

# Medical Drug Clinical Criteria

<b>Subject:</b>	Jelmyto (mitomycin gel)		
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## Overview

This document addresses the use of Jelmyto (mitomycin) for pyelocalyceal solution. Jelmyto is a sustained-release formulation of mitomycin C, an alkylating agent that disrupts cancer growth. Incorporation of a reverse thermal gel that solidifies at body temperature enables longer exposure of mitomycin C to the urinary tract tissue. Jelmyto is approved for the treatment of low-grade Upper Tract Urothelial Cancer (UTUC) and is only approved for pyelocalyceal use. Pyelocalyceal application may be administered via ureteral catheter or a nephrostomy tube.

Individuals with UTUC are typically treated with kidney-sparing management and/or radical nephroureterectomy (RNU) where the kidney and ureter are removed. Jelmyto is the first drug approved for first-line treatment of low-grade UTUC. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Jelmyto including the caveat that complete or near complete endoscopic resection or ablation is recommended before gel application. NCCN considers Jelmyto most appropriate for patients with a solitary residual, low-grade, UTUC tumor that is low volume and who are not candidates for or are not seeking nephroureterectomy as a definitive treatment.

### Definitions and Measures

**Metastasis:** The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

**Urothelial carcinoma:** A type of bladder cancer which occurs in the urinary tract system.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Jelmyto (mitomycin gel)

Requests for Jelmyto (mitomycin gel) may be approved if the following criteria are met:

- I. Individual has a diagnosis of low-grade Upper Tract Urothelial Cancer; **AND**
- II. Cancer is non-metastatic; **AND**
- III. Individual has at least one visible tumor with a diameter of at least 5 mm but no more than 15 mm located above the ureteropelvic junction (Kleinmann 2020).

Requests for Jelmyto (mitomycin gel) may not be approved for the following:

- I. Individual with perforation of the bladder or upper urinary tract; OR
- II. When the above criteria are not met and for all other indications.

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

## HCPCS

J9281 Mitomycin pyelocalyceal instillation, 1 mg [Jelmyto]

## ICD-10 Diagnosis

C65.1-C65.9 Malignant neoplasm of unspecified renal pelvis

## Document History

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Document History:

- 11/15/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/23/2024 – Annual Review: No changes. Coding Reviewed: No changes. 02/24/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes. 02/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 06/08/2020 – Annual Review: Add new clinical criteria document for Jelmyto. Coding Reviewed: Added HCPCS J3490, J9999, C9399. All diagnosis pend. 9/25/2020 Removed HCPCS C9399, Added HCPCS C9064, Added ICD-10-CM C67.0-C67.9. 10/26/2020 Removed C67.0-C67.9, added ICD-10-CM C65.1-C65.9. Effective 1/1/2021 Added HCPCS J9281, 12/31/2020 Removed HCPCS J3490, J9999, C9064.

## References

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3. 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. *The Lancet Oncology*, April 29, 2020, Online first.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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