PASS-THROUGH STATUS AND C CODE APPROVED FOR JELMYTO® (mitomycin) for pyelocalyceal solution[1]:

C9064*

As of October 1, 2020, a new C code for JELMYTO is approved to use instead of C9399 (Unclassified drugs or biologicals) for use only in Medicare FFS patients treated in HOPDs/ASCs.[1]

No Longer Use: Miscellaneous C Code[2,3]	Now Approved: Unique C Code[1]
C9399 Unclassified drugs or biologicals (Medicare HOPD/ASC)	**C9064** **JELMYTO in Medicare HOPD/ASC**

*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.

ASC=ambulatory surgical center; FFS=fee-for-service; HOPD=hospital outpatient department.

TO WHICH PATIENTS DOES THE NEW C CODE APPLY?

The new C code (C9064) should be used for patients in HOPDs or ASCs who are Medicare FFS beneficiaries and receive JELMYTO on or after October 1, 2020.[1]

WHAT IS PASS-THROUGH STATUS?

For providers in HOPDs or ASCs, the Centers for Medicare & Medicaid Services (CMS) allows pass-through status for reimbursement for separately payable regimens like JELMYTO. Pass-through status ensures that reimbursement for JELMYTO will not be bundled with reimbursement for the procedure used for administration in the appropriate patients. JELMYTO will maintain pass-through status for a minimum of 2 and no more than 3 years. As CMS states, "[t]he purpose of transitional pass-through payments for new drugs and biologicals is to enable beneficiaries' access to technologies that are too new to be captured in the data used to determine APC payment rates."[2]

HOW DOES THIS IMPACT CLAIMS PROCESSING?

Your practice may find the new C code beneficial, with quicker claims processing and expedited reimbursement.[2]

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.

Reference: 1. CMS. MLN Matters MM11960. August 2020. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10331cp. Accessed September 9, 2020. **2.** CMS. Innovators' guide to navigating Medicare, v3 (2015). https://www.cms.gov/Medicare/ Coverage/CouncilonTechInnov. Accessed September 1, 2020. **3.** HCPCS codes. https://hcpcs.codes/c-codes/C9399/. Accessed September 8, 2020.

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