# Mitomycin Gel (Jelmyto®)

**NDC CODE(S)** 72493-0101-XX JELMYTO 40MG Vial (UROGEN PHARMA)
72493-0103-XX JELMYTO 80(2x40)MG Kit (UROGEN PHARMA)

**DESCRIPTION**

Mitomycin is an alkylating drug isolated from the broth of *Streptomyces caespitosus*. A cytotoxic drug, mitomycin inhibits the synthesis of deoxyribonucleic acid (DNA) and at high concentrations, cellular RNA and protein synthesis are also suppressed. In a gel preparation strictly for pyelocalyceal solution, the solution consists of mitomycin 40 mg and mannitol 80 mg in each single-dose vial.

The mitomycin gel-form must be reconstituted in sterile hydrogel and administered by instillation into the pyelocalyceal system via ureteral catheter or nephrostomy tube. There it forms a semisolid gel which dissolves from normal kidney urine flow, releasing mitomycin for up to 4 to 6 hours.

While primarily metabolized in the liver, metabolism occurs in other tissues as well. The rate of clearance is likely inversely proportional to the maximal serum concentration due to saturation of the degradative pathways.

**POLICY**

- Mitomycin Gel is considered ***medically necessary*** for the treatment of Upper Tract Urothelial Cancer (UTUC) if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Mitomycin Gel for the treatment of other conditions/diseases is considered ***investigational.***

## MEDICAL APPROPRIATENESS

### INITIAL APPROVAL CRITERIA

- Patient must be at least 18 years old; **AND**

### Universal Criteria

- Patient does not have a perforation of the bladder or upper urinary tract; **AND**
- Therapy will be used for intra-pyelocalyceal instillation only; **AND**
- Must be used as a single agent; **AND**

### Urothelial Carcinoma

- Patient has a diagnosis of low-grade, upper tract urothelial cancer (LG-UTUC); **AND**
- Patient has newly diagnosed or recurrent non-invasive disease; **AND**
- Patient has at least one measurable papillary tumor 5 to ≤ 15 mm, located above the ureteropelvic junction (in the absence of or following tumor debulking); **AND**
- Patient has not received intravesical BCG treatment within the previous 6 months of starting therapy; **AND**
- Patient does NOT have any of the following:
  - History of carcinoma in situ (CIS) in the urinary tract;
  - Invasive urothelial carcinoma within 5 years;
  - High grade papillary urothelial carcinoma within 2 years

### RENEWAL CRITERIA

- Patient continues to meet the universal and indication specific criteria as identified in the Initial Approval Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has a complete response (CR) to initial therapy (consisting of 6 weekly cycles) defined as a negative ureteroscopic evaluation and negative cytology wash (required for extending treatment for an additional 11 monthly instillations); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe ureteric obstruction, severe thrombocytopenia and/or neutropenia, etc.; **AND**
- Patient has not received more than a total of 17 drug doses/instillations

**DOSAGE/ADMINISTRATION**

| INDICATION | DOSE |
|---|---|
| Upper Tract Urothelial Carcinoma | • The dose to be instilled is 4 mg/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).<br>• Instill Jelmyto once weekly for six weeks. For patients with a complete response 3 months after therapy initiation, instillations may be administered once a month for a maximum of 11 additional instillations.<br>**Note: Careful measurement of renal pelvic volumes under fluoroscopic control is necessary to determine an accurate dose.* |

**LENGTH OF AUTHORIZATION**

Coverage will be provided initially for three months and may be renewed one time only for 11 months *(maximum total of 17 doses from initial and maintenance treatments).*

**DOSING LIMITS**

**Max Units (per dose and over time) [HCPCS Unit]:**

- Initial: 80 billable units per week for six weeks
- Maintenance: 80 billable units per month for 11 months

**APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS**

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

**IMPORTANT REMINDER**

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health

plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

**ADDITIONAL INFORMATION**

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

**SOURCES**

1. Jelmyto [package insert]. Princeton, NJ; Urogen Pharm, Inc; January 2021. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for mitomycin. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 3.2021. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
4. Kleinmann N, Pierorazio P, Matin S, et al. LBA25 Non-Surgical Management Of Low Grade Upper Tract Urothelial Cancer: An Interim Analysis Of The International Multicenter Olympus Trial (NCT02793128). J Uro 2018.199:45;e1166. https://doi.org/10.1016/j.juro.2018.03.097
5. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2021, March). *Mitomycin*. Retrieved May 4, 2021 from MICROMEDEX Healthcare Series.

**EFFECTIVE DATE** 8/31/2021

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