

Jelmyto™ (mitomycin) (Intra-pyelocalyceal)

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I. Length of Authorization

Coverage will be provided initially for three months and may be renewed one time only for 11 months (*maximum total of 17 doses from initial and maintenance treatments*).

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Jelmyto single-use carton/kit: Initially, 1 carton per every 7 days for 6 weeks, followed by 1 carton per every 28 days for 11 months

B. Max Units (per dose and over time) [HCPCS Unit]:

- Initial: 80 billable units per week for six weeks
- Maintenance: 80 billable units per month for 11 months

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient must be at least 18 years old; **AND**

Universal Criteria ¹

- Patient does not have a perforation of the bladder or upper urinary tract; **AND**
- Therapy will be used for intra-pyelocalyceal instillation only; **AND**
- Must be used as a single agent; **AND**

Urothelial Carcinoma †/Φ ^{1,4}

- Patient has a diagnosis of low-grade, upper tract urothelial cancer (LG-UTUC); **AND**
- Patient has newly diagnosed or recurrent non-invasive disease; **AND**
- Patient has at least one measurable papillary tumor 5 to ≤ 15 mm, located above the ureteropelvic junction (in the absence of or following tumor debulking); **AND**
- Patient has not received intravesical BCG treatment within the previous 6 months of starting therapy; **AND**

- Patient does NOT have any of the following:
 - History of carcinoma in situ (CIS) in the urinary tract;
 - Invasive urothelial carcinoma within 5 years;
 - High grade papillary urothelial carcinoma within 2 years

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,4}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has a complete response (CR) to initial therapy (consisting of 6 weekly cycles) defined as a negative ureteroscopic evaluation and negative cytology wash (required for extending treatment for an additional 11 monthly instillations) ; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe ureteric obstruction, severe thrombocytopenia and/or neutropenia, etc.; **AND**
- Patient has not received more than a total of 17 drug doses/instillations

V. Dosage/Administration

Indication	Dose
Upper Tract Urothelial Carcinoma	<ul style="list-style-type: none"> • The dose to be instilled is 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 of mitomycin). • Instill Jelmyto once weekly for six weeks. For patients with a complete response 3 months after therapy initiation, instillations may be administered once a month for a maximum of 11 additional instillations. <p><i>*Note: Careful measurement of renal pelvic volumes under fluoroscopic control is necessary to determine an accurate dose.</i></p>

VI. Billing Code/Availability Information

HCPCS Code:

- J9281 – Mitomycin pyelocalyceal instillation, 1 mg; 1 billable unit=1 mg

NDC:

- Jelmyto single-dose carton: 72493-0103-xx
 - Two 40 mg single-dose vials of lyophilized mitomycin: 72493-0101-xx

- One 20 mL single dose vial of vehicle for reconstitution: 72493-0102-xx

VII. References

1. Jelmyto [package insert]. Princeton, NJ; Urogen Pharm, Inc; January 2021. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for mitomycin. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 3.2021. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
4. Kleinmann N, Pierorazio P, Matin S, et al. LBA25 Non-Surgical Management Of Low Grade Upper Tract Urothelial Cancer: An Interim Analysis Of The International Multicenter Olympus Trial (NCT02793128). J Uro 2018.199:45:e1166. <https://doi.org/10.1016/j.juro.2018.03.097>

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC