Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

BILLING AND CODING GUIDE

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)

Table of contents

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

*Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment. The provider is solely responsible for determining appropriate treatment for the patient based on the unique medical needs of each patient and the independent judgment of the provider. It is also 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.

Please see Important Safety Information on page 14, and click here for Full Prescribing Information for JELMYTO.

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

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, ambulatory surgical center (ASC), or hospital outpatient department (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 is typically an instill and bill oncolytic agent covered under Medicare 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.

Commercial 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.

UroGen is committed to optimizing JELMYTO access across payer channels

JELMYTO coverage stands at 100%* for all major insurance types (Medicare Part B, Medicare Advantage, Commercial)[1]

100%

MEDICARE FEE-FOR-SERVICE

MEDICARE ADVANTAGE

COMMERCIAL

*Based on total JELMYTO patient enrollment from January 1, 2023 to November 26, 2023.[1]

Please see Important Safety Information on page 14, and click here for Full Prescribing Information for JELMYTO.

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

JELMYTO PRODUCT INFORMATION

JELMYTO® (mitomycin) for pyelocalyceal solution is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

JELMYTO is supplied in a single-dose kit containing 2 vials of sterile lyophilized mitomycin for pyelocalyceal solution, 40 mg each, and 1 vial of 20 mL of sterile hydrogel, to be used as a vehicle for reconstitution.[2]

Mitomycin for pyelocalyceal solution is a sterile, lyophilized, grey to greyish-purple cake or powder that contains mitomycin 40 mg and mannitol 80 mg in each vial.[2]

Sterile hydrogel is a sterile, clear, colorless gel with or without bubbles at room temperature or clear, colorless liquid at 2°C to 8°C (36°F to 46°F), which contains 0.04 g hydroxypropyl methylcellulose, 5.67 g poloxamer, 0.21 g polyethylene glycol, and water for injection in each vial.[2]

Once reconstituted, JELMYTO is a clear, purple, viscous liquid at 2°C to 8°C (36°F to 46°F) or semisolid gel at room temperature with a concentration of 4 mg/mL of mitomycin, which may contain a few visible particles and have a pH between 6.0 and 8.0.[2]

Dispensing pack	1 kit
NDC[2]	72493-103-03 or 72493-0103-03
Description[2]	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
HCPCS Level II code[3]*	J9281

*Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment.
HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

DIAGNOSTIC CODING TO SUPPORT PATIENT IDENTIFICATION

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)[4]

Code	Description
C65.9	Malignant neoplasm of unspecified renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C66.9	Malignant neoplasm of unspecified ureter
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C68.9	Malignant neoplasm of urinary organ, unspecified

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.

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

HARNESS THE TUMOR-FIGHTING POWER OF JELMYTO: NONSURGICAL TREATMENT FOR ADULTS WITH LOW-GRADE UPPER TRACT UROTHELIAL CANCER

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

The OLYMPUS study evaluated JELMYTO in patients with low-grade upper-tract urothelial cancer (N=71)[5]

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

58% **of patients treated with JELMYTO achieved a complete response (CR)** (n=41/71 [95% CI,45,69])[2§]

17% No response | **11%** Partial Response[¶] | **9%** Other[#] | **4%** Indeterminant

Patients with recurrent low-grade upper tract urothelial cancer and newly diagnosed patient achieved comparable CR at 3 months

59% **of patients with unresectable tumors achieved CR with JELMYTO** (n=20/34)[5]

In the OLYMPUS Study, the most common adverse reactions (>20%) reported were ureteric obstruction, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal dysfunction, vomiting, fatigue, and abdominal pain[2]

DOR 12 MONTHS

56% **of patients remained in CR with JELMYTO at 12 months** (n=23/41)[2]

8 patients had recurrence | **10** patients were inevaluable

Median Duration of Response (mDOR) was not reached (range 0-18.8+ months)

Study design: A phase 3, open-label, single arm, multicenter trial in patients with treatment-naive or recurrent low-grade upper tract urothelial cancer with ≥ 1 measurable papillary tumors (N=71).[2]

*Forty-two patients achieved CR at primary disease evaluation; however, 1 patient withdrew consent.[5]
[†]Defined as any decrease in tumor size or number of tumors that was not a complete response.[2]
[‡]Emergence of high-grade disease (not detected at baseline).[5]
[§]This treatment is most suitable for a residual, low-trade, 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.
CI=confidence interval; CR=complete response.

