Local Coverage Determination (LCD): Bladder/Urothelial Tumor Markers (L36680)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
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LCD Information

Document Information

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Bladder/Urothelial Tumor Markers

Notice Period End Date
05/15/2017

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CMS National Coverage Policy Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Title XVIII of the Social Security Act, §1862(a)(7) and 42 Code of Federal Regulations (CFR), §411.15, exclude routine physical examinations.

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

42 Code of Federal Regulations (CFR) §410.32 and §410.33, indicates that diagnostic tests are payable only when ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in such treatment.

CMS Internet-Only Manual, Publication 100-08, *Medicare Program Integrity Manual,* Chapter 3, §3.4.1.3, Diagnosis code requirements.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

INDICATIONS

Gross painless hematuria is often the first manifestation of a urothelial tumor. Since the degree of hematuria bears no relation to the seriousness of the underlying disease, the microscopic finding of blood in the urine is a serious symptom until significant pathology has been excluded.

At this time, there is no published consensus from the following national organizations: National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), American Urological Association (AUA) and the International Bladder Cancer Consensus Group (IBCCG) regarding the management of persistent asymptomatic microscopic hematuria. Due to insufficient supporting data, the AUA's 2001 best practices policy could not recommend routine use of voided urinary markers in the evaluation of patients with microscopic hematuria.(3)

Recommended surveillance schedules for patients with a previous negative evaluation for unexplained microscopic hematuria include annual urinalysis and voided urinary cytology until the hematuria resolves, or for

up to three years if microscopic hematuria persists. The AUA has been silent regarding practice guidelines due to the paucity of prevalence studies on asymptomatic microscopic hematuria.

Cystoscopy in conjunction with bladder tumor markers is the standard practice to evaluate patients with symptoms suggesting bladder cancer and to monitor treated patients for recurrence or progression. Although cystoscopy is considered the "gold standard", studies have shown that up to 20% of tumor can be missed. Urinary cytology has close to a 90%-100% specificity, but only 10%-50% sensitivity for low grade urinary cancer (UC) detection. Due to this deficit, clinicians have sought noninvasive tumor markers detectable in urine.

Upwards of 50% of patients have recurrence of bladder cancer within five (5) years.

After initial diagnosis and treatment, patients with UC are frequently monitored every three months for the first two years, every four months for the third year then usually twice a year for the fourth year. Annual monitoring is recommended during years 5 through 15.

Diagnostic and Surveillance Tests

- **BTA TRAK®** - a quantitative determination of human complement factor H-related protein
- **Nuclear matrix protein 22 (NMP-22)** – detects nuclear mitotic apparatus protein believed to be released during apoptosis; a quantitative assay, which is either positive of negative
- **NMP-22 BladderChek®** – a CLIA-waved assay, point of care test with an immunochromographic qualitative format taking 20 minutes to perform
- **The UroVysion®** Bladder Cancer Kit is fluorescence in situ hybridization (FISH) DNA probe technology. It is designed to detect aneuploidy for chromosomes 3, 7, 17 and loss of the 9p21 locus. This assay involves visualization of nucleic acid sequences within cells by creating short sequences of fluorescently labeled, single-strand DNA probes that match target sequences. The probes bind to complementary strands of DNA to identify the targeted chromosome(s) location. It is 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.

Scientific studies demonstrate the sensitivity of BTA and NMP-22 are superior to urinary cytology.(1) Studies affirm the adjunctive value of BTA stat® and NMP-22 in suspected and known bladder cancer in conjunction with cystoscopy. However, false positive results occur more frequently in the presence of hematuria, nephrolithiasis, recent GU instrumentation, inflammation and other urological malignancies. Administration of BCG within 2 years of testing decreases specificity to 28%.

The DNA probe assay has high sensitivity (81%) and specificity (96%) for high grade tumors but lower sensitivity (36-57%) for low grade and stage tumors. The assay specificity approaches that of cytology, and can be utilized in patients recently treated with intravesical bacillus Calmette-Guerin (BCG). This can result in a positive UroVysion® test with a negative study for UC. This assay has also been shown to be useful in predicting tumor recurrence following BCG therapy.

At present the IBCCG has recommended that tumor markers be used in conjunction with cystoscopy. They also concluded that routine screening for bladder cancer is not cost-effective.(3) The US Preventive Services Task Force concluded bladder tumor markers do not have a proven role in screening of asymptomatic patients for early detection of bladder cancer.(3) NCCN, ASCO, and AUA are silent regarding the utilization of these bladder tumor markers.

