MEDICAL POLICY

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Medical Policy Title	**Urinary Tumor Markers for Bladder and Urothelial Cancers**
Policy Number	**2.02.12**
Current Effective Date	July 17, 2025
Next Review Date	July 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Urinary tumor markers are considered **investigational** in the diagnosis, monitoring, or screening for bladder cancers.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The Health Plan and its employees adhere to all State and Federal laws concerning the confidentiality of genetic testing and the results of genetic testing. All records, findings and results of any genetic test performed on any person shall be deemed confidential and shall not be disclosed without the written informed consent of the person to whom such genetic test relates. This information shall not be released to any person or organization not specifically authorized by the individual subject of the test or in compliance with applicable law.

II. Genetic testing is appropriate only when performed by a qualified laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and offered in a setting with adequately trained health care professionals who are qualified to provide appropriate pre- and post-test counseling.

III. Genetic testing is contract dependent. Coverage only applies to members with a valid contract; coverage is not provided for family members without a valid contract.

DESCRIPTION

Bladder Cancer

Bladder cancer (transitional cell carcinoma or TCC) typically presents as a tumor confined to the superficial mucosa of the bladder and is treated with transurethral resection. The only symptom of early bladder cancer is hematuria; confirmatory diagnosis of bladder cancer must be made by cystoscopic examination, which is considered to be the "gold standard." There is a 75% incidence of recurrence in bladder cancer patients, and follow-up care includes surveillance cystoscopy and serial evaluations of urine cytology. While urine cytology is a specific test (90-100%), its sensitivity is lower (50-60%) and is considered even lower for low-grade tumors. Therefore, there has been interest in

identifying tumor markers in voided urine that would provide a more sensitive and objective test for tumor recurrence.

Bladder Tumor Antigen (BTA) Tests

The BTA stat test is a single-step qualitative test performed on voided urine. It measures human complement factor H-related proteins produced by several human bladder cell lines, but not by other epithelial cell lines. The BTA TRAK test provides a quantitative determination of the same protein. The BTA tests have an improved sensitivity compared to cytology, but lower specificities due to high false-positive rates associated with recent instrumentation, stones, or inflammatory conditions such as benign prostatic hypertrophy (BPH).

ImmunoCyt Tests

The ImmunoCyt test uses fluorescence immunohistochemistry with antibodies to a mucin glycoprotein and a carcinoembryonic antigen (CEA), these antigens are found on bladder tumor cells. It detects cellular markers specific for transitional call cancer using voided urine in patients with bladder cancer.

Nuclear Matrix Protein (NMP-22) Tests

The NMP-22 test is a quantitative test for tumor-related proteins measured in urine. The NMP-22 assay measures nuclear matrix proteins that are involved in DNA replication and RNA synthesis during mitosis. NMP-22 is a protein associated with the nuclear mitotic apparatus. It is thought that this protein is released from the nuclei of tumor cells during apoptosis. Normally, only very low levels of NMP-22 can be detected in the urine, but elevated levels may be associated with bladder cancer. The specificity and sensitivity of NMP-22 are similar to BTA stat.

Fluorescence In Situ Hybridization (FISH) DNA Probe Technology Tests

FISH DNA probe technology has been used to detect chromosomal abnormalities in voided urine, to assist not only in bladder cancer surveillance, but also in the initial identification of bladder cancer. FISH DNA probe technology is a technique to visualize nucleic acid sequences within cells by creating short sequences of fluorescently labeled, single-strand DNA, called probes, that match target sequences. The probes bind to complementary strands of DNA, allowing for identification of the location of the chromosomes targeted. The sensitivity and specificity of the FISH assay are proposed to be higher than for the BTA tests.

These tests are proposed for use in conjunction with cystoscopy in the surveillance of patients for recurrent bladder cancer, but not intended to replace the procedure. The BTA, NMP-22, and FISH DNA probe technique tests have additionally been proposed as an initial test in patients with signs and symptoms suggestive of bladder cancer.

