

# Specialty Guideline Management

## Jelmyto

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Jelmyto	mitomycin

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication<sup>1</sup>

Jelmyto (mitomycin) is indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC).

All other indications are considered experimental/investigational and not medically necessary.

### Documentation

Submission of the following information is necessary to initiate a prior authorization for continuation of therapy review: urine cytology and ureteroscopy report 3 months after the initiation of therapy documenting complete response.

Reference number(s)
3820-A

# Coverage Criteria

## Urothelial Cancer<sup>1-2</sup>

Authorization of 6 doses (3 months) may be granted for treatment of non-metastatic, low-grade, low volume (5-15 mm), upper tract urothelial cancer when all of the following criteria are met:

- The requested drug will be given via pyelocalyceal administration.
- The requested drug will be administered once weekly for the first six weeks for initiation.

## Continuation of Therapy

Authorization of 12 months may be granted for a maximum of 11 additional doses for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there has been a complete response (as defined as a complete absence of tumor lesions by urine cytology and ureteroscopy) at 3 months after the initiation of the requested drug.

## References

1. Jelmyto [package insert]. Princeton, NJ: UroGen Pharma, Inc.; October 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed May 23, 2025.