

# Jelmyto® (mitomycin pyelocalyceal solution) Effective 04/01/2023

Plan	<ul><li>☑ MassHealth UPPL</li><li>☐ Commercial/Exchange</li></ul>		Program Type	☑ Prior Authorization	
Benefit	☐ Pharmacy Benefit ☐ Medical Benefit (NLX)			<ul><li>☑ Quantity Limit</li><li>☐ Step Therapy</li></ul>	
Specialty Limitations					
	Specialty Medications				
Contact Information	All Plans	Ph	one: 866-814-5506	Fax: 866-249-6155	
	Non-Specialty Medications				
	MassHealth	Ph	Phone: 877-433-7643 Fax: 866-255-7569		
	Commercial	Ph	Phone: 800-294-5979 Fax: 888-836-0730		
	Exchange	Ph	ione: 855-582-2022	Fax: 855-245-2134	
	Medical Specialty Medications (NLX)				
	All Plans	Ph	one: 844-345-2803	Fax: 844-851-0882	
Exceptions					

### Overview

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

No PA	Drugs that require PA	
Please refer to the relevant NCCN guidelines	Jelmyto® (mitomycin pyelocalyceal solution) <sup>MB</sup>	

MB This drug is available through the medical benefit.

#### **Coverage Guidelines**

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with Jelmyto, 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, and documentation is provided:

- 1. Diagnosis of low-grade upper tract urothelial cancer
- 2. Prescriber is an oncologist or urologist
- 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.

### 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-grade-upper-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.

### **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.

