

**Jelmyto (mitomycin pyelocalyceal solution)**  
 Effective 02/18/2025

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

### Overview

Jelmyto (mitomycin pyelocalyceal solution) is an alkylating drug indicated for the treatment of adult patients with low-grade upper tract urothelial cancer.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of low-grade upper tract urothelial cancer (LG-UTUC)
2. Prescriber is an oncologist or urologist or consult notes from an oncologist or urologist are provided
3. Appropriate dosing

### Continuation of Therapy

Reauthorizations requires physician documentation of continuation of therapy as evidenced by a complete response three months after initiation.

### Limitations

1. Initial approvals will be granted for 6 weeks.
2. Reauthorizations will be granted for 11 months. Requests beyond one year of treatment will be reviewed on a case by case basis.
3. Members who have already started treatment may be approved for any FDA-approved indication for the remaining treatment time. (max 1 year)

### References

1. Jelmyto® [prescribing information]. Princeton (NJ): UroGen Pharma, Inc.; 2020 Apr.

2. FDA Approves First Therapy for Treatment of Low-Grade Upper Tract Urothelial Cancer [press release on the internet]. Silver Spring (MD): Food and Drug Administration; 2020 Apr 15 [cited 2021 Nov 1] Available from: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapytreatment-low-gradeupper-tract-urothelial-cancer>.

3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Bladder Cancer Version 5.2021 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2021 Oct 20 [cited 2021 Nov 1]. Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf).

### **Review History**

01/11/23 - Reviewed and update for Jan P&T; matched MH UPPL. Created criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23

01/2025 – Reviewed and updated for P&T. Clarified diagnosis and prescriber specialty. No clinical changes. Effective 2/18/25

