Billing and Coding Guide

Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
Introduction
This guide serves as a comprehensive resource to help ensure proper billing, coding, and reimbursement for JELMYTO® (mitomycin) for pyelocalyceal solution.*

Efficient preparation of forms for acquiring JELMYTO and submitting reimbursement claims depends in part on the site of care where JELMYTO is administered to the patient. This guide is divided into the following sections, based on site of care:

- **Physician office**
- **Ambulatory Surgical Center (ASC)**
- **Hospital Outpatient Department (HOPD)**

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Your UroGen Field Reimbursement Manager (FRM) is available to answer your JELMYTO billing and coding questions.

855-JELMYTO (855-535-6986) | 833-664-7216 | www.JELMYTO.com/hcp/support | Contact@UroGenSupport.com

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Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
Basic coverage information
Billing and coding requirements for JELMYTO will vary based on many factors, including the administration site of the drug, the patient’s type of insurance, and the benefit type under which JELMYTO is covered.

Site of care
JELMYTO may be administered at a number of sites. This guide concentrates on coverage, coding, and billing for JELMYTO when administered at a physician office, ASC, or HOPD.

Benefit category
Most payers cover physician-administered products such as JELMYTO under the medical benefit rather than the pharmacy benefit. In the case of Medicare, JELMYTO will typically be covered under Part B.

Payer type
Coverage, as defined by each payer type and benefit type, may vary depending on the site of care and the patient’s status and medical history.

Medicare
Medicare may be the most common payer for patients who receive JELMYTO. For non-self-administered drugs, Medicare typically covers and separately reimburses for the drug and required services. This includes instillation of JELMYTO in urology practices, ASCs, and HOPDs.

Private payers
Private (or commercial) payers may cover JELMYTO and the medical services associated with its administration. However, there may be restrictions on coverage, such as special requirements for distribution and precertification. Private payers may also vary in the use of payment methods to reimburse the sites of service where JELMYTO is administered.

Medicaid
Medicaid coverage and payment for JELMYTO can vary by state or by the specific managed Medicaid plan. Providers should check with the state program or plan for specific coverage information and all payer types for fee schedules.

Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
JELMYTO key information¹

FDA approval date
April 15, 2020

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).

Class
Alkylating drug, novel formulation

How supplied
JELMYTO is supplied in a single-dose carton containing two vials of sterile lyophilized mitomycin for pyelocalyceal solution, 40 mg each, and one vial of 20 mL of sterile hydrogel, to be used as a vehicle for reconstitution.

Dosage and administration
JELMYTO is for pyelocalyceal use only. General anesthesia, local anesthesia, sedation, prophylactic antibiotics and/or antihistamines may be used at the discretion of the treating urologist. The dose to be instilled is 4 mg per mL via ureteral catheter or a nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin). See Instructions for Administration for further details.

Clinical trials
JELMYTO was studied in OLYMPUS, an open-label, single-arm trial in 71 patients with treatment-naïve or recurrent noninvasive LG-UTUC.

Efficacy
Major efficacy endpoints were complete response (CR) and durability of response. JELMYTO achieved:
• 58% CR (95% CI: 45, 69)
• 82% durability of response (95% CI: 66, 91) estimated probability by Kaplan-Meier analysis that a patient will remain in CR for 12 months²³
Median duration of response was not reached, with a range of 0-18.8+ months.
At the 12-month assessment of durability (n=41):
• 23 patients remained in CR
• 8 patients had disease recurrence
• 10 patients were inevaluable

Kaplan-Meier 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).

Safety
Serious adverse reactions occurred in 39% of patients who received JELMYTO. Serious adverse reactions in >3% of patients included ureteric obstruction (including ureteric stenosis and hydronephrosis), flank pain, and urosepsis. Two deaths occurred due to cerebrovascular accident and failure to thrive.

Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
Physician office: Relevant codes

Note: The site of care determines specific coding requirements. It is always the provider’s responsibility to determine the medical necessity for a specific service, the proper site for delivery of any services, and to submit the appropriate codes, charges, and modifiers for services rendered.

This section provides information for physician office administrators on billing, coding, and reimbursement for JELMYTO.

Healthcare Common Procedure Coding System (HCPCS)

The Centers for Medicare and Medicaid Services (CMS) produce and update the HCPCS. The HCPCS is a collection of standardized codes representing medical procedures, supplies, products, and services. CMS, its contractors, and other payers use these codes to process health insurance claims.

