

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: PAY.052
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SUBJECT: Bladder Tumor Antigen Test
INDEX TITLE: Medical Management
ORIGINAL DATE: October 2007

This policy applies to the following lines of business: (Check those that apply.)

Commercial:				
HMO ()	POS ()	PPO ()	OOA/DOC ()	
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)	
Medicare Select ()	Medicare Supplement ()			
DPW-MA:				
Health Choices ()		Voluntary ()		All (X)
CMS-MA:				
OH ()	WV ()	PA ()	All (X)	Other ()
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X) All ()
PID-CHIP:				
Free ()	Sub ()	Full ()	All (X)	
APPLICABLE TO:				
Community Care ()	Work Partners ()			

I. POLICY

It is the policy of UPMC Health Plan to recognize Bladder Tumor Antigen testing as appropriate and consistent with good medical practice when performed for the indications listed in this policy. Coverage for this service is based upon medical necessity as detailed in this policy and according to the individual member's benefit plan.

II. DEFINITIONS

Bladder tumor antigen testing is a test for the detection of bladder tumor antigen in the urine to monitor the progression and recurrences of bladder cancer.

Cystoscopy is an examination with a narrow, flexible tube-like instrument passed through the urethra to examine the bladder and urinary tract for structural abnormalities or obstructions, such as tumors or stones.

IV pyelography is an X-ray of the urinary tract. A dye is injected to make urine visible on the X-ray and show any blockage in the urinary tract.

Retrograde pyelography uses special contrast agent (dye) to produce detailed X-ray pictures of the ureters and kidneys – the dye is injected into the ureters rather than a vein. **Urine cytology** is the microscopic examination of cells obtained from a urine sample.

III. PURPOSE

The purpose of this policy is to define the appropriate indications for coverage of Bladder Tumor Antigen testing.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description/Background

Bladder tumor antigen (BTA) is a latex agglutination assay for the qualitative detection of bladder tumor antigen in the urine. This tumor marker can be used in the monitoring and surveillance of treatments for patients with previously diagnosed bladder cancer. It is considered experimental when used for the screening of bladder cancer.

Because of the low sensitivity of cytology, several urine based tests have been developed as an adjunct to cytology and cystoscopy for the diagnosis and follow-up of patients with transitional cell carcinoma (TCC). These tests are usually objective, qualitative or quantitative and have higher sensitivity than cytology but some have lower specificity. No single bladder tumor marker has emerged as the generally accepted test of choice and none is a screening tool for detecting bladder malignancy. The urine based marker tests have been shown to be accurate in detecting low grade bladder tumors. These tests may be of help in deciding the need for further diagnostic testing of patients with a previous history of bladder cancer and negative results on urine cytology. An elevated level of bladder tumor marker in a patient with a history of TCC may warrant earlier rather than delayed cystoscopic examination. Likewise, consideration may be given to lengthening cystoscopic evaluation when values of the tumor markers are normal.

Some of the U.S. Food & Drug Administration's (