MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

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MP.052.MH – Bladder Cancer Biomarker Tests

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers Bladder Cancer Biomarker Tests medically necessary for the following indications:

UroVysion™ is considered medically necessary when performed in conjunction with current standard diagnostic procedures (i.e. cystoscopy and cytology) for either of the following conditions:
a. Diagnosis of person with hematuria suspected of having bladder carcinoma
b. Subsequent monitoring for tumor recurrence

Limitations
1) UroVysion™ is considered not medically necessary when cystoscopy/cytology results are diagnostic for bladder cancer.
2) Bladder tumor marker testing is considered experimental/investigational for population-based screening of asymptomatic patients for bladder cancer.

Background
According to the National Cancer Institute, bladder cancer is the fourth most common cancer in men and ninth most common cancer in women in the United States. The American Urological Association reports that more than 60,000 new cases of bladder cancer are diagnosed each year in the Untied States, accounting for nearly 13,000 deaths annually. Bladder cancer, also known as transitional cell carcinoma (TCC), is a heterogeneous disease, and the most common malignancy of the urinary tract (>90% of the cases). Several urine based bladder tumor marker tests have been developed as an adjunct to cytology and cystoscopy for the diagnosis and follow-up of patients with TCC. Some of the U.S. Food & Drug Administration's (FDA) approved bladder tumor detection tests include:

Tests for detecting urinary bladder tumor-associated antigen (BTA):

- The Bard BTA (bladder tumor antigen) Test Kit - this test was the first approved by the FDA November 29, 1995. Its indication was expanded in 1998 to include home use.
- The BTA TRAK test – this test was FDA approved April 15, 1998 and is completed in the laboratory.

Tests for detecting nuclear matrix protein 22 (NMP22):

- Matritech NMP22 Test Kit – this test was FDA approved July 2, 1996.
- NMP22 BladderCheck Test – this test was FDA approved July 30, 2002. This test can be used in the doctor's office or at home.

UroVysion™ fluorescent in situ hybridization (FISH) test by Abbott – in 2001 (August 3, 2001) the FDA granted premarket approval for this Class II test for monitoring tumor recurrence in patients with a history of bladder cancer and in 2005 (January 24, 2005) also as an aid for initial diagnosis of bladder cancer in patients in conjunction with cystoscopy

These tests and other bladder tumor marker tests have low specificity. Urine is a dynamic fluid, and the results of a bladder tumor marker test can be influenced by conditions such as infection or hematuria affecting the composition of the urine. For this reason, no single bladder tumor marker has emerged as the generally accepted test of choice and none can be used as a screening tool for detecting bladder malignancy.

UroVysion™ (Abbott Molecular, Inc., Des Plaines, IL) is a multitarget FISH assay that detects aneuploidy in chromosomes 3, 7, and 17 as well as loss of 9p21 locus via FISH in urine. This test is used in conjunction with cystoscopy and cytology when results from these procedures are inconclusive.

There is insufficient published medical evidence to support the use of bladder tumor markers other than UroVysion™. There is limited evidence that the NMP22 test could help in a clinician's decision making toward immediate versus delayed cystoscopy in patients with risk factors, signs/symptoms, and/or a history of bladder cancer.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT Codes	

88120	*Cytopathology, in situ hybridization (e.g. FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual (Urovysion™)*
ICD-9 codes covered if selection criteria are met:	
188.0-188.9	Malignant neoplasm of the bladder
198.1	Secondary malignant neoplasm other urinary organs
233.7	Carcinoma in situ of bladder
236.7	Neoplasm of uncertain behavior of genitourinary organs, bladder
239.4	Neoplasm of unspecified nature of bladder
599.70-599.72	Hematuria
V10.51	Personal history of malignant neoplasm of the bladder
ICD-10 codes covered if selection criteria are met:	
C67.0-C67.9	Malignant neoplasm of the bladder
C79.10-C79.11	Secondary malignant neoplasm of bladder
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-R31.9	Hematuria
Z85.51	Personal history of malignant neoplasm of the bladder

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