Multiplex Protein-based Immunoassay Test

Oncuria, DiaCarta, Ltd is a test for predicting the response to bacillus Calmette-Guérin (BCG) therapy via midstream voided urine. The Oncuria assay and proprietary algorithms use 10-biomarkers (A1AT & SERPIN A1, ANG, APOE, CA9, IL-8, MMP-9, MMP-10, PAI-1 & SERPIN E1, SDC1, and VEGF-A) to aid in the diagnosing of bladder cancer, monitoring people with early-stage bladder cancer and

predicting whether patients with intermediate- to high-risk, early-stage bladder cancer will respond to BCG therapy.

SUPPORTIVE LITERATURE

Urinary Biomarkers

Soputro et al (2022) conducted a systematic review and meta-analysis to evaluate the diagnostic performance of FDA approved urinary biomarkers in the evaluation of primary hematuria without a prior history of bladder cancer. Included were 18 studies, and within those studies the biomarkers that were assessed were, Cxbladder, AssureMDx, BTA, NMP22, UroVysion and Immunocyt/uCyt+. The sensitivities of the biomarkers range between 0.659 and 0.973 and their specificities range between 0.577 and 0.833. Based on the results, and the variability in the performance of the biomarker testing, researchers are suggesting more high-quality prospective studies be completed to analyze when biomarkers would best be utilized.

Ecke et al (2023) conducted a multicenter study comparing all available rapid tests (BTA stat, NMP22 BladderChek, UBC Rapid Test, and CancerCheck UBC rapid VISUAL) on a cohort of 732 urine samples; 464 with histologically confirmed urothelial tumors of the bladder, 77 with no evidence of disease, and 91 healthy controls. The sensitivities that were calculated for low-grade were BTA stat 62.4%, NMP22 Bladder Chek 13.4%, UBC Rapid Test 58.2%, CancerCheck UBC rapid VISUAL 28.6%, and cytology 36.2%. For high-grade non-muscle invasive sensitivities were BTA stat 83.4%, NMP22 Bladder Chek 49.5%, UBC Rapid Test 84.5%, CancerCheck UBC rapid VISUAL 63.1%, and cytology 71.2%. For high-grade muscle-invasive, sensitivities were BTA stat 95.8%, NMP22 Bladder Chek 35.2%, UBC Rapid Test 76.1%, CancerCheck UBC rapid VISUAL 50.7%, and cytology 67.7%. Due to infections, other tumor diseases, diabetes, stones and mechanical manipulation most of the tests have relatively high rates of false positive tests.

Cxbladder Triage (CxbT)

Lotan et al (2024) conducted a multicenter prospective randomized controlled trial (RCT) to compare the use of CxbT to traditional cystoscopy (control) in patients with microhematuria. Participants were categorized as lower risk (3 to 29 RBCs/hpf and minimal smoking history of less than 10 packs/year) and not lower risk (NLR) (greater than 30 RBC/hpf or greater than 10 pack/year smoking history). All participants provided urine for a CxbT. The lower risk participants were randomized into two groups, the test group (provided with eh CxbT results) and the standard of care control group. There were 255 participants in the not lower risk group that received CxbT but otherwise received standard of care. 135 participants were randomized to the CxbT informed decision or standard of care group. Results from the CxbT overall were 63% negative. 82% of the NLR participants received a cystoscopy. In the low-risk control group cystoscopy was performed 67% of the standard of care group and 27% in the test group. When comparing cystoscopy to CxbT, it stated that CxbT had 90% sensitivity, 56% specificity and 99% negative predictive value for urothelial cancer. There were some limitations to the study that could have influenced the study results. First follow-up was lower than expected in participants who did not have a cystoscopy, resulting in many of them not having the requested repeat CxbT values or ultrasounds. The risk stratification for the study did not align with the most current 2020 American Urological Association (AUA) guidelines for microhematuria; leading

to many of the participants in the low-risk group being miscategorized and they would have likely been labeled as intermediate or high-risk. Finally, 10 of the low-risk patients in the test arm were given an additional test, Cxbladder Detect with the results, without those results the participants may have chosen to not have a cystoscopy.

