Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP363

Section: Medical Policy

Subject: Urinary Tumor Markers for Bladder Cancer

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Urinary Tumor Markers for Bladder Cancer

II. Purpose/Objective:

To provide a policy of coverage regarding Urinary Tumor Markers for Bladder Cancer

III. Responsibility:

A. Medical Directors

B. Medical Management

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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 of 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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- 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: The purpose of using urinary tumor markers in the evaluation of members who exhibit signs or symptoms of bladder cancer is to serve as an adjunct to cytology and biopsy. The current standard for a confirmatory diagnosis of bladder cancer is cystoscopic examination with biopsy.

CRITERIA FOR COVERAGE:
Urinary biomarkers (bladder tumor antigen (BTA) test, nuclear matrix protein (NMP22) test, or fluorescence in situ hybridization (FISH) {*UroVysion Bladder Cancer* test} may be covered when used as:

a. An adjunct in the diagnosis of bladder cancer for members who have an atypical or equivocal cytology
b. An adjunct in the monitoring of high-risk, non-muscle invasive bladder cancer

The use of fluorescence immunocytology {*ImmunoCyt/uCyt*} may be covered as an adjunct to cystoscopy or cytology in the monitoring of members with bladder cancer.

See Also: AHS G2125 Urinary Tumor Markers For Bladder Cancer

Medicare Business Segment:
In compliance with Novitas LCD A58529 Response to Comments: Biomarkers for Oncology, **Cxbladder™ Detect, Cxbladder™ Monitor** will be covered when meeting the reasonable and necessary guidelines as outlined in Title XVIII of the Social Security Act, Section 1862(a)(1)(A).

EXCLUSIONS:
There is insufficient evidence in the peer-reviewed, published medical literature to support the use of urinary biomarkers (bladder tumor antigen (BTA) test, nuclear matrix protein (NMP22) test, fluorescence in situ hybridization (FISH) UroVysion Bladder Cancer test) or fluorescence immunocytology (ImmunoCyt/uCyt) as mechanisms for bladder cancer screening, evaluation of hematuria, or diagnosing bladder cancer in symptomatic members. These tests are considered to be **Experimental, Investigational or Unproven** for those indications and are therefore **NOT COVERED**.

There is insufficient evidence in the peer-reviewed, published medical literature to support the use of gene expression profiling by real-time quantitative PCR {Cxbladder Detect, Cxbladder Monitor}. Unless otherwise mandated (eg, Medicare), , the Plan does **NOT** provide coverage for Proteomic Serum analysis to bladder cancer. These tests are considered to be **Experimental, Investigational or Unproven** for those indications and are therefore **NOT COVERED.**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:
Any requests for services that do not meet criteria set in the PARP may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Urinary Tumor Markers for Bladder Cancer
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

86294 Immunoassay for tumor antigen, qualitative and semiquantitative (eg, bladder tumor antigen), {*BTA stat test*} BTA or NMP-22
88120 Cytopathology, in situ hybridization (eg. FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen, manual
88121 using computer-assisted technology
88346 ImmunoCyt test
88365 fluorescence in situ hybridization (FISH
86386 Nuclear Matrix Protein 22 [NMP22], qualitative {*NMP-22*}
0012M: Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having

urothelial carcinoma {*Cxbladder Detect*}

0013M: Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma {*Cxbladder Monitor*}

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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NCCN Clinical Practice Guidelines in Oncology, Bladder Cancer v3.2023

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

Devised: 8/22

Revised:

Reviewed: 8/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies