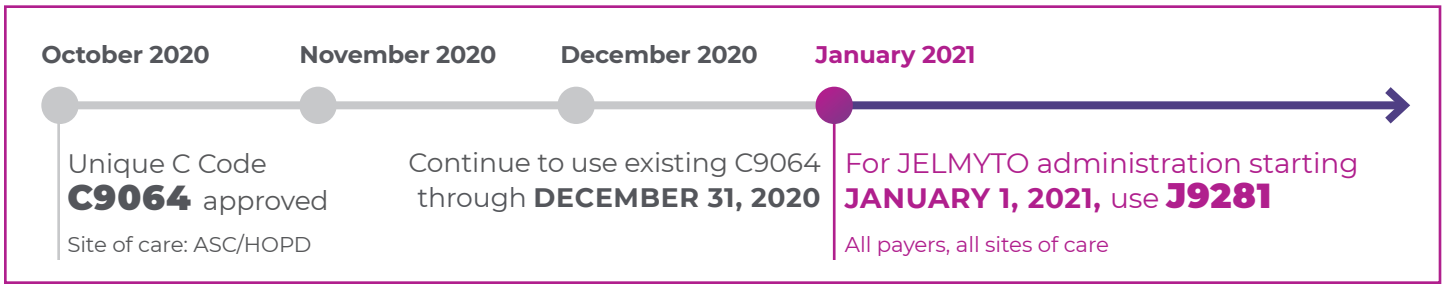
PERMANENT J CODE APPROVED FOR JELMYTO® (mitomycin) for pyelocalyceal solution[1]: J9281*

Effective January 1, 2021, a permanent J code for JELMYTO is approved for use: J9281 JELMYTO (mitomycin) for pyelocalyceal instillation, 1 mg. The new J code J9281 will use the same language and dose descriptor as existing code C9064.[1]



*Providers are responsible for the selection of appropriate codes for claims 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.

PASS-THROUGH STATUS CONTINUES FOR UP TO 3 YEARS[2]

JELMYTO continues to have pass-through status in the hospital outpatient department (HOPD) and ambulatory surgical center (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.

CMS GUIDANCE FOR BILLING FOR WASTAGE USING THE C CODE AND THE PERMANENT J CODE

Existing modifier JW "Drug Amount Discarded, Not Administered to Any Patient" may be used as appropriate to report any drug wastage.

FOR FULL CMS CODING DECISION, VISIT:

https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-3-2020-drugs-and-biologics.pdf

HOW SUPPLIED[3]

Dispensing pack	1 carton
NDC	72493-103-03 or 72493-0103-03
Description	Two 40 mg (each) single-dose vials of mitomycin for pyelocalyceal solution, totaling 80 mg. One 20 mL single-dose vial of sterile hydrogel to be used for reconstitution.

How can I learn more or get help?

Contact your UroGen Field Reimbursement Manager, who can answer your questions about utilizing the new code. You may also contact UroGen Support for access and reimbursement services.

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

Please see full Important Safety Information on reverse side.

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, renal dysfunction, fatigue, nausea, abdominal pain, 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 cytotoxic drug. Follow applicable special handling and disposal procedures.

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

References: 1. Centers for Medicare & Medicaid Services (CMS). CMS Healthcare Common Procedure Coding System (HCPCS) application summaries and coding decisions: third quarter, 2020 coding cycle for drug and biological products. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-3-2020-drugs-and-biologics.pdf. Accessed November 10, 2020. **2.** CMS. Innovators' guide to navigating Medicare, v3 (2015). https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov. Accessed September 1, 2020. **3.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2020.

UroGen Pharma