

| Market Applicability |    |    |    |    |    |    |    |
|----------------------|----|----|----|----|----|----|----|
| Market               | DC | GA | KY | MD | NJ | NY | WA |
| Applicable           | X  | X  | X  | X  | X  | X  | X  |

## Jelmyto (mitomycin gel)

| Override(s)         | Approval Duration |
|---------------------|-------------------|
| Prior Authorization | 1 year            |

| Medications  |
|--|
| Jelmyto (mitomycin gel) for pyelocalyceal solution |

### APPROVAL CRITERIA

Requests for Jelmyto (mitomycin gel) may be approved if the following criteria are met:

- I. Individual has a diagnosis of low-grade Upper Tract Urothelial Cancer; **AND**
- II. Cancer is non-metastatic; **AND**
- III. Individual 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 (Kleinmann 2020).

Requests for Jelmyto (mitomycin gel) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. Individual with perforation of the bladder or upper urinary tract.

### Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: May 27, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Kleinmann N, Matin SF, Pierorazio PM, et al. Primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel (OLYMPUS): an open-label, single-arm, phase 3 trial. The Lancet Oncology, April 29, 2020, Online first.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on May 27, 2020.
  - a. Bladder Cancer. V5.2020. Revised May 12, 2020.

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New Program Date 08/17/2020

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

| <b>Market Applicability</b> |           |           |           |           |           |           |           |
|-----------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| <b>Market</b>               | <b>DC</b> | <b>GA</b> | <b>KY</b> | <b>MD</b> | <b>NJ</b> | <b>NY</b> | <b>WA</b> |
| <b>Applicable</b>           | X         | X         | X         | X         | X         | X         | X         |

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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