The following permanent J code for JELMYTO was approved for all sites of care on January 1, 2021:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9281</td>
<td>JELMYTO (mitomycin) for pyelocalyceal instillation, 1 mg</td>
</tr>
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</table>

JW modifier

The exact amount of JELMYTO instilled from each single-use vial depends on the kidney volume of each patient. The JW modifier tracks the remaining amount of JELMYTO that is not instilled. For every mL instilled, 4 mg/mL of JELMYTO should be billed. The total amount of billable units allowed for JELMYTO is 80 mg. The equation below shows an example of how wastage is calculated if a patient receives 15 mL of JELMYTO.

\[
15 \text{ mL} \times 4 \text{ mg/mL} = 60 \text{ mg}
\]

\[
80 \text{ mg} - 60 \text{ mg} = 20 \text{ mg}
\]


CPT® codes are used to universally identify medical, surgical, diagnostic, and therapeutic services. JELMYTO can be instilled via nephrostomy tube or ureteral catheter. Select the correct code for the method the urologist uses for each instillation of the drug.

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<tr>
<th>Code</th>
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<tbody>
<tr>
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Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
**National Drug Code (NDC)**

Universal 10- or 11-digit product identifier for human drugs; each NDC identifies the labeler, product, and trade package size.

Many NDCs listed on drug packaging are in a 10-digit format. However, to be recognized by payers, it must be formatted into an 11-digit 5-4-2 sequence. This requires a zero to be placed in a specific position to meet the 5-4-2 format requirement. Both NDC formats for JELMYTO are shown here:

<table>
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<tr>
<th>10-digit NDC</th>
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<td>72493-0103-03</td>
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*Note:* Many practice management systems automatically remove hyphens, so be sure they are excluded from your claim submission. Check with the patient’s insurance plan to determine sequence requirements.

**International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)**

Diagnosis codes used for identifying and capturing a specific diagnosis.

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Please see Important Safety Information on page 18, and click [here](#) for Full Prescribing Information for JELMYTO.
Physician office: Sample claim form

The CMS-1500 form is used to bill for JELMYTO in a urology practice setting. Refer to the notes below when populating the essential fields that health plans require for reimbursement. You are required to code to the highest level of specificity. Contact the third-party payer if you have questions on their specific procedures.

Box 17: Name of referring provider or other source
Enter the appropriate provider to the left side of the dotted line:
DK – Ordering provider     DQ – Supervising provider     DN – Referring provider

Box 17b: National Provider Identifier (NPI)
Enter the referring provider’s NPI.

Box 19: Comment field
This area may be used to list the drug name, NDC, the route of administration, and the amount administered.

Box 21: Diagnosis code(s)
Enter the appropriate ICD-10-CM diagnosis code(s) that reflect(s) the patient’s condition. Do not insert a period in the ICD-10-CM code.

Box 21: ICD indicator
Enter the ICD indicator as a single digit between the vertical, dotted lines: 0 – ICD-10-CM diagnosis.

Box 24A: Dates of service
In the non-shaded area, list the date of service. In the shaded area, give a detailed drug description. List the N4 indicator first, then the 11-digit NDC number. Third is the unit of measurement qualifier; the unit quantity is listed at the end. (Note: Some payers may ask for the NDC number in Box 19.)

Box 24B: Place of service
Enter the appropriate site of service code: 11 – Physician office

Box 24D: HCPCS and CPT® codes
Product
Bill for JELMYTO with HCPCS code J9281.

Administration procedure
Enter the CPT® code that accurately describes the administration service performed. Use CPT® code 52005 for cystoscopy and ureter catheter. Use CPT® code 50391 via nephrostomy tube and catheter.

Box 24G: Days or service units
Product
When billing with HCPCS code J9281, bill for units instilled. For the remaining mg not instilled, bill wastage with HCPCS code J9281 with the JW modifier.

Example: The total billable units for JELMYTO is 80 mg. For every mL of JELMYTO instilled, 4 mg/mL should be billed. If a patient received 15 mL, then the units billed equal 60 mg and the wastage billed equals 20 mg.

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Sample CMS-1500 claim form
The image shown is not a complete depiction of the CMS-1500 form; portions of the full form are not shown.
ASC: Relevant codes

**Note:** The site of care determines specific coding requirements. It is always the provider’s responsibility to determine the medical necessity for a specific service, the proper site for delivery of any services, and to submit the appropriate codes, charges, and modifiers for services rendered.