Surveillance Tests

- **BTA (bladder tumor antigen) stat®** - a qualitative CLIA-waved test that identifies a human complement factor H-related protein produced by several human bladder cell lines

- **The ImmunoCyt™** test is cleared for monitoring bladder cancer recurrence only in conjunction with cytology and cystoscopy. The assay uses fluorescent labeled antibodies to 3 markers (carcinoembryonic antigen, and musicians LDQ10 and M344) commonly found on malignant exfoliated urothelial cells. The ImmunoCyt™ assay has also been shown to be more sensitive than urine cytology.

LIMITATIONS

Cystoscopy in conjunction with bladder tumor markers is standard practice to evaluate patients with symptoms suggesting bladder cancer and to monitor treated patients for recurrence or progression. Exceptions, such as high grade bladder cancers s/p radical cystectomy, do exist which preclude cystoscopy prior to testing. Testing indications, limitations and frequency do not apply to urine cytology.

Bladder cancer tumor markers performed by any technology, immunoassay, molecular or FISH testing are not covered for screening of all patients with hematuria. Bladder tumor markers are not expected to be performed until other diagnostic studies fail to identify the etiology of the hematuria. Urine cytology is not considered a bladder tumor marker.

All other bladder cancer marker assays, including but not limited to the following, regardless of the methodology are considered investigational and not covered by Medicare:

- BCLA-4
- BLCA-1
- Hyaluronic acid
- Hyaluronidase
- Lewis X antigen
- Microsatellite markers
- Quanticyt
- Soluble FAS TATI (tumor associated trypsin inhibitor)
- Soluble e-cadherin
- Survivin
- Telomerase
- UBC™ Rapid Test (urinary bladder cancer test for cytokeratins 8 and 18)

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A
Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999 Not Applicable

CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:

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

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.098	Malignant carcinoid tumors of other sites
C7A.8	Other malignant neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
C78.00	Secondary malignant neoplasm of unspecified lung
D09.0	Carcinoma in situ of bladder
D41.4	Neoplasm of uncertain behavior of bladder
D49.4	Neoplasm of unspecified behavior of bladder
R31.0	Gross hematuria
R31.1	Benign essential microscopic hematuria
R31.21*	Asymptomatic microscopic hematuria
R31.29*	Other microscopic hematuria
R31.9	Hematuria, unspecified
Z78.9*	Other specified health status
Z85.51	Personal history of malignant neoplasm of bladder

Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation: R31.21 and R31.29 To be used only when repeat testing is believed to be medically reasonable and necessary, and must be listed as secondary with the primary neoplastic diagnosis.

Z78.9 To be used only when repeat testing is believed to be medically reasonable and necessary, and must be listed as secondary with the primary neoplastic diagnosis.

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information

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General Information

Associated Information
Documentation Requirements

The medical record must clearly identify the number and frequency of bladder marker testing.

Medical record documentation must be legible, must be maintained in the patient's medical record (hard copy or electronic copy), and must meet the criteria contained in this LCD and be made available to the A/B MAC upon request.

Utilization Guidelines

- Only one bladder cancer test per single date of service (e.g., FISH then reflex cytology) are 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 1 year of the original attempted diagnosis.

Follow-up after initial/most recent occurrence and treatment

- Maximum of four (4) bladder tumor marker studies per year for years 1-2
- Maximum of three (3) bladder tumor marker studies per year for year 3
- Maximum of two (2) bladder tumor marker studies for year 4 and
- Maximum of one (1) bladder tumor marker studies follow-up annually for up to 15 years.

Sources of Information and Basis for Decision

1. BTA stat® test package insert.

2. Grossfeld GD, Litwin MS, Wolf JS Jr, et al. Evaluation of asymptomatic microscopic hematuria in adults: the American Urological Association best practice policy part II: patient evaluation, cytology, voided markers, imaging, cystoscopy, nephrology evaluation, and follow-up. *Urology*. 2001;57(4):604-10.

3. Guide to Clinical Preventive Services, www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/section2.html#Bladder" Accessed on January 13, 2015.

4. Lokeshwar VB, Habuchi T, Grossman HB, et al. Bladder tumor markers beyond cytology: International Consensus Panel on bladder tumor markers. *Urology.* 2005;66:35.

5. Messing EM, Teot L, Korman H, et al. Performance of urine test in patients monitored for recurrence of bladder cancer: a multicenter study in the United States. *J Urol.* 2005;174(4 pt 1):1238-41.

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Revision History Information

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55029 - Bladder Tumor Marker FISH Billing and Coding Guidelines A55458 - Response to Comments: Bladder/Urothelial Tumor Markers LCD(s) DL36680 - Bladder Tumor Markers

Related National Coverage Documents N/A

Keywords

- Bladder
- Tumor
- Markers
- UroVysion®
- NMP-22
- BTA
- Trak
- ImmunoCyt™
- 86294
- 86316
- 86386
- 88120
- 88121

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