IMPORTANT SAFETY INFORMATION (cont'd)

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 Important Safety Information on page 14, and click here for Full Prescribing Information for JELMYTO.

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

Longitudinal follow-up analysis of OLYMPUS complete responders[1]

- Of the 41 patients in OLYMPUS who achieved initial CR, mDOR was 47.8 months (95% CI: 13.0, NE)
- Probability as estimated by KM analysis of these 41 patients remaining in response at 12 months was 74.3%
- In the 20 patients who consented to the long-term follow-up study and maintained CR, the mDOR was NE (95% CI: 43.5, NE)
- Median follow-up was 53.3 months

Study overview: 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 instillation 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.

The primary analysis evaluated DOR in the 41 patients who achieved CR. The statistical methods were repeated in the subset of 20 patients who were analyzed for efficacy in the follow-up.

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

[5]This treatment is most suitable for a residual, low-trade, 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.
KM=Kaplan-Meier; NE=not estimable.

Most commonly reported adverse reactions (all grades)[2]

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

IMPORTANT SAFETY INFORMATION (cont'd)

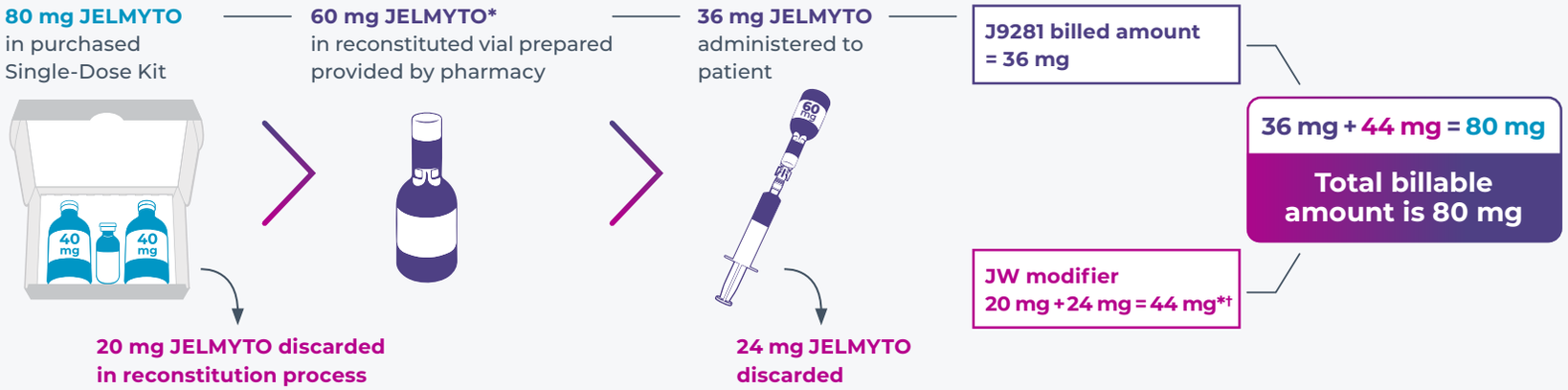
Bone Marrow Suppression

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.

SIMPLIFIED BILLING AND CODING ACROSS SITE OF CARE SETTINGS

JELMYTO is an instill and bill oncolytic agent reimbursed through Medicare Part B as a medical benefit

- HCPCS code J9281 covers JELMYTO units instilled for multiple care settings[3]
- JW modifier [J9281-JW] covers remaining mg not instilled (wastage), so you are reimbursed for the full amount of JELMYTO purchased[6]



This is for illustrative purposes only. The dose is individualized based on volumetric measurements.

*Maximum dose is 60 mg.
†Additional ancillary codes may apply. Please review your manuals for current details.
Please see the latest Quarterly Coding and Payment Guide and Reimbursement Guide for more details.

PHYSICIAN OFFICE: RELEVANT CODES

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

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

Current Procedural Terminology (CPT®) and J codes

Medicare Fee-for Service, Medicare Advantage, and Commercial*[7-9]

Retrograde approach using cystoscope	
J9281	Mitomycin pyelocalyceal instillation, 1 mg
J9281-JW	JW modifier for wastage
52005	Cystourethroscopy, with ureteral catheterization
74420	Urography, retrograde, with or without KUB
74420-26	Urography, retrograde, with or without KUB (professional component)
74420-TC	Urography, retrograde, with or without KUB (technical component)
Antegrade approach via nephrostomy tube	
J9281	Mitomycin pyelocalyceal instillation, 1 mg
J9281-JW	JW modifier for wastage
50391	Instillation of therapeutic agent into renal pelvis and/or ureter through established nephrostomy tube
50431	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy), and all associated radiological supervision and interpretation; existing access

Contract disclaimer: For managed Medicaid/Medicare Advantage/Commercial administration of JELMYTO, payer contract fee schedules should always be verified prior to treatment to ensure separate and adequate JELMYTO (J9281) reimbursement for your place of service.
*Additional ancillary codes may apply. Please review your manuals for current details.
Please see the latest Quarterly Coding and Payment Guide and Reimbursement Guide for more details.

