Priority Health	BILLING POLICY No. 074

URINARY TUMOR MARKERS FOR BLADDER CANCER

Effective date: Apr. 21, 2025 **Date of origin: Feb. 18, 2025**	**Review dates: None yet recorded**

APPLIES TO

- Commercial
- Medicare follows CMS unless otherwise stated
- Medicaid follows MDHHS unless otherwise stated

DEFINITION

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 bladder cancer.

FOR MEDICARE

For indications that do not meet criteria of NCD, local LCD or specific medical policy, a Pre-Service Organization Determination (PSOD) will need to be completed. Find more information on PSOD in our Provider Manual.

MEDICAL POLICY

#91540 – Genetics: Counseling, Testing & Screening

POLICY SPECIFIC INFORMATION

Frequency

- Only one bladder cancer test per single date of service (e.g., FISH then reflex cytology) is considered reasonable and necessary.
- For high-risk patients with persistent hematuria and a negative FISH assay following a comprehensive diagnostic (no tumor identified) workup, one repeat FISH testing in conjunction with cystoscopy is considered reasonable and necessary within one year of the original attempted diagnosis.

Follow-up after initial diagnosis

Maximum of:

- 4 bladder tumor marker studies per year for years 1-2
- 3 bladder tumor marker studies per year for year 3
- 2 bladder tumor marker studies for year 4 and
- 1 bladder tumor marker studies follow-up annually for up to 15 years

Coding specifics

- **86294**: Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen)
- **86316**: Immunoassay for tumor antigen; other antigen, quantitative, 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
- **88350**: Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
- **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, algorithm reported as a probability of 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
- **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.

Place of service
Coverage will be considered for services furnished in the appropriate setting to the patient's medical needs and condition. Authorization may be required. Get more information.

Documentation requirements
Get more information on laboratory and pathology documentation requirements in Priority Health billing policy #015 – Lab and Pathology.

Modifiers
Priority Health follows standard billing and coding guidelines which include CMS NCCI. Modifiers should be applied when applicable based on this guidance and only when supported by documentation.

Incorrect application of modifiers will result in denials. Find more information on modifier use in our Provider Manual.

Resources
- Article: Billing and Coding: Bladder/Urothelial Tumor Markers (A56471) (CMS)
- LCD: Bladder/Urothelial Tumor Markers (L36975) (CMS)
- Urinary Tumor Markers for Bladder Cancer (BCBS of Tennessee)

DISCLAIMER
Priority Health's billing policies outline our guidelines to assist providers in accurate claim submissions and define reimbursement or coding requirements if the service is covered by a Priority Health member's benefit plan. The determination of visits, procedures, DME, supplies and other services or items for

coverage under a member's benefit plan or authorization isn't being determined for reimbursement. Authorization requirements and medical necessity requirements appropriate to procedure, diagnosis and frequency are still required. We use Current Procedural Terminology (CPT), Centers for Medicare and Medicaid Services (CMS), Michigan Department of Health and Human Services (MDHHS) and other defined medical coding guidelines for coding accuracy.

An authorization isn't a guarantee of payment when proper billing and coding requirements or adherence to our policies aren't followed. Proper billing and submission guidelines must be followed. We require industry standard, compliant codes defined by CPT, HCPCS and revenue codes for all claim submissions. CPT, HCPCPS, revenue codes, etc., can be reported only when the service has been performed and fully documented in the medical record to the highest level of specificity. Failure to document for services rendered or items supplied will result in a denial. To validate billing and coding accuracy, payment integrity pre- or post-claim reviews may be performed to prevent fraud, waste and abuse. Unless otherwise detailed in the policy, our billing policies apply to both participating and non-participating providers and facilities.

If guidelines detailed in government program regulations, defined in policies and contractual requirements aren't followed, Priority Health may:

- Reject or deny the claim
- Recover or recoup claim payment

An authorization on file for an item or services doesn't supersede coding, billing or reimbursement requirements.

These policies may be superseded by mandates defined in provider contracts or state, federal or CMS contracts or requirements. We make every effort to update our policies in a timely manner to align to these requirements or contracts. If there's a delay in implementation of a policy or requirement defined by state or federal law, as well as contract language, we reserve the right to recoup and/or recover claim payments to the effective dates per our policy. We reserve the right to update policies when necessary. Our most current policy will be made available in our Provider Manual.

CHANGE / REVIEW HISTORY

Date	Revisions made