Reference number(s)
3870-A

STANDARD MEDICARE PART B 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 Indications
Jelmyto is indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC).

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions for continuation of therapy: 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 the treatment of non-metastatic, low-grade, low volume (5-15mm), 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member has received the first 6 doses of initiation therapy
2. Jelmyto is being used to treat an indication enumerated in Section III
3. The member will only receive a maximum of 11 additional doses of therapy

4. The member is receiving benefit from therapy. Benefit is defined as a complete response (a complete absence of tumor lesions by urine cytology and ureteroscopy) at 3 months after the initiation of the requested drug.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Jelmyto.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Bladder cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Jelmyto are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.
Support for using Jelmyto to treat upper genitourinary tract tumors can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen). Jelmyto is recommended as primary treatment for a non-metastatic, residual, low-grade, low volume (5-15 mm), solitary tumor in the upper urinary tract for patients who are not a candidate for or not seeking nephroureterectomy as a definitive treatment.
Complete or near complete endoscopic resection or ablation is recommended prior to mitomycin ureteral gel application. Mitomycin for pyelocalyceal application may be administered via ureteral catheter or a nephrostomy tube.

VII. REFERENCES

1. Jelmyto [package insert]. Princeton, NJ: UroGen Pharma, Inc.; January 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 12, 2022.