Jelmyto (mitomycin gel)
PAM – 019

Iowa Medicaid Program	Prior Authorization	**Effective Date**	01/01/2021
Revision Number	5	**Last Reviewed**	04/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	04/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	04/16/2021

Overview

Medication: [1]	mitomycin gel
Brand Name:	Jelmyto®
Pharmacologic Category:	Antineoplastic agent, alkylating drug
FDA-Approved Indication(s):	Treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC)
How Supplied:	Single-dose carton containing: • Two single-dose vials of mitomycin (40 mg each) • One single-dose vial of sterile hydrogel (20 mL)
Dosage and Administration:	• For pyelocalyceal use only and not for intravenous use, topical use, or oral administration • Instill 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) • Instill once weekly for 6 weeks • For patients with a complete response 3 months after initiation, instillations may be administered once a month for a maximum of 11 additional instillations
Benefit Category:	Medical

Descriptive Narrative

Bladder cancer is the most common malignancy involving the urinary system and the ninth most common malignancy worldwide. In the US, approximately 80,000 new cases and 17,000 deaths occur each year due to bladder cancer. The 5-year survival rate for those diagnosed with bladder cancer in the US is approximately 80 percent (most bladder cancer patients do not die of their disease but do experience multiple recurrences). Urothelial carcinoma (previously known as transitional cell carcinoma) is the predominant histologic type in the US, accounting for approximately 90 percent of all bladder cancers. Bladder cancer is typically diagnosed in older individuals: a majority (73 percent) of patients are older than 65 years of age (median age at diagnosis is 69 years in males and 71 years in females).

Environmental exposures account for most cases of bladder cancer, with cigarette smoking being the most important factor contributing to the overall incidence of urothelial cancer in western countries. Smoking cessation decreases but does not eliminate the increased risk of bladder cancer.[2]

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[3,4]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[5]

- Bladder Cancer (v.1.2025 – March 25, 2025)

NCCN Guidelines® Recommendation(s)
(1) Mitomycin gel for pyelocalyceal use (Jelmyto®) is recommended by NCCN as a Category 2A, preferred treatment option for radiosensitizing chemotherapy (in combination with 5-FU).
(2) Mitomycin gel for pyelocalyceal use (Jelmyto®) is recommended by NCCN as a Category 1 single-dose immediate postoperative intravesical chemotherapy [within 24 hours of transurethral resection of a bladder tumor (TURBT)].
(3) Mitomycin gel for pyelocalyceal use (Jelmyto®) is recommended by NCCN as a Category 2A, single-dose immediate postoperative intravesical chemotherapy for upper GU tract urothelial carcinoma (complete or near complete endoscopic resection or ablation is recommended before gel application).

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Criteria

Prior authorization is required.

Jelmyto® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of non-metastatic, low-grade upper tract urothelial cancer (LG-UTUC); **AND**
2. Member does not have a perforation of the bladder or upper urinary tract; **AND**
3. Member has at least one measurable tumor with a diameter between 5 and 15 mm in size and located above the ureteropelvic junction; **AND**
4. Member is 18 years of age or older; **AND**
5. Prescribed by, or in consultation with, a urologist or oncologist; **AND**
6. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling.

Jelmyto® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. If member has received six instillations, complete response has been achieved at 3 months after initiation of therapy, as evidenced by complete absence of tumor lesions on urine cytology and ureteroscopy; **AND**
3. Member does not have a perforation of the bladder or upper urinary tract; **AND**
4. Member has not received more than 17 instillations of Jelmyto®; **AND**
5. Prescribed by, or in consultation with, a urologist or oncologist; **AND**
6. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	3 months (six once-weekly instillations)	11 months (up to 11 once-monthly instillations)* ➔ Only approved if member has a complete response 3 months after initiation
Quantity Limits	Not to exceed 60 mg per instillation	Not to exceed 60 mg per instillation

* Approval is allowed for a maximum of 17 doses based on FDA approval information.

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9281	Mitomycin pyelocalyceal instillation, 1 mg

ICD-10	Description
C65.9	Malignant neoplasm of unspecified renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
72493-0103-03 (contains two single-dose vials [40 mg each])	UroGen Pharm, Inc. (72493)	1 mg	1	EA	80

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current

literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Jelmyto® prescribing information (10/2024). UroGen Pharma, Inc.: Princeton, NJ. Available online: www.jelmyto.com/hcp. Accessed March 3, 2025.

[2] Daneshmand S. Epidemiology and risk factors of urothelial (transitional cell) carcinoma of the bladder. Shah SM, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 3, 2025.

[3] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[5] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

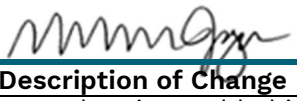
- Bladder Cancer (v.1.2025 – March 25, 2025)

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

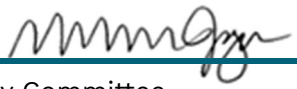
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
04/18/2025	CAC	Annual review. Reviewed NCCN Guidelines® for Bladder Cancer – no changes.	5
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/19/2024	CAC	Annual review. Added information on age at time of diagnosis and environmental exposure into "Descriptive Narrative." Updated NCCN Guidelines®.	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/21/2023	CAC	Annual review. Updated NCCN Guidelines® recommendations.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/15/2022	CAC	Annual review.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/16/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee