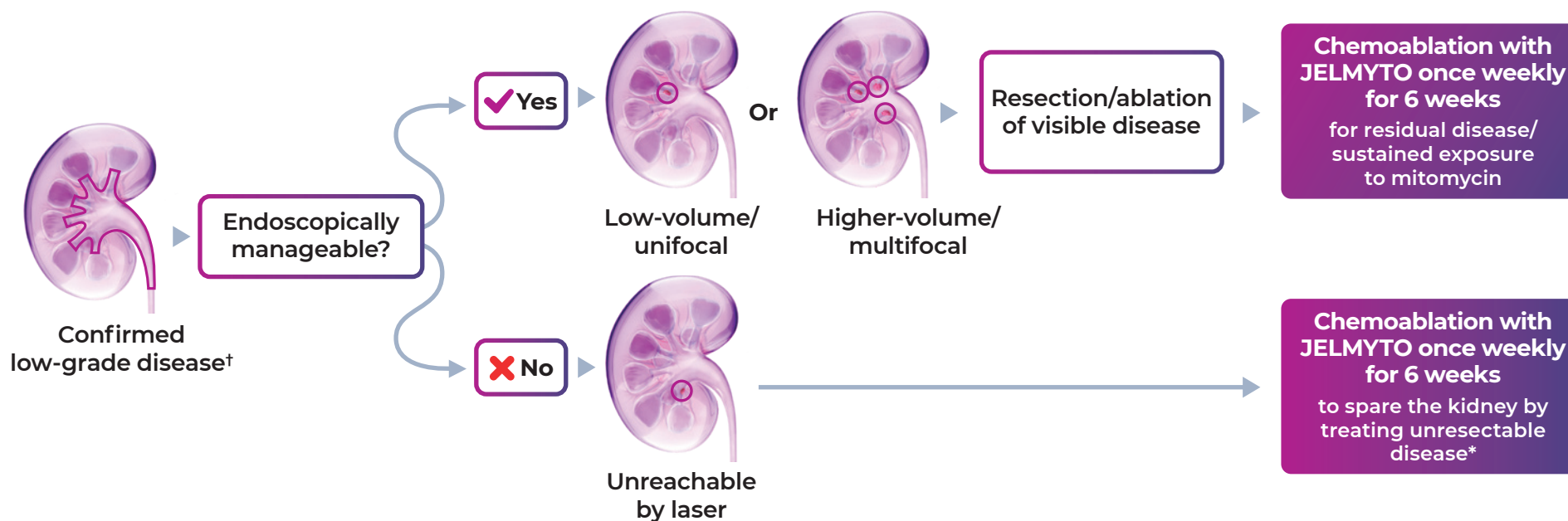


# Every patient with low-grade UTUC deserves a chance to spare their kidney<sup>1\*</sup>

JELMYTO is part of the primary treatment approach across diverse presentations<sup>1-3</sup>



JELMYTO should NOT be instilled immediately following resection or ablation.

\*JELMYTO is instilled via the pyelocalyceal system in a procedure that spares the kidney.

<sup>†</sup>Also includes patients with bilateral disease. In the OLYMPUS Study, these patients were included if one side met the inclusion criteria and the other was treated or surgically removed prior to the beginning of the study.<sup>2,4</sup>

## Indications and Usage

JELMYTO<sup>®</sup> (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.

Please see additional Important Safety Information on next page and visit [JELMYTO.com/hcp](http://JELMYTO.com/hcp) for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

## Important Safety Information (cont'd)

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

### 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 cytotoxic drug. Follow applicable special handling and disposal procedures.

**Please visit [JELMYTO.com/hcp](https://www.jelmyto.com/hcp) for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.**

**References:** **1.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2021. **2.** 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. **3.** Rouprêt M, Babjuk M, Burger M, et al. European Association of Urology guidelines on upper urinary tract urothelial carcinoma: 2020 update. *Eur Urol.* 2021;79(1):62-79. **4.** Data on file. UroGen Pharma, Inc., Princeton, NJ.

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US-JEL-00563 09/22

