Definition
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
Max Units (per dose and over time) [Medical Benefit]:
- 240mg per 42 days

JELMYTO™ (MITOMYCIN SOLUTION FOR PYELOCALYCEAL ADMINISTRATION) PRESCRIBER INFORMATION

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. The patient has undergone endoscopic resection or ablation; AND
   D. 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

- Patient continues to meet INITIAL APPROVAL CRITERIA.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Low-grade Upper Tract Urothelial Cancer (LG-UTUC)</td>
<td>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.</td>
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</table>

Applicable Procedure Codes

- **J9281** Mitomycin pyelocalyceal instillation; 1 billable unit = 1 mg
- **C9064** Mitomycin pyelocalyceal instillation, 1 mg (Jelmyto). Code deleted 12/31/2020

Applicable NDCs

- **72493-0103-03** Jelmyto™ (mitomycin solution for pyelocalyceal administration) Kit

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>C65.1</td>
<td>Malignant neoplasm of right renal pelvis</td>
</tr>
<tr>
<td>C65.2</td>
<td>Malignant neoplasm of left renal pelvis</td>
</tr>
<tr>
<td>C65.9</td>
<td>Malignant neoplasm of unspecified renal pelvis</td>
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</tbody>
</table>

Revision History

- **7/7/2021** Removed C Code
- **1/1/2021** Added J-code J9281
- **9/11/2020** Added C-Code (C9064) Mitomycin pyelocalyceal instillation, 1 mg (Jelmyto). C-Code effective date: 10/1/2020
- **06/23/2020** New Medical Policy
References