PHYSICIAN OFFICE SAMPLE CLAIM FORM[10]

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.

Providers are responsible for the selection of appropriate codes for claim forms. This document contains possible coding options relating to the use of Company products, which may vary by health insurance or healthcare provider. The Company cannot guarantee that the billing codes listed in this document will result in coverage or payment. Please verify all codes with private and public plan sponsors prior to submitting claims. Since final coding is at the discretion of the health plan or healthcare provider, the codes in this document should be used for reference purposes only.

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 J9281.

Administration procedure

Enter the code for the JELMYTO instillation. C9789 covers the entire JELMYTO instillation procedure, either antegrade or retrograde, including related imaging.

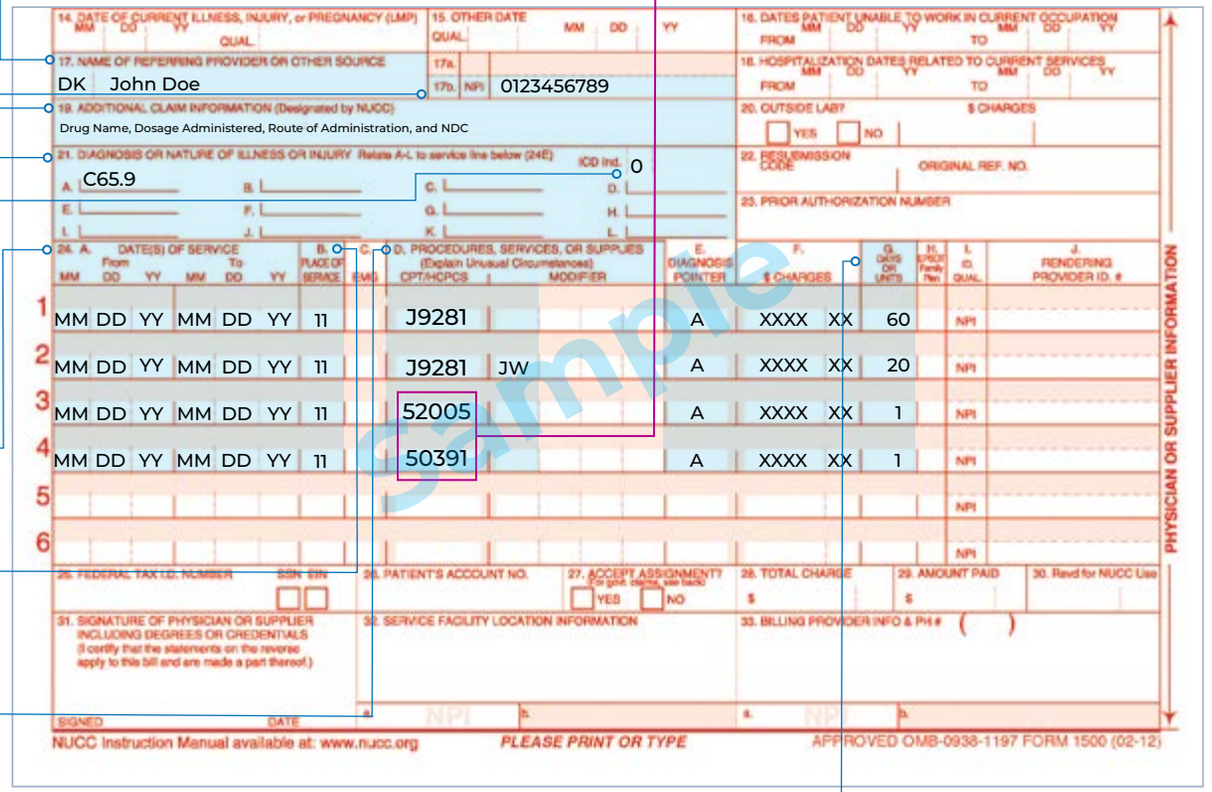
Box 24G: Days or service units

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.