This section provides information for ASC administrators on billing, coding, and reimbursement for JELMYTO.

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Pass-through status continues for up to 3 years

JELMYTO continues to have pass-through status in the HOPD and ASC settings for Medicare fee-for-service beneficiaries. The status indicator of G in the HOPD and K2 in the ASC will denote pass-through for the J code.

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Healthcare Common Procedure Coding System (HCPCS)

The Centers for Medicare and Medicaid Services (CMS) produce and update the HCPCS. The HCPCS is a collection of standardized codes representing medical procedures, supplies, products, and services. CMS, its contractors, and other payers use these codes to process health insurance claims.

The following permanent J code for JELMYTO was approved for all sites of care on January 1, 2021:

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**JW modifier**

The exact amount of JELMYTO instilled from each single-use vial depends on the kidney volume of each patient. The JW modifier tracks the remaining amount of JELMYTO that is not instilled. For every mL instilled, 4 mg/mL of JELMYTO should be billed. The total amount of billable units allowed for JELMYTO is 80 mg. The equation below shows an example of how wastage is calculated if a patient receives 15 mL of JELMYTO.

\[
15 \text{ mL} \times 4 \text{ mg/mL} = 60 \text{ mg}
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\]

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Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
Current Procedural Terminology (CPT®)\textsuperscript{5}

CPT\textsuperscript{*} codes are universally used to identify medical, surgical, diagnostic, and therapeutic services. JELMYTO can be instilled via a nephrostomy tube or ureteral catheter. Select the correct code for the method the ASC uses for each instillation of the drug.

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National Drug Code (NDC)\textsuperscript{1}

Universal 10- or 11-digit product identifier for human drugs; each NDC identifies the labeler, product, and trade package size.

Many NDCs listed on drug packaging are in a 10-digit format. However, to be recognized by payers, it must be formatted into an 11-digit 5-4-2 sequence. This requires a zero to be placed in a specific position to meet the 5-4-2 format requirement. Both NDC formats for JELMYTO are shown here:

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Note: Many practice management systems automatically remove hyphens, so be sure they are excluded from your claim submission. Check with the patient’s insurance plan to determine sequence requirements.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)\textsuperscript{6}

Diagnosis codes used for identifying and capturing a specific diagnosis.

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ASC: sample claim form

The CMS-1500 form is used to bill Medicare for JELMYTO in the ASC setting. Some commercial payers may also use the CMS-1500 form while other commercial payers may require the UB-04. Providers are responsible for the selection of the correct claim form per payer requirements.

Refer to the notes below when populating the essential fields that health plans require for reimbursement. You are required to code to the highest level of specificity. Contact the third-party payer if you have questions on their specific procedures.

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Enter the appropriate provider to the left side of the dotted line:
- **DK** – Ordering provider
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- **DN** – Referring provider

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Enter the referring provider’s NPI.

Box 19: Comment field
This area may be used to list the drug name, NDC, the route of administration, and the amount administered.

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Enter the ICD indicator as a single digit between the vertical, dotted lines:
- **0** – ICD-10-CM diagnosis.

Box 24A: Dates of service
In the non-shaded area, list the date of service. In the shaded area, give a detailed drug description. List the N4 indicator first, then the 11-digit NDC number. Third is the unit of measurement qualifier; the unit quantity is listed at the end. (Note: Some payers may ask for the NDC number in Box 19.)

Box 24B: Place of service
Enter the appropriate site of service code: 24 – Ambulatory surgical center.

Box 24D: HCPCS and CPT® codes
Product
Bill for JELMYTO with HCPCS J9281.

Administration procedure
Enter the CPT® code that accurately describes the administration service performed. Use CPT® code 52005 for cystoscopy and ureter catheter. Use CPT® code 50391 via nephrostomy tube and catheter.

Box 24G: Days or service units
Product
When billing with HCPCS code J9281, bill for units instilled. For the remaining mg not instilled, bill wastage with HCPCS code J9281 with the JW modifier. Example: The total billable units for JELMYTO is 80 mg. For every mL of JELMYTO instilled, 4 mg/mL should be billed. If a patient received 15 mL, then the units billed equal 60 mg and the wastage billed equals 20 mg.

Contact information
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HOPD: Relevant codes

**Note:** The site of care determines specific coding requirements. It is always the provider’s responsibility to determine the medical necessity for a specific service, the proper site for delivery of any services, and to submit the appropriate codes, charges, and modifiers for services rendered.

