JELMYTO is available at the US Department of Veterans Affairs (VA) as formulary with prior authorization using Criteria for Use

For appropriate patients at the VA, submit a prior authorization request for JELMYTO

- Providers should consult the VA Criteria for Use at pbm.va.gov/apps/vanationalformulary/ to ensure patient is clinically eligible for JELMYTO
- Enter a prior authorization request

The first and only FDA-approved, nonsurgical treatment for adults with low-grade upper tract urothelial cancer (LG-UTUC)

UroGen's Olympus study evaluated JELMYTO in patients with LG-UTUC (N=71)[1]

Median (range) age 71 (42-87) years

Chemoablate with JELMYTO to deliver a complete response, while sparing the kidney for tomorrow*

58% N=71 (95% CI: 45, 69) — **Complete Response (CR)[1]**

82% (95% CI: 66, 91) — **Durability of Response†** Estimated probability by KM analysis that a patient will remain in CR for 12 months[2,3]

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-naive or recurrent low-grade non-invasive UTUC with ≥1 measurable papillary tumor between 5-15 mm (partial resection/debulking was permitted of >15 mm). Patients were treated with 6 instillations once a week. The dosage of JELMYTO was individualized based on volumetric measurements using pyelography with the intent to fill the renal pelvis (max dose was 15 mL or 60 mg mitomycin). CR was defined as complete absence of tumor lesions 3 months after initiation of treatment and evaluated via urine cytology, ureteroscopy, and biopsy (if warranted). The primary endpoint was CR. Secondary endpoint: durability of response at 12 months follow-up of CR evaluation.

At the 12-month assessment of durability (n=41)[1]:

- 23 (56%) patients remained in CR
- 8 (20%) patients had disease recurrence
- 10 (24%) patients were inevaluable

*JELMYTO is instilled via the pyelocaliceal system in a kidney-sparing procedure.

†KM analysis estimates probability of durable response. It does not represent an actual percentage of patients. In the Olympus trial, at the time of the 12-month assessment for durability, not all patients had a recurrence (patients may have still been in CR, died, or discontinued). The KM analysis accounts for these missing data. The analysis has potential limitations: the sample size was small (n=41) and median duration of response was not reached due to the limited number of recurrences (n=8); this may be reflective of a short follow-up time (12 months).[2]

CI, confidence interval; FDA, US Food and Drug Administration; KM, Kaplan-Meier.

Most commonly reported adverse reactions[1]

58%	ureteric obstruction	**41%**	flank pain	**34%**	urinary tract infection	**34%**	hematuria	**28%**	abdominal pain
27%	fatigue	**25%**	renal dysfunction	**25%**	nausea	**23%**	dysuria	**20%**	vomiting

Please see next page for Important Safety Information and click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

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

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.

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.

Please click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

References: 1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2024. **2.** Matin SF, Pierorazio PM, Kleinmann N, et al. Durability of response to primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel: Olympus trial final report. *J Urol.* 2022;207(4):779-788. **3.** Rouprêt M, Babjuk M, Burger M, et al. European Association of Urology guidelines on upper urinary tract urothelial carcinoma: 2017 update. *Eur Urol*. 2018;73(1):111-122.

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Jelmyto® (mitomycin) for pyelocalyceal solution