

Mitomycin Gel (JELMYTO)

Criteria for Use

November 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or [PBM INTRAnet](#) for further information.

Exclusion Criteria[^]

If the answer to ANY item below is met, then the patient should NOT receive mitomycin gel.

- Perforation of the bladder or upper urinary tract
- Contraindication or known sensitivity to mitomycin
- Glomerular Filtration Rate of <30 mL/minute
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

[^] CBC at baseline (i.e. WBC $\geq 3 \times 10^9/L$, ANC $\geq 1.5 \times 10^9/L$, Platelets $\geq 100,000 \times 10^9/L$, Hgb ≥ 9.0 mg/dL)

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA/VA Community Care urology or oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Goals of care and role of Palliative Care consult have been discussed and documented
- Patients of child-bearing potential and patients with partners of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Patients of child-bearing potential should use effective contraception during therapy and for 6 months after the last dose. Patients with partners of child-bearing potential should use effective contraception during therapy and for 3 months after the last dose.

Additional Inclusion Criteria

The answer to ONE of the following must be fulfilled in order to meet criteria:

- Treatment naïve, residual disease, or recurrent low- grade Upper Tract Urothelial Carcinoma- treat weekly for 6 weeks[^]

[^] Data on monthly maintenance therapy is not robust; monthly maintenance therapy (for 1 year) after complete response can be considered on a case-by-case basis.

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