This section provides information for HOPD administrators on billing, coding, and reimbursement for JELMYTO.

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**Code** | **Description**
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J9281 | JELMYTO (mitomycin) for pyelocalyceal instillation, 1 mg

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\[
80 \text{ mg} - 60 \text{ mg} = 20 \text{ mg}
\]

Total billable units | Units billed | Wastage billed
--- | --- | ---
80 mg | 60 mg | 20 mg

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Current Procedural Terminology (CPT®)⁵

CPT® codes are universally used to identify medical, surgical, diagnostic, and therapeutic services. JELMYTO can be instilled via a nephrostomy tube or ureteral catheter. Select the correct code for the method the HOPD provider uses for each instillation of the drug.

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National Drug Code (NDC)¹

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International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)⁶

Diagnosis codes used for identifying and capturing a specific diagnosis.

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HOPD: Sample claim form

The CMS 1450 (UB-04) form is used for billing for prescribed medications like JELMYTO administered in HOPD settings. Refer to the notes below when populating the essential fields that health plans require for reimbursement. You are required to code to the highest level of specificity. Contact the third-party payer if you have questions on their specific procedures.

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Form Locator (FL) 42
Enter the 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.

FL 43
Enter a detailed description of the drug for the payer. List the N4 indicator first and the 11-digit NDC number second. Third, add the unit of measurement qualifier, then the unit quantity at the end.

FL 44-46a
Enter the HCPCS code (J9281). To report the administration procedure, enter the appropriate CPT® code. Enter service units. When billing with HCPCS code J9281, bill 4 mg/mL for each mL instilled. For the remaining mg not instilled, bill wastage with HCPCS code J9281 with the JW modifier. The total amount of billable units allowed for JELMYTO is 80 mg. The equation below shows an example of how wastage is calculated if a patient receives 15 mL of JELMYTO. For questions about commercial insurance, please contact UroGen Support™:

\[
15 \text{ mL} \times 4 \text{ mg/mL} = 60 \text{ mg}
\]

15 mL \times 4 mg/mL = 60 mg
Milliliters instilled Units billed

80 mg - 60 mg = 20 mg
Total billable units Units billed Wastage billed

FL 66
Enter the appropriate ICD-10-CM diagnosis codes for LG-UTUC being treated.

FL 80
Enter the drug name, the quantity of drug administered, route of administration, and NDC in the remarks section as needed. This can be required by payers when billing an HCPCS code. Note the JELMYTO for pyelocalyceal solution instillation route (eg, ureteral catheter or nephrostomy tube). Some payers may require a separate attachment for the basis of measurement.

Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
Checklists and sample letters

This section contains checklists to help you with claims submission, prior authorizations, and appeals. It also includes a sample letter of medical necessity and a sample letter of appeal. You can also access these through UroGen Support™ at https://www.jelmyto.com/hcp/support/

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JELMYTO Claim Submission Checklist

Utilize this checklist to streamline the claim submission process and to ensure complete, timely, and accurate filing for prompt payment. For more comprehensive information on billing and coding for JELMYTO®, please see the JELMYTO Billing and Coding Guide at www.JELMYTO.com/hcp/support.

- Ensure all patient information (name, address, DOB, insurance ID) is accurate
- Verify the name of the healthcare provider and National Provider Identifier (NPI)
- JELMYTO information (as required by the payer)
  - CPT code(s), unit(s), drug name, drug description, dose, route of administration, NDC (72493-0103-03)
  - Additional information in box 19 of CMS-1500 form or field 80 of the CMS-1450 (UB-04) form
- Diagnosis code(s) (as required by the payer)
  - Primary diagnosis code required for Medicare (as applicable for other payers)
  - Ensure punctuation of codes is correct
- Use the correct HCPCS codes and modifier where and when appropriate
- Include additional documentation supporting medical necessity with the claim form (if requested by the payer)
  - Most Medicare carriers do not require additional documentation upon initial claim submission. However, upon processing, additional documents may be requested
- Specify the setting or place of service (POS) codes where the service was provided (services billed with incorrect POS could result in a claim denial/rejection), that is:
  - Office = 11
  - Off-campus outpatient hospital = 19
  - On-campus outpatient hospital = 22
  - Ambulatory surgery center = 24
- Prior authorization (as required by the payer)
  - Failure to obtain a prior authorization before initiating treatment or failure to include the prior authorization approval number on the form may result in a denied claim
- Claim submitted within the required time frame (as required by the payer)
- Track claim submission and provider reimbursement

Additional documentation for claim filing

The following documentation may be requested by payers when processing a claim for JELMYTO:

- Patient medical history
- Physician clinical notes on the patient’s condition and prior treatment for the condition
- Letter of medical necessity
- Prescribing Information
- FDA approval letter
- Drug purchase invoice

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Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.
Basic coverage information

Physician office JELMYTO key information

ASC HOPD Important safety information

Checklists and sample letters

Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.

