details.

Return Policy

- For UNMIXED product, reassign to a current patient or retain for future use. If dose is not reassigned or product is expired, you must destroy or return. For MIXED product, destroy and request a replacement dose or credit (subject to eligibility rules)
 - In most scenarios, your replacement dose can be delivered in **3-5 business days**. Allow at least 30 business days for credit review and processing
- To access the Return Request Form, request the form from your UroGen representative or download the form from UroGenSupport.com. Complete the form and send to returns@UroGenSupport.com with the following information:

1 PO number

(HUB ID or distributor PO number, patient initials, and date of birth)

2 Order date

3 Replacement dose or credit request

4 Reason patient did not receive treatment with JELMYTO

5 Confirmation product is destroyed and discarded (certificate of destruction where applicable)

- See the [UroGen Return Goods Policy](#)

NEED HELP? Contact us. 833-UROGEN1 (833-876-4361) Monday-Friday 8 AM-6 PM EST or visit UroGenSupport.com or email Contact@UroGenSupport.com

References: **1.** Raman J, Shore MD. Management of low-grade upper tract urothelial carcinoma: an unmet need. *Rev Urol.* 2020;22(1):1-8. **2.** Cutress ML, Stewart GD, Zakikhani P, Phipps S, Thomas BG, Tolley DA. Ureteroscopic and percutaneous management of upper tract urothelial carcinoma (UTUC): systematic review. *BJUI.* 2012;110(5):614-628. **3.** Kaag M, Trost L, Thompson RH, et al. Preoperative predictors of renal function decline after radical nephroureterectomy for upper tract urothelial carcinoma. *BJUI.* 2013;114(5):674-679. **4.** Xylinas E, Kluth L, Passoni N, et al. Prediction of intravesical recurrence after radical nephroureterectomy: development of a clinical decision-making tool. *Eur Urol.* 2014;65(3):650-658. **5.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; October 2024. **6.** Data on file, UroGen Pharma Inc., Princeton, NJ. **7.** 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. **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 21, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **9.** Drug approval letter: Jelmyto. US Food and Drug Administration. Accessed June 6, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/211728Orig1s000Approv.pdf **10.** Hutchinson R, Haddad A, Sagalowsky A, Margulis V. Upper tract urothelial carcinoma: special considerations. *Clin Adv Hematol Oncol.* 2016;14(2):101-109. **11.** Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. *CA Cancer J Clin.* 2024;74(1):12-49. **12.** 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. **13.** Gottlieb J, Linehan J, Murray KS. Advances in chemoablation in upper tract urothelial carcinoma: overview of indications and treatment patterns. *Transl Androl Urol.* 2023;12(9):1449-1455. **14.** Khargi R, Connors C, Ricapito A et al. Adjuvant intraluminal therapies for upper tract urothelial carcinoma. *Transl Androl Urol.* 2023;12(9):1439-1448. **15.** ICD-10-CM/PCS MS-DRG v37.0 definitions manual. Centers for Medicare & Medicaid Services. Accessed June 6, 2025. <https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode-cms/P0255.html> **16.** 2018 CPT code for ureteroscopy. PRS Network. Accessed June 6, 2025. <https://info.prsnetwork.com/cpt-code-ureteroscopy>

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).

IMPORTANT SAFETY INFORMATION

Contraindications

JELMYTO® (mitomycin) for pyelocalyceal solution is contraindicated in patients with perforation of the bladder or upper urinary tract.

Warnings and Precautions

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.

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.

Adverse Reactions

Common Adverse Reactions

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

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in $< 10\%$ and $\geq 2\%$ 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.

Please [click here](#) for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.



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