Wu et al (2024) conducted a double-blinded, multicenter, prospective study, evaluating the feasibility of a multitarget urine tumor DNA test, UI-seek, for urothelial cancers (UC). A total of 947 participants were included which consisted of 417 individuals that had confirmed UC pathology, 391 participants with benign urologic diseases and 139 with non-urinary UC. The test demonstrated a sensitivity of 91.37% and a specificity of 95.09%. The sensitivity for low-grade Ta tumors was 75.81% and high-grade Ta and higher stages (T1 to T4) was 93%. Simultaneous identification of both bladder and upper urinary tract tumors was enabled with sensitivities exceeding 90%. The test showed improved sensitivities over urine cytology, the NMP22 test, and UroVysion FISH alongside comparable specificities. The single target accuracy was greater than 98%. Post-surgery UC-score decreased in 97.7% of subjects. Limitations include, the number of individuals enrolled, enrollment was based on systematic population needing a larger-scale prospective study, and lack of long-term follow-up.

FISH Technology

Placer et al (2002) conducted a comparison of cystoscopy with biopsy or tumor resection to urine cytology and FISH analysis in urine sample of 86 patients reported finding overall sensitivity of FISH to be 80.4% vs. 63.8% for urine cytology. Sensitivities reported by tumor grades 1, 2 and 3 were 53.3%, 83.3% and 100% for FISH and 25%, 66% and 94.7% for urine cytology, respectively. Two multicenter trials compared FISH to the BTA Stat test and voided urine cytology. In the first study of 176 patients with known transitional cell carcinoma (TCC), sensitivities were 71% for FISH, 50% for BTA Stat, and 26% for cytology. In the second study of 275 healthy volunteers and patients with conditions other than TCC, the specificity of FISH was 94.5%.

Multiplex Protein-based Immunoassay Test (Oncuria, DiaCarta Ltd)

There are three clinical trials that are currently recruiting (NCT03193541, NCT03193528) these large multicenter, international prospective clinical trials will include first-event diagnosis and disease recurrence monitoring (Hirasawa et al, 2021). The diagnostic performance of Oncuria was performed by Hirasawa et al. (2021), the test was evaluated in a multi-institutional cohort of 362 prospectively collected subjects presenting for bladder cancer evaluation. The parallel measurement of 10 biomarkers (A1AT, APOE, ANG, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) was performed in an independent clinical laboratory. Bladder cancer status was confirmed by cystoscopy and tissue biopsy. The hybrid signature achieved an overall sensitivity of 0.93, specificity of 0.93, PPV of 0.65 and NPV of 0.99 for bladder cancer classification. Sensitivity values of the diagnostic panel for high-grade bladder cancer, low-grade bladder cancer, MIBC and NMIBC were 0.94, 0.89, 0.97 and 0.93, respectively. Additional studies are needed to evaluate the value of the test in clinical decision making.

PROFESSIONAL GUIDELINE(S)

National Comprehensive Cancer Network (NCCN) guidelines for Bladder Cancer (Version 1.2025) discuss the use of urinary urothelial tumor markers for surveillance in high-risk, non-muscle invasive bladder cancer they state:

- "Many of the tests have higher sensitivity for detecting bladder cancer than urinary cytology, but the specificity is lower. It remains unclear whether these tests offer additional useful information for detection and management of non-muscle invasive bladder tumors. Therefore, the panel considers them to be a category 2B recommendation."

The American Urological Association (AUA) and Society of Urologic Oncology (SUO) made an amendment in 2024 to the guidelines for the diagnosis and treatment of non-muscle invasive bladder cancer (NMIBC) which addresses urine biomarkers.

- "In a patient with NMIBC, a clinician may use biomarkers to assess response to intravesical BCG (UroVysion FISH) and adjudicate equivocal cytology (UroVysion FISH and ImmunoCyt). (Expert Opinion)"
- "Novel urinary biomarkers-The current consensus of the panel describes a limited role to replace cystoscopic surveillance in NMIBC, the future direction in this field holds promise for future clinical application."

AUA and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) 2020 guidelines (Amended 2025) for microhematuria state:

- "Clinicians should not routinely use urine cytology or urine-based tumor markers to decide whether to perform cystoscopy in the initial evaluation of low/negligible- or high-risk patients with microhematuria. (Strong Recommendation; Evidence Level: Grade C)."
- "Clinicians should not routinely use cytology or urine-based tumor markers as adjunctive tests in the setting of a normal cystoscopy. (Strong Recommendation; Evidence Level: Grade C)."
- "Clinicians may obtain urine cytology for high-risk patients with equivocal findings on cystoscopic evaluation or those with persistent microhematuria and irritative voiding symptoms or risk factors for carcinoma in situ after a negative work up. (Expert Opinion)."