Please only use 1 of these codes.



The image shown is not a complete depiction of the CMS-1500 form; portions of the full form are not shown.
NPI= National Provider Identifier.

Please see Important Safety Information on page 14, and click here for Full Prescribing Information for JELMYTO.

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

RELEVANT CODES: AMBULATORY SURGICAL CENTER (ASC)

CMS has created an HCPCS code for the JELMYTO instillation procedure effective October 1, 2023.[11] C9789 should be used on conjunction with the permanent J code, including the JW modifier for waste. C9789 is on applicable for Medicare fee-for-service beneficiaries in the HOPD and ASC settings.

This section provides information for ASC administrators on billing, coding, and reimbursement for JELMYTO for Medicare Fee-for-Service patients.

Addendum AA: ASC covered surgical procedures CY 2024

Code[11]	Description	ASC Status Indicator	APC
C9789*	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	G2	1559

Addendum BB: ASC covered ancillary services integral to covered surgical procedures for CY 2024

Code[3]	Description	ASC Status Indicator	APC
J9281	Mitomycin pyelocalyceal instillation, 1 mg	K2	9374

Medicare payment will vary by locality.

*G2: Non-office based surgical procedure added in CY 2008 or later: payment based on OPPS relative payment weight.[11]
Note: C9789 is intended to identify the entire JELMYTO instillation procedure and not just the use of JELMYTO.
OPPS=Outpatient Prospective Payment System.

Current Procedural Terminology (CPT®) codes[7-9]

Note: Check with your individual plan to confirm the appropriate CPT code.

Retrograde approach using cystoscope	
J9281	Mitomycin pyelocalyceal instillation, 1 mg
J9281-JW	JW modifier for wastage
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed

Antegrade approach via nephrostomy tube	
J9281	Mitomycin pyelocalyceal instillation, 1 mg
J9281-JW	JW modifier for wastage
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Contract disclaimer: For managed Medicaid/Medicare Advantage/Commercial administration of JELMYTO, payer contract fee schedules should always be verified prior to treatment to ensure separate and adequate JELMYTO (J9281) reimbursement for your place of service. Please see the latest Quarterly Coding and Payment Guide and Reimbursement Guide for more details.

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.

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: 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

