Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 266.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Jelmyto (mitomycin ureteral gel)

I. Policy:
Jelmyto (mitomycin ureteral gel)

II. Purpose/Objective:
To provide a policy of coverage regarding Jelmyto (mitomycin ureteral gel).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION: Mitomycin alkylates DNA to produce DNA cross-linking (primarily with guanine and cytosine pairs) and inhibits DNA and RNA synthesis. Mitomycin is not cell cycle specific but has its maximum effect against cells in late G and early S phase. Following instillation into the pyelocalyceal system, mitomycin (ureteral gel) forms a semisolid gel that dissolves from normal kidney urine flow, releasing mitomycin.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Jelmyto (mitomycin ureteral gel) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Jelmyto is prescribed by or in consultation with a hematologist, oncologist or urologist **AND**
- Medical record documentation of a diagnosis of low-grade Upper Tract Urothelial Cancer (LG-UTUC) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION LIMITATIONS:
Initial approval: Authorization duration – 3 months (for a total of 6 doses) or less if the reviewing provider feels it is medically appropriate.

Subsequent approval: Authorization duration – 12 months (for a total of 11 doses) or less of the reviewing provider feels it is medically appropriate requiring medical record documentation of a complete response 3 months after Jelmyto initiation as evidenced by urine cytology and ureteroscopy.

The medication will no longer be covered if patient experiences toxicity, worsening of disease, experiences a perforation of the bladder or upper urinary tract or if the patient has received 17 total instillations (maximum number of instillations per FDA approved labeling).

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/20/22

Revised:

Reviewed: