Jelmyto®
(mitomycin) for pyelocalyceal solution

ACCURATELY OPTIMIZE REIMBURSEMENT CLAIMS FOR JELMYTO using HCPCS code J9281[1,a]

ALWAYS BILL FOR THE PURCHASED AMOUNT OF 80 MG JELMYTO regardless of the amount prepared by pharmacy or instilled into patient

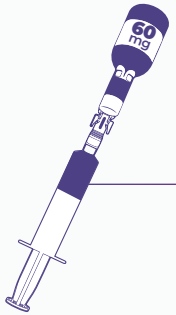
80 mg JELMYTO in purchased Single-Dose Carton

JELMYTO is supplied in a Single-Dose Carton containing **two 40 mg vials that need to be mixed**[2]

20 mg JELMYTO discarded in reconstitution process

60 mg JELMYTO in reconstituted vial prepared by pharmacy

After the two 40 mg vials are reconstituted by an in-house pharmacy or mixing partner, **a single vial with 60 mg JELMYTO** is available for administration[2]



JELMYTO instillation amount depends on patient's kidney volume

Maximum dose of JELMYTO is 60 mg[2]

Variable amount of JELMYTO discarded, depending on patient's kidney volume

[a] **CMS Final Decision: The existing modifier JW "Drug Amount Discarded, Not Administered to Any Patient" may be used as appropriate to report any drug discarded, for example: the 20 mg difference between the 80 mg supplied in the kit ((2) 40 mg vials), and the 60 mg maximum dose.**[1]

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).

See next page for billing example ›

Please see Important Safety Information on page 4, and click here for Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration for JELMYTO.

USE THE CORRECT HCPCS CODE AND MODIFIER TO ENSURE ACCURATE REIMBURSEMENT[a]

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

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

Sample CMS-1500 claim form[3]
Box 24G: Days or service units

When billing with **HCPCS code J9281**, bill for units instilled. For the remaining mg not instilled, bill with HCPCS code J9281 and the JW modifier. Click here for detailed information in the JELMYTO Billing and Coding Guide. The images shown are not a complete depiction of the CMS-1500 form; portions of the full form are not shown.

EXAMPLE 1:

The total billable units under J9281 are 80 mg because JELMYTO is supplied in two 40 mg vials, resulting in 80 mg total purchased amount.[1,2] Upon reconstitution, the concentration is 4 mg JELMYTO per mL.[2] Therefore, if a patient received 9 mL, then the **units billed equal 36 mg** and the **amount billed for discarded product equals 44 mg**.

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
1									J9281				36
2									J9281	JW			44

80 mg JELMYTO in purchased Single-Dose Carton

20 mg JELMYTO discarded

60 mg JELMYTO in reconstituted vial prepared provided by pharmacy

36 mg JELMYTO administered to patient

24 mg JELMYTO discarded

J9281 billed amount = 36 mg

JW modifier 20 mg + 24 mg = 44 mg[a]

36 mg + 44 mg = 80 mg

Total billable amount is 80 mg

[a] **CMS Final Decision: The existing modifier JW "Drug Amount Discarded, Not Administered to Any Patient" may be used as appropriate to report any drug discarded, for example: the 20 mg difference between the 80 mg supplied in the kit ((2) 40 mg vials), and the 60 mg maximum dose.[1]**

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.

See next page for another billing example >

Please see Important Safety Information on page 4, and click here for Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration for JELMYTO.

Jelmyto® (mitomycin) for pyelocalyceal solution

USE THE CORRECT HCPCS CODE AND MODIFIER TO ENSURE ACCURATE REIMBURSEMENT[a] (continued)

Continued from previous page

EXAMPLE 2:

The total billable units under J9281 are 80 mg because JELMYTO is supplied in two 40 mg vials, resulting in 80 mg total purchased amount.[1,2] Upon reconstitution, the concentration is 4 mg JELMYTO per mL.[2] Therefore, if a patient received 15 mL, then the **units billed equal 60 mg** and the **amount billed for discarded product equals 20 mg**.

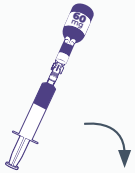
	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
1									J9281				60
2									J9281	JW			20

80 mg JELMYTO in purchased Single-Dose Carton

20 mg JELMYTO discarded

60 mg JELMYTO in reconstituted vial prepared provided by pharmacy

60 mg JELMYTO administered to patient



0 mg JELMYTO discarded

J9281 billed amount = 60 mg

JW modifier 20 mg + 0 mg = 20 mg[a]

60 mg + 20 mg = 80 mg

Total billable amount is 80 mg

[a] **CMS Final Decision: The existing modifier JW "Drug Amount Discarded, Not Administered to Any Patient" may be used as appropriate to report any drug discarded, for example: the 20 mg difference between the 80 mg supplied in the kit ((2) 40 mg vials), and the 60 mg maximum dose.[1]**

See Billing and Coding Guide for additional details. Your UroGen FRM is available to answer your JELMYTO billing and coding questions.

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.

Please see Important Safety Information on page 4, and click here for Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration for JELMYTO.

Jelmyto® (mitomycin) for pyelocalyceal solution

IMPORTANT SAFETY INFORMATION

Contraindications

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

Ureteric Obstruction

Ureteric obstruction, including ureteral stenosis and hydronephrosis, occurred in patients receiving JELMYTO. Monitor patients for signs and symptoms of ureteric obstruction, including flank pain, and fever, and for changes in renal function. Patients who experience obstruction may require transient or long-term ureteral stents or alternative procedures. Withhold or permanently discontinue JELMYTO based on the severity of ureteric obstruction.

Bone Marrow Suppression

The use of JELMYTO can result in bone marrow suppression, particularly thrombocytopenia and neutropenia. The following tests should be obtained prior to each treatment: Platelet count, white blood cell count differential and hemoglobin. Withhold JELMYTO for Grade 2 thrombocytopenia or neutropenia. Permanently discontinue for Grade 3 or greater thrombocytopenia or neutropenia.

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, JELMYTO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with JELMYTO and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JELMYTO and for 3 months following the last dose.

Common Adverse Reactions

The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria, and vomiting.

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in < 10% and ≥ 2% of patients who received JELMYTO include urinary tract inflammation, bladder spasm, urosepsis, hypersensitivity, and instillation site pain.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with JELMYTO and for 1 week following the last dose.

Preparation and Administration Information

JELMYTO is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration. JELMYTO must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the JELMYTO Instructions for Pharmacy and administration instructions found in the JELMYTO Instructions for Administration.

JELMYTO may discolor urine to a violet to blue color following the instillation procedure. Advise patients to avoid contact with urine for at least six hours post-instillation, to void urine sitting on a toilet, and to flush the toilet several times after use.

JELMYTO is a hazardous drug. Follow applicable special handling and disposal procedures.

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

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

References: 1. Centers for Medicare & Medicaid Services (CMS). Healthcare Common Procedure Coding System (HCPCS) application summaries and coding decisions, third quarter, 2020 coding cycle for drug and biological products. Accessed April 27, 2022. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-3-2020-drugs-and-biologics.pdf **2.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2022. **3.** Centers for Medicare & Medicaid Services (CMS). Health insurance claim form. Accessed April 27, 2022. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf

JELMYTO® and UroGen® are registered trademarks of UroGen Pharma, Ltd.
©2023 UroGen Pharma, Inc. All rights reserved.
US-JEL-00581 06/23

Jelmyto® (mitomycin) for pyelocalyceal solution