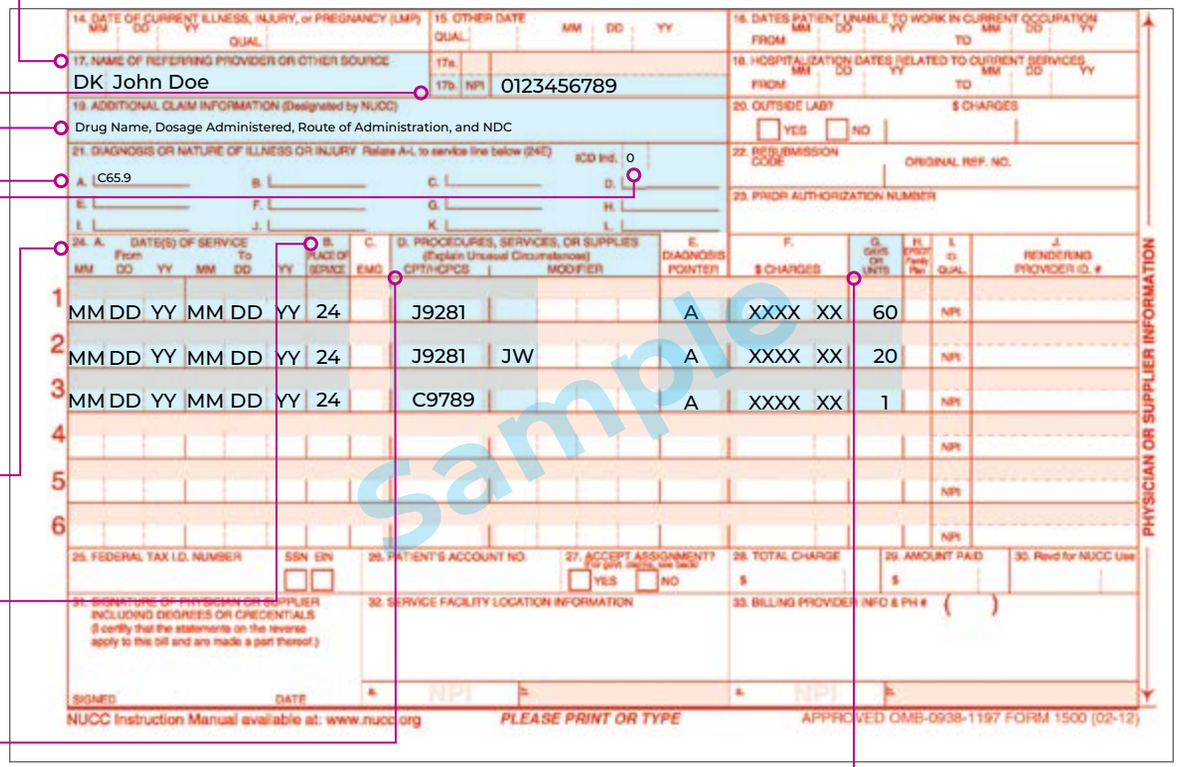
Product

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.

Sample CMS-1500 claim form[10]

The image shown is not a complete depiction of the CMS-1500 form; portions of the full form are not shown.



Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment. The provider is solely responsible for determining appropriate treatment for the patient based on the unique medical needs of each patient and the independent judgment of the provider. It is also 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. 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.

Your UroGen 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

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

Please see Important Safety Information on page 14, and click here for Full Prescribing Information for JELMYTO.

RELEVANT CODES: HOSPITAL OUTPATIENT DEPARTMENT (HOPD)

CMS has created an HCPCS code for the JELMYTO instillation procedure effective October 1, 2023.[11] C9789 should be used on conjunction with the permanent J code, including the JW modifier for waste. C9789 is on applicable for Medicare fee-for-service beneficiaries in the HOPD and ASC settings.

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

April OPPS Addendum B			
Code[3,11]	**Description**	**HOPD Status Indicator**	**APC**
C9789*	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	**T**	**1559**
J9281	Mitomycin pyelocalyceal instillation, 1 mg	**K**	**9374**
Medicare payment will vary by locality.			

Current Procedural Terminology (CPT®) codes[7-9]

Note: Check with your individual plan to confirm the appropriate CPT code.

Retrograde approach using cystoscope	
J9281	Mitomycin pyelocalyceal instillation, 1 mg
J9281-JW	JW modifier for wastage
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed

Antegrade approach via nephrostomy tube	
J9281	Mitomycin pyelocalyceal instillation, 1 mg
J9281-JW	JW modifier for wastage
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Contract disclaimer: For managed Medicaid/Medicare Advantage/Commercial administration of JELMYTO, payer contract fee schedules should always be verified prior to treatment to ensure separate and adequate JELMYTO (J9281) reimbursement for your place of service. Please see the latest Quarterly Coding and Payment Guide and Reimbursement Guide for more details.

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.

Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment. The provider is solely responsible for determining appropriate treatment for the patient based on the unique medical needs of each patient and the independent judgment of the provider. It is also 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. 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.

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 44-46[3]

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™.

$$\underset{\text{Milliliters instilled}}{15\ \text{mL}} \times 4\ \text{mg/mL} = \underset{\text{Units billed}}{60\ \text{mg}}$$

$$\underset{\text{Total billable units}}{80\ \text{mg}} - \underset{\text{Units billed}}{60\ \text{mg}} = \underset{\text{Wastage billed}}{20\ \text{mg}}$$

