



**Jelmyto**  
**Jelmyto (mitomycin) J9281**  
**Prior Authorization Request**  
**Medicare Part B Form**

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

**New Start or Initial Request: (Clinical documentation required for all requests)**

- Patient has a diagnosis of low-grade Upper Tract Urothelial Cancer; AND
- Cancer is non-metastatic; AND
- Patient has at least one visible tumor with a diameter of at least 5 mm but no more than 15 mm located above the ureteropelvic junction.

- Requests for Jelmyto (mitomycin gel) may not be approved for patients with perforation of the bladder or upper urinary tract;

**Continuation Requests: (Clinical documentation required for all requests)**

- Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.**
- Patient had an adequate response or significant improvement while on this medication.  
 If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group – Jelmyto Drug PA

### Drug Name(s):

JELMYTO

MITOMYCIN

### Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and Tiering will be determined by the Plan.

### Exclusion Criteria:

N/A

### Prescriber Restrictions:

Oncologist, Urologist or another related specialist

### Coverage Duration:

Initial Approval will be for 6 months

Continuation will be approved for 12 months

### FDA Indications:

Jelmyto

- Gastric cancer, Disseminated adenocarcinoma, in combination with other agents
- Operation for glaucoma, Ab externo; Adjunct
- Pancreatic cancer, Disseminated adenocarcinoma, in combination with other agents
- Transitional cell carcinoma of upper urinary tract, Low-grade

### Off-Label Uses:

Jelmyto

- Biliary tract cancer, Advanced
- Breast cancer
- Carcinoma of bladder
- Cervical cancer
- Colorectal cancer
- Head and neck cancer
- Malignant mesothelioma
- Malignant neoplasm of liver
- Non-small cell lung cancer
- Primary malignant neoplasm of anus
- Rectal cancer
- Sarcoma

### Age Restrictions:

N/A

**Other Clinical Consideration:**

- History of hypersensitivity or idiosyncratic reaction to mitomycin
- Thrombocytopenia, coagulation disorder, or an increase in bleeding tendency due to other causes
- Perforation of the bladder or upper urinary tract (pyelocalyceal solution)

**Resources:**

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/493C21/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYNC/7724C6/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=379200&contentSetId=100&title=Mitomycin&servicesTitle=Mitomycin&brandName=Jelmyto&UserMdxSearchTerm=Jelmyto&=&null#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/493C21/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/7724C6/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=379200&contentSetId=100&title=Mitomycin&servicesTitle=Mitomycin&brandName=Jelmyto&UserMdxSearchTerm=Jelmyto&=&null#)

Clinical / CMS  
Only