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# 5.21.150

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	June 26, 2020
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**Last Review Date:** June 16, 2022

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## 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

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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** in patients 18 years of age or older with upper tract urothelial cancer and if the conditions indicated below are met.

Jelmyto may be considered **investigational** in patients less than 18 years of age and 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:

- Prescriber agrees to monitor platelet count, white blood cell count differential, and hemoglobin

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- 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

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## 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.; January 2021.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Mitomycin 2022. National Comprehensive Cancer Network, Inc. Accessed on April 19, 2022.

## 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

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June 2022      Annual review and reference update

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**