of Tennessee

Policy

Reimbursement Policy

Urinary Tumor Markers for Bladder Cancer

I. Policy Description

Bladder cancer is defined as a malignancy that develops from the tissues of the bladder. It is the most common cancer of the urinary system. The cancer typically arises from the urothelium, although it may originate in other locations such as the ureter or urethra.[1]

Tumor biomarkers are proteins detected in the blood, urine, or other body fluids that are produced by the tumor itself or in response to it. Urinary tumor markers may be used to help detect, diagnose, and manage some types of cancer including bladder cancer.[2]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) Urinary biomarkers (bladder tumor antigen (BTA) test, nuclear matrix protein (NMP22) test, or fluorescence in situ hybridization (FISH) UroVysion Bladder Cancer test) **MEET COVERAGE CRITERIA** in any of the following situations:

   a) As an adjunct in the diagnostic exclusion of bladder cancer for individuals who have an atypical or equivocal cytology.

   b) As an adjunct in the monitoring of high-risk, non-muscle invasive bladder cancer.

2) As an adjunct to cystoscopy or cytology in the monitoring of individuals with bladder cancer, the use of fluorescence immunocytology (ImmunoCyt/uCyt) **MEETS COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

3) For the evaluation of hematuria, to screen for bladder cancer in asymptomatic individuals, to diagnose bladder cancer in symptomatic individuals, or for any other indication not discussed above, the following tests **DO NOT MEET COVERAGE CRITERIA**:

a) Urinary biomarkers (bladder tumor antigen (BTA) test, nuclear matrix protein (NMP22) test, or fluorescence in situ hybridization (FISH) UroVysion Bladder Cancer test).

b) Fluorescence immunocytology (ImmunoCyt/uCyt).

4) Any other urinary tumor markers for bladder cancer not mentioned above **DO NOT MEET COVERAGE CRITERIA**.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: http://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

On April 16, 1997, the FDA approved the *Bard BTA stat™ Test*, created by Bard Diagnostic Sciences Inc. From the FDA site: "the BTA stat test is an *in vitro* diagnostic immunoassay indicated for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer. This test is indicated for use as an aid in the management of bladder cancer patients in conjunction with cystoscopy."[63]

On April 15, 1998, the FDA approved the *BTA TRAK™ Test*, created by Bard Diagnostic Sciences Inc. From the FDA site: "the BTA TRAK test is an *in vitro* diagnostic immunoassay indicated for the quantitative detection of bladder tumor associated antigen in human urine. This test is indicated for use as an aid in the management of bladder cancer patients in conjunction with cystoscopy."[64]

On July 2, 1996, the FDA approved the *MATRITECH NMP22™ TEST KIT*, created by Alere Scarborough Inc. From the FDA site: "The Matritech NMP22 Test Kit is an enzyme immunoassay (EIA) for the in vitro quantitative determination of nuclear matrix protein NMP22 in stabilized voided urine."[65]

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On July 30, 2002, the FDA approved the *NMP22 BladderChek*, created by Matritech Inc. From the FDA site: "The Matritech NMP22 BladderChek Test is indicated for professional and prescription home use as an aid in monitoring bladder cancer patients, in conjunction with standard diagnostic procedures." This assay is qualitative.[66]

On January 24, 2005, the FDA approved the *UROVYSION BLADDER CANCER KIT*. From the FDA site: "The UroVysion Bladder Cancer Kit (UroVysion Kit) is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer."[67]

On February 23, 2000, the FDA approved the *ImmunoCyt,* created by Diagnocure Inc. From the FDA site: "ImmunoCyt is a qualitative direct immunofluorescence assay intended for use in conjunction with cytology to increase overall sensitivity for the detection of tumor cells exfoliated in the urine of patients previously diagnosed with bladder cancer. ImmunoCyt is indicated for use as an aid in the management of bladder cancer in conjunction with urinary cytology and cystoscopy."[68]

All of the FDA-approved tests apart from ImmunoCyt are approved for both diagnosis and surveillance of bladder cancer whereas ImmunoCyt is only approved for surveillance.[69]

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86294	Immunoassay for tumor antigen, qualitative or semiquantitative (eg, bladder tumor antigen)
86316	Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each
86386	Nuclear Matrix Protein 22 (NMP22), qualitative
88120	Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual
88121	Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology
88346	Immunofluorescence, per specimen; initial single antibody stain procedure

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CPT	Code Description
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
0012M	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 urothelial carcinoma Proprietary test: Cxbladder™ Detect Lab/manufacturer: Pacific Edge Diagnostics USA, Ltd
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 Proprietary test: Cxbladder™ Monitor Lab/manufacturer: Pacific Edge Diagnostics USA, Ltd
0363U	"Oncology (urothelial), mRNA, gene-expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma Proprietary test: Cxbladder™ Triage Lab/Manufacturer: Pacific Edge Diagnostics USA, Ltd
0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA), by immunoassays, urine, diagnostic algorithm, including patient's age, race and gender, reported as a probability of harboring urothelial bladder cancer Proprietary test: Oncuria® Detect Lab/Manufacturer: DiaCarta Clinical Lab
0366U	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 Proprietary test: Oncuria® Monitor Lab/Manufacturer: DiaCarta Clinical Lab

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CPT	Code Description
0367U	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 Proprietary test: Oncuria® Predict Lab/Manufacturer: DiaCarta Clinical Lab
0420U	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. Proprietary test: Cxbladder Detect Lab/Manufacturer: Pacific Edge Diagnostics USA LTD
0452U	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 Proprietary test: EarlyTect® Bladder Cancer Detection (EarlyTect® BCD) Lab/Manufacturer: Promis Diagnostics, Inc
0465U	Oncology (urothelial carcinoma), DNA, quantitative methylationspecific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative Proprietary test: UriFind® Blood Cancer Assay Lab/Manufacturer: DiaCarta, Inc, AnchorDx
0549U	Oncology (urothelial), DNA, quantitative methylated realtime 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) Proprietary test: Bladder CARETM Lab/Manufacturer: Pangea Laboratory

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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