Medical Policy:

Jelmyto™ (mitomycin solution for pyelocaliceal administration)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.217	March 31, 2025	June 23, 2020

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Mitomycin inhibits the synthesis of deoxyribonucleic acid (DNA). The guanine and cytosine content correlates with the degree of mitomycin-induced cross-linking. At high concentrations of the drug, cellular RNA and protein synthesis are also suppressed.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Initial: 80 billable units per week for 6 weeks

Maintenance: 80 billable units per month for 11 months

Guideline

I. Initial Approval Criteria

Jelmyto *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Low-grade Upper Tract Urothelial Cancer (LG-UTUC)**
    A. The patient is ≥ 18 years of age; **AND**
    B. The patient has non-metastatic disease; **AND**
    C. Patient has low-grade disease; **AND**
    D. The patient has undergone endoscopic resection or ablation; **AND**
    E. Jelmyto is prescribed by or in consultation with an oncologist or urologist.

Limitations/Exclusions

Jelmyto is not considered medically necessary for when any of the following selection criteria is met:

1. Disease progression while on Jelmyto
2. Jelmyto is contraindicated in patients with perforation of the bladder or upper urinary tract
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA.

Dosage/Administration

Indication	Dose
Low-grade Upper Tract Urothelial Cancer (LG-UTUC)	Jelmyto is for pyelocalyceal use only. The recommended dose is 4 mg/mL of mitomycin administered by ureteral catheter or a nephrostomy tube, with total instillation volume determined on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin). The dose is instilled once weekly for 6 weeks and in patients with a complete response 3 months after initiating Jelmyto, therapy can continue once a month for an additional 11 instillations.

Applicable Procedure Codes

Code	Description
J9281	Mitomycin pyelocalyceal instillation; 1 billable unit = 1 mg

Applicable NDCs

Code	Description
72493-0103-03	Jelmyto™ (mitomycin solution for pyelocalyceal administration) Kit - 80(2x40) vials
72493-0102-xx	Jelmyto™ (mitomycin solution for pyelocalyceal administration) Kit - 20 mg vial
72493-0101-xx	Two 40 mg single-dose vials of lyophilized mitomycin

ICD-10 Diagnoses

Code	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
C66.1	Malignant neoplasm of right ureter

C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/31/2025	Annual Review: Updated ICD-10. No criteria changes.
EmblemHealth & ConnectiCare	2/15/2024	Annual Review: Updated dosing limits; added NDC 72493-0101-xx, no criteria changes
EmblemHealth & ConnectiCare	6/22/2023	Annual Review: Upper Tract Urothelial Cancer Initial Criteria: Added "c. Patient has low-grade disease; AND" Removed NDC: 72493-0101-40, added 72493-0102-xx
EmblemHealth & ConnectiCare	07/25/2022	Transferred policy to new template, updated billing codes
EmblemHealth & ConnectiCare	7/7/2021	Removed C Code
EmblemHealth & ConnectiCare	1/1/2021	Added J-code J9281
EmblemHealth & ConnectiCare	9/11/2020	Added C-Code (C9064) Mitomycin pyelocalyceal instillation, 1 mg (Jelmyto). C-Code effective date: 10/1/2020
EmblemHealth & ConnectiCare	06/23/2020	New Medical Policy

References

1. Jelmyto™ for pyelocalyceal solution [prescribing information]. Princeton, NJ: UroGen Pharma; April 2020.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 4.2020 – April 28, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed April 29, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 29, 2020. Search term: Jelmyto.