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.

Download this resource

*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.
Note to physician: This template may be used to create your own institution’s independent letter of medical necessity to be sent to a patient’s health plan to obtain a prior authorization decision from a health plan and/or in the event that there is a denial of coverage for JELMYTO® (mitomycin) for pyelocalyceal solution.

RE: JELMYTO

Patient Name: [Patient Name]
Patient DOB: [mm/dd/yyyy]
Patient Insurance ID: [Patient ID]
Provider ID: [Provider ID]

Dear [Utilization Review Staff],

I am the prescribing physician for patient [Patient Name]. This patient has been diagnosed with low-grade upper tract urothelial cancer (UTUC) and requires JELMYTO as the most suitable therapy, based on the patient’s unique clinical needs. Important clinical factors such as my patient’s [tailor to inclusion criteria addressed in specific patient profile, including but not limited to: renal function, tumor location, tumor grade, tumor size, absence of high-grade disease, staging, molecular marker status, and/or the presence of co-morbidities like chronic kidney disease, hypertension, type 2 diabetes or dyslipidemia] have led me to consider a less invasive, kidney-sparing management strategy. For the reasons stated, as well as those listed below, neither radical surgery nor endoscopic management alone is a suitable treatment for this patient in my medical judgment.

[Provide specific information regarding the workup leading to a confirmed diagnosis of low-grade UTUC.]

[If applicable, provide specific information regarding the treatments this patient has already received.]

[Provide specific information regarding the patient’s current state of health, and why JELMYTO is the most appropriate treatment option.]

In my medical judgment, this patient is an appropriate candidate for treatment with JELMYTO.

I appreciate your consideration to approve my request for [Patient Name].

Please contact me at [XXX-XXX-XXXX] or [Physician Email] if I can provide any further information.

Sincerely,

[Physician Name]
[Physician Signature]

Sample Letter of Appeal

Note to physician: This template may be used to create your own institution's independent letter of appeal to be sent to a patient's health plan in the event that there is a denial of coverage for JELMYTO® (mitomycin) for pyelocalyceal solution.

RE: Letter of Appeal for JELMYTO® (mitomycin) for pyelocalyceal solution

Patient Name: [Patient Name]
Patient DOB: [mm/dd/yyyy]
Date of Service: [mm/dd/yyyy]
Denied Item: [enter item (Example: J3490)]
Reason for Denial: [enter denial reason. (Example: medical necessity)]
Patient Insurance ID: [Patient ID]
Provider ID: [Provider ID]

Dear [Medical / Appeals Reviewer or Medical Director],

Please accept this letter as a formal request to appeal the denied claim for JELMYTO® (mitomycin) for pyelocalyceal solution for my patient [insert patient name] for dates of service [insert dates of service]. It is my understanding that coverage has been denied because [insert specific denial reason]. Please see the enclosed documentation that discusses [insert patient name] medical history and supporting information in more detail.

[Provide specific information regarding medical history, prognosis, and medical rationale for selecting JELMYTO.]

[If applicable, provide specific information regarding the treatments this patient has already received.]

[Provide specific information regarding the patient’s current state of health and why JELMYTO is the most appropriate treatment option.]

I appreciate your prompt review and consideration to reverse your previous decision concerning coverage of JELMYTO for [insert patient name].

Please contact me at [XXX-XXX-XXXX] or [Physician Email] if I can provide any further information.

Sincerely,

[Physician Name]
[Physician Signature]
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, 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 ≥ 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.
For all your billing, coding, and reimbursement questions
Contact your UroGen FRM, who can answer your questions about implementing the new code. You may also contact UroGen Support™ for assistance.

855-JELMYTO (855-535-6986)  833-664-7216  www.JELMYTO.com/hcp/support  Contact@UroGenSupport.com

Please see Important Safety Information on page 18, and click here for Full Prescribing Information for JELMYTO.