Reference number(s)
3820-A

SPECIALTY GUIDELINE MANAGEMENT

JELMYTO (mitomycin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Jelmyto (mitomycin) is indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate a prior authorization for continuation of therapy review: urine cytology and ureteroscopy report 3 months after the initiation of therapy documenting complete response.

III. CRITERIA FOR INITIAL APPROVAL

Urothelial Cancer
Authorization of 6 doses (3 months) may be granted for treatment of non-metastatic, low-grade, low volume (5-15 mm), upper tract urothelial cancer when all of the following criteria are met:
1. The requested drug will be given via pyelocalyceal administration.
2. The requested drug will be administered once weekly for the first six weeks for initiation.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for a maximum of 11 additional doses for continued treatment in members requesting reauthorization for an indication listed in Section III when there has been a complete response (as defined as a complete absence of tumor lesions by urine cytology and ureteroscopy) at 3 months after the initiation of the requested drug.

V. REFERENCES

1. Jelmyto [package insert]. Princeton, NJ: UroGen Pharma, Inc.; September 2022.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 12, 2024.

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