The U.S. Preventive Services Task Force (USPSTF) concluded that tumor markers do not have a proven role in screening of asymptomatic persons for early detection of bladder cancer.

- The August 2011 USPSTF and 2019 recommendation statement, Screening for Bladder Cancer, conclude that the current evidence is insufficient to assess the balance of benefits and harms of screening for bladder cancer in asymptomatic adults.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety,

efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2025 May 13]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2025 May 13]

The U.S. Food and Drug Administration (FDA) has approved the following tests, including but not limited to:

- Bard BTA Stat test (1995)
- NMP-22 test (1996), NMP22 BladderChek kit (2002)
- Vysis UroVysion Bladder Cancer Recurrence kit (2001)
- ImmunoCyt test (2000)
- Oncuria received breakthrough device designation (2021)

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
86294 (E/I)	Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen [BTA])
86386 (E/I)	Nuclear Matrix Protein 22 (NMP22), qualitative
88120 (E/I)	Cytopathology, in situ hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual
88121 (E/I)	Cytopathology, in situ hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology
0012M (E/I)	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
0013M (E/I)	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

Code	Description
0363U (E/I)	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, andCXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma (Cxbladder triage, Pacific Edge Diagnostic USA)
0365U (E/I)	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer (Oncuria Predict, DiaCarta Clinical Lab, DiaCarta, Inc)
0366U (E/I)	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer (Oncuria Predict, DiaCarta Clinical Lab, DiaCarta, Inc)
0367U (E/I)	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection (Oncuria Predict, DiaCarta Clinical Lab, DiaCarta, Inc)
0420U (E/I)	Oncology (urothelial), mRNA expression profiling by real-time quantitative PCR of MDK, HOXA13, CDC2, IGFBP5, and CXCR2 in combination with droplet digital PCR (ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) genes TERT and FGFR3, urine, algorithm reported as a risk score for urothelial carcinoma (Cxbladder Detect Plus, Pacific Edge Diagnostics USA LTD)
0452U (E/I)	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer (EarlyTect Bladder Cancer Detection (EarlyTect BCD), Promis Diagnostics, Inc)
0465U (E/I)	Oncology (urothelial carcinoma), DNA, quantitative methylation-specific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative (UriFind Urothelial Carcinoma Assay, DiaCarta, Inc, AnchorDx)
0549U (E/I)	Oncology (urothelial), DNA, quantitative methylated real-time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC) (Bladder CARE, Pangea Laboratory LLC) (Effective 04/01/2025)

HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
C67.0-C67.9	Malignant neoplasm of bladder (code range)
D09.0	Carcinoma in situ of bladder
D49.4	Neoplasm of unspecified behavior of bladder
R31.0-R31.9	Hematuria (code range)
Z85.51	Personal history of malignant neoplasm of bladder

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National or Regional Medicare coverage determinations or policies for Urinary Tumor Markers for Bladder Cancer or Urothelial Cancers.

Medicare Managed Care Manual/Chapter 4: Benefits and Beneficiary Protections (Rev.121, Issued: 04-22-16)/Section 90 National and Local Coverage Determinations/Subsection 90.4.1 MAC with Exclusive Jurisdiction over a Medicare Item or Service:

In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare beneficiaries around the country. This generally occurs when there is only one provider of a particular item or service (for example, certain pathology and lab tests furnished by independent laboratories). In this situation, MA plans must follow the coverage policy reflected in an LCD issued by the A/B MAC that enrolled the provider and processes all the Medicare claims for that item or service. Medicare Managed Care Manual 100-16 [accessed 2025 Jun 02]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates	
09/16/99, 09/19/01, 06/20/02, 05/21/03-12/20/12, 10/17/13, 11/20/14, 09/17/15, 07/21/16, 07/20/17, 07/19/18, 07/18/19, 07/16/20, 07/15/21, 07/21/22, 07/20/23, 07/18/24, 07/17/25	
Date	**Summary of Changes**
07/17/25	• Annual review, policy intent unchanged. Code edits, removed 88367, 88373, 88368, and 88369 they are unmanaged and do not pertain to this policy.
01/01/25	• Summary of changes tracking implemented.
09/16/99	• Original effective date