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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 26, 2020
Subject:	Jelmyto	**Page:**	1 of 5

Last Review Date: December 13, 2024

Jelmyto

Description

Jelmyto (mitomycin)

Background
Jelmyto (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 (1).

Regulatory Status
FDA-approved indication: Jelmyto is an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC) (1).

Jelmyto is for pyelocalceal use only and not for intravenous use, topical use, or oral administration (1).

Jelmyto is instilled via ureteral catheter or a nephrostomy tube once weekly for six weeks. Patients with a complete response 3 months after Jelmyto initiation, may receive once monthly doses for a maximum of 11 additional instillations (1).

Jelmyto is contraindicated in patients with perforation of the bladder or upper urinary tract (1).

Patients should be monitored for signs and symptoms of ureteric obstruction, including flank pain, and fever, and for changes in renal function. The use of Jelmyto can also result in bone marrow suppression, particularly thrombocytopenia and neutropenia. The following tests should

be obtained prior to each treatment: platelet count, white blood cell count differential, and hemoglobin (1).

Jelmyto can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Jelmyto and for 6 months after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Jelmyto and for 3 months after the last dose (1).

The safety and efficacy of Jelmyto in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jelmyto may be considered **medically necessary** if the conditions indicated below are met.

Jelmyto may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Low-grade Upper Tract Urothelial Cancer (LG-UTUC)

AND ALL of the following:

a. Prescriber agrees to monitor platelet count, white blood cell count differential, and hemoglobin
b. **NO** perforation of the bladder or upper urinary tract

c. Instilled via catheter once weekly and **NOT** for IV use, topical use, or oral administration
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jelmyto and for 6 months after the last dose
e. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jelmyto and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Low-grade Upper Tract Urothelial Cancer (LG-UTUC)

AND ALL of the following:

a. Patient had a complete response 3 months after Jelmyto initiation
b. Prescriber agrees to monitor platelet count, white blood cell count differential, and hemoglobin
c. **NO** perforation of the bladder or upper urinary tract
d. Instilled via catheter once monthly and **NOT** for IV use, topical use, or oral administration
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jelmyto and for 6 months after the last dose
f. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jelmyto and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 instillations

Duration 3 months

Prior – Approval *Renewal* Limits

Quantity 11 instillations

Duration 12 months (one renewal only)

Rationale

Summary
Jelmyto (mitomycin) is an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC). Jelmyto carries warnings for ureteric obstruction, bone marrow suppression and embryo-fetal toxicity. Jelmyto is contraindicated in patients with perforation of the bladder or upper urinary. The safety and efficacy of Jelmyto in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Jelmyto while maintaining optimal therapeutic outcomes.

References

1. Jelmyto [package insert]. Princeton, NJ: UroGen Pharma, Inc.; September 2022.
2. NCCN Drugs & Biologics Compendium® Mitomycin 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.

Policy History

Date	Action
June 2020	Addition to PA
September 2020	Annual review. Added requirement to be instilled via catheter once weekly/monthly and not for IV use, topical use, or oral administration per SME. Added “one renewal only” limit.
June 2021	Annual editorial review and reference update

June 2022	Annual review and reference update
June 2023	Annual review and reference update
December 2023	Annual review and reference update
June 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.