

Steps for scheduling and ordering JELMYTO

1-855-JELMYTO (535-6986) • Contact@UroGenSupport.com



Getting started with JELMYTO

We know that **obtaining access to JELMYTO is a crucial step** in your patient's treatment. To make the scheduling and ordering process for JELMYTO **as simple as possible**, this brochure provides direction on the **important steps** you will need to complete.

STEPS TO ACQUIRE JELMYTO FOR YOUR PATIENTS



Remember, the UroGen Support team is here to help, so please reach out with questions at Contact@UroGenSupport.com; 1-855-JELMYTO (535-6986)



Pre-enrollment

In order to receive JELMYTO for your patients, **all customers are required** to complete a [Declaration Letter](#) to open a new JELMYTO account with Cardinal Health Specialty Pharmaceutical Distribution,* **regardless if you already have existing accounts with Cardinal Health for other products.** Once the Declaration Letter is completed, please send to Distribution@UroGenSupport.com.



Be sure to complete the *required* information on the JELMYTO Declaration Letter—it's important!

- ✓ Practice contact information and shipping details for the site of care
- ✓ Potential date of first treatment
- ✓ Estimated number of doses per month



Once the Declaration Letter is received, you may be contacted by Cardinal Health to confirm details and to provide additional documentation

For questions, contact Cardinal Health at 1-877-488-3572 or email Distribution@UroGenSupport.com.



NOTE: If you already have an account with Cardinal Health, **you will still need to open a NEW account for JELMYTO.** Orders for JELMYTO are serviced through UroGen Support and are separate from your other existing Cardinal Health accounts.*



[Access the JELMYTO Declaration Letter here](#)

*Due to the detailed and thorough JELMYTO registration process, **it may take approximately 5 business days** for Cardinal Health to set up most accounts.



Enrollment

- A **patient enrollment form (PEF)** must be completed and signed by the prescriber and patient
- Send the completed PEF to UroGen Support via fax (1-833-664-7216) or email (Contact@UroGenSupport.com) in order for UroGen Support to initiate the benefits investigation
- Urogen Support will notify you via fax or email when a PEF has been received

NOTE: To ensure there is no delay in the enrollment process, please check that **all required fields** on the PEF are completed and the form is **signed by the provider and patient.**



[Access the JELMYTO PEF here](#)

| 4 | Please see page [9](#) for Important Safety Information, and [click here](#) for Full Prescribing Information for JELMYTO.

UroGen Support™ Patient Enrollment Form for JELMYTO
For an overview of key steps, please visit www.JELMYTO.com/hcp/support

UroGen Support Program Offerings
Once completed, this enrollment form allows UroGen Support to provide access and reimbursement information and support to eligible JELMYTO patients. The program offerings include benefits investigation, informational support and assistance with prior authorization and coverage appeal process, billing and coding, patient affordability, and logistical assistance around product acquisition, preparation, and delivery.

Jelmyto
(mitomycin) for pyelocalyceal solution

UroGen Support™

If you have questions regarding patient enrollment or require assistance, please call 855-JELMYTO (855-535-6986).
Once completed, please fax this form to UroGen Support at 833-664-7216 or email it to Contact@UroGenSupport.com.

Patient Information (REQUIRED)

Check here if a copy of the patient's Face Sheet is included. | If the patient's Face Sheet is not included, please complete this section.

First Name: _____ Last Name: _____ DOB: _____ Gender: _____

US Resident: Yes No How many people, including the patient, live in the household? _____

Address: _____ City: _____ State: _____ ZIP: _____

Preferred Phone: _____ Home Mobile (Check here if it is appropriate to leave a detailed voice message) Last 4 Digits SSN: _____

Patient Preferred Language (other than English): _____ Alternate Contact Name: _____

Relationship to Patient: _____ Alternate Contact Phone: _____

EMR Chart ID: _____

Patient Insurance Information (REQUIRED)

Check here if front and back copies of the patient's medical insurance card are included. | If the patient's medical insurance card is not included, please complete this section.

Check here if the patient does not have insurance coverage.

Medical Insurance Provider: _____ Insurance Provider Phone: _____

Primary Insurance Holder (if not the patient): _____ Primary Insurance Holder DOB: _____

Primary Insurance Holder Last 4 Digits SSN: _____ Policy Number: _____ Member ID: _____

Group Number: _____

Secondary Medical Insurance Provider: _____ Insurance Provider Phone: _____

Primary Insurance Holder (if not the patient): _____ Primary Insurance Holder DOB: _____

Primary Insurance Holder Last 4 Digits SSN: _____ Policy Number: _____ Member ID: _____ Group Number: _____

Check here if you would like to enroll the patient in the UroGen Support Patient Assistance Program.

Check here if you would like to enroll the patient in the UroGen Support Commercial Copay Program.

Visit www.JELMYTO.com/hcp/support for program eligibility criteria.

Prescriber Information (REQUIRED)

Practice Name: _____ Prescriber Name: _____

Address 1: _____ Address 2: _____ City: _____ State: _____ ZIP: _____

Office Contact Name: _____ Phone Number: _____ Fax Number: _____

Email: _____ (Please indicate preferred method of communication) Phone Fax Email

PTAN: _____ NPI Number: _____ DEA Number: _____ State License Number: _____

Expiration Date: _____ Tax ID Number: _____ Medicaid Number: _____

Diagnosis Information (REQUIRED)

C65.9 Malignant neoplasm of unspecified renal pelvis C65.2 Malignant neoplasm of left renal pelvis

C65.1 Malignant neoplasm of right renal pelvis Other ICD-10 code(s): _____

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Jelmyto
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UroGen Support™



Benefits investigation

- Based on patient enrollment information, UroGen Support will conduct a benefits investigation (BI)
- After the BI is complete, Urogen Support will fax or email you the BI summary, which will include details regarding the patient's coverage determination for JELMYTO
 - Results may include notifying your office of prior authorization (PA) requirements or available support options for the patient
 - If necessary, the provider may need to complete a PA and/or write a letter of medical necessity
 - Access the [JELMYTO Prior Authorization and Appeals Checklists here](#)



UroGen Support can confirm patient details and copay options, as well as provide information and assistance in the event of a PA or in appealing denials.



Communicate information regarding PAs and appeals in a timely manner to UroGen Support at Contact@UroGenSupport.com; 1-855-JELMYTO (535-6986)

JELMYTO Prior Authorization and Appeals Checklists



Patient Name: _____ Patient DOB: _____

Utilize these checklists to streamline the prior authorization (PA) process and/or the filing of an appeal.*

PA Checklist

The items below are commonly requested to receive a PA decision from a health plan. Ensure all the information is available before the PA is submitted.

- Completed PA request form.**[†] Include the following:
 - Patient name, insurance policy number, and date of birth
 - Physician name and tax ID number
 - PTAN
 - Facility name and tax ID number
 - Date of service
 - Patient diagnosis (ICD-10 code[s])
 - Relevant procedure and HCPCS codes for services/products to be performed/provided
 - Product NDC
 - Site of care
- Letter of medical necessity and relevant clinical support**
 - Include the Provider ID number in the letter
 - **Documentation to support treatment decision,** such as:
 - Previous treatments/therapies
 - Patient-specific clinical notes detailing the relevant diagnosis
 - Relevant laboratory results
 - Product Prescribing Information

PA requirements vary by health plan and may require pre-approval. Contact the patient's health plan for specific requirements, if any, to ensure efficient and timely review. Failure to obtain a PA can result in non-payment by the plan. Prior to submission, please keep track of dates and methods of communication (phone, email, and written); record names of health plan contacts and reviewers with whom you speak; and summarize conversations and written documents from the health plan.

Denial/Appeals Checklist

If the health plan denies a PA for JELMYTO:

- Review the denial notification** to understand the reason and circumstances that need to be outlined in the appeal/letter of medical necessity.
- Review the plan's most recent explanation of benefits** or contact a representative at the health plan.
- Verify where the appeal/letter of medical necessity should be sent** and any deadlines.
- Write an appeal/letter of medical necessity.** If you need assistance, please contact UroGen Support™ for a sample.

If you or your patient have not received a decision within 30 days:

- Contact the health plan.** Confirm that the appeal/letter of medical necessity was received and check its status. If the coverage denial was upheld, you may resubmit the appeal/letter of medical necessity with new information or ask for assistance from a supervisor or manager.

If the denial is upheld again:

- Ask for a one-time exception** or consider filing a complaint with your State's Insurance Commissioner.
- If the health plan continues to deny the claim:** Your patient may request an external appeal, in which an independent third-party will review the claim and make a final, binding decision.[‡]
- Please contact your Field Reimbursement Manager or UroGen Support for assistance.

*Providers and patients are encouraged to contact the patient's health plan for detailed instructions on completing a PA or appealing/overturning a denial.

†PA requirements vary by health plan. Review your patients' health plan to ensure the correct documentation is submitted.

‡The external appeal process varies by state law.

UroGen Support is here for you and your patients

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Acquisition

Once confirmed that your account is established with Cardinal Health and benefits coverage has been determined for your patient, you may proceed with ordering JELMYTO. **Remember, JELMYTO can only be ordered through UroGen Support.***

UroGen Support will contact you to obtain the following information:

- ✓ Patient's name and date of birth or UroGen Support ID number
- ✓ Appointment date and time
- ✓ Shipping address
- ✓ WAC vs 340B, if applicable
- ✓ Customer PO number, if applicable
- ✓ Permission to order the first dose



You may also proactively call UroGen Support at 1-855-JELMYTO (535-6986) to place the patient's first order of JELMYTO.

*Please **allow at least one week** prior to the patient's scheduled appointment to order JELMYTO to avoid potential shipment delays.



Administration

JELMYTO doses are ordered weekly, prior to each instillation appointment

Order JELMYTO through UroGen Support at least one week prior to the patient's appointment. A confirmation email with tracking information will be provided the day after the order is placed.

UroGen Support may contact you the day before the patient's appointment via phone or email to confirm that the appointment is still on the schedule.

Schedule each instillation appointment the same day each dose of JELMYTO is administered to the patient at the designated appointment time.

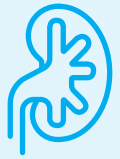


UroGen Support will contact you approximately 2 hours or more after each instillation to obtain the following information:

- ✓ JELMYTO instillation was completed (yes/no)—if no, please provide reason
- ✓ Next scheduled appointment date and time
- ✓ Customer PO number, if applicable
- ✓ Permission to order next JELMYTO doses (yes/no)
- ✓ Additional JELMYTO doses requested and corresponding treatment dates



See next page for important administration reminders and recommendations



Administration



Reminders:

- Contact UroGen Support as soon as you are aware of any **appointment date changes**
- A **Urogen Support ID number** that is unique to each patient will be provided to you, so please keep the number readily available
- Orders placed before 2 PM EST are scheduled to ship for **next-day delivery**
- It is recommended orders are placed **one week prior** to instillation (to ensure the product arrives on time)
- Your delivery may arrive **prior to receiving the tracking information**
- **Two hours or more after the patient's appointment**, UroGen Support will contact you to inquire about the success of the JELMYTO instillation and obtain permission to order the next dose
 - As always, UroGen Support is here for you, so feel free to proactively reach out to us at **1-855-JELMYTO (535-6986)** if you have questions



It is recommended that customers **order at least one dose in advance** to mitigate any risk associated with potential shipping delays



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 $\geq 20\%$ 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 [click here](#) for Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration.



Acquiring JELMYTO for your patients—a streamlined process



DID YOU KNOW?

JELMYTO is the **first and only FDA-approved treatment for low-grade upper tract urothelial cancer (LG-UTUC)** in adult patients¹

[Click here](#) for more information!

Reference: 1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2021.

Please see page [9](#) for Important Safety Information, and [click here](#) for Full Prescribing Information for JELMYTO.



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