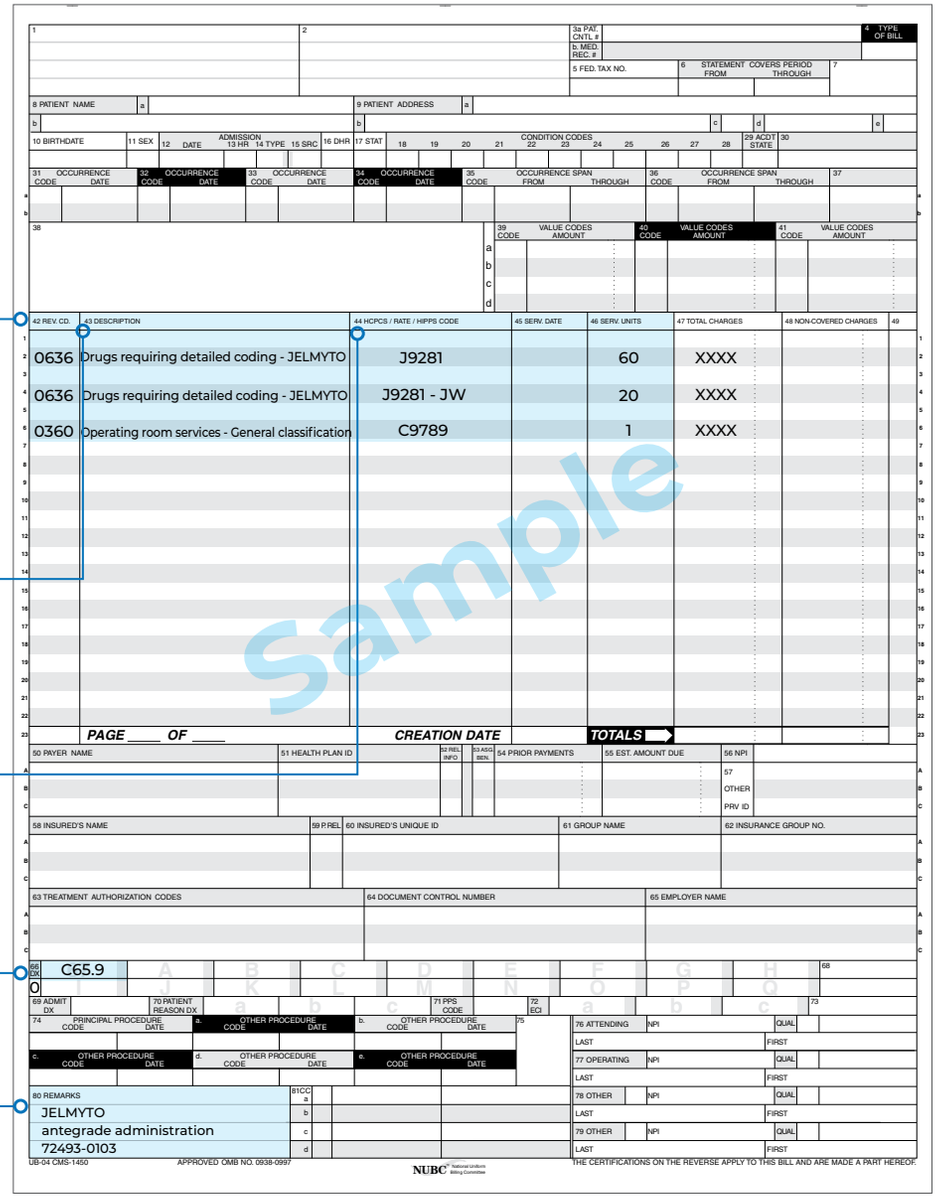
FL 66

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.

Annotated CMS-1450 (UB-04) hospital outpatient form[12]



Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™

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.

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 14, and click here for Full Prescribing Information for JELMYTO.

References: 1. Data on file. Urogen Pharma, Inc., Princeton, NJ. **2.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc; 2022. **3**. Centers for Medicare & Medicaid Services. CMS manual system: pub 100-04 Medicare claims processing – transmittal 10540. Accessed June 3, 2024. https://www.cms.gov/files/document/r10540cp.pdf **4.** Centers for Medicare & Medicaid Services (CMS). ICD-10-CM/PCS MS-DRG v37.0 definitions manual. Centers for Medicare & Medicaid Services. Accessed June 3, 2024. https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0255.html **5.** 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. **6.** Centers for Medicare & Medicaid Services (CMS). Discarded drugs and biologicals – JW modifier and JZ modifier policy. HCPCS codes. Accessed June 3, 2024. https://www.cms.gov/files/document/jw-modifier-and-jz-modifier-policy-hcpcs-codes.pdf **7.** Centers for Medicare and Medicaid Services. Addendum B update. Accessed January 1, 2024. https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/addendum-and-addendum-b-updates/addendum-b **8.** Centers for Medicare and Medicaid Services. ASP pricing files. Accessed January 1, 2024. https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files **9.** Centers for Medicare and Medicaid Services. ASC payment rates – addenda. Accessed January 1, 2024. https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files/rvu24a **10.** Centers for Medicare and Medicaid Services. CMS 1500 form. Accessed June 5, 2024. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf **11.** Centers for Medicare & Medicaid Services. CMS manual system: pub 100-04 Medicare claims processing – transmittal 12227. Accessed March 28, 2024. https://www.cms.gov/files/document/r12227cp.pdf **12**. Centers for Medicare and Medicaid Services. Pub 100-04 Medicare claims processing. Uniform billing (UB-04) form. Accessed June 5, 2024. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450

UroGen Pharma

Jelmyto® (mitomycin) for pyelocalyceal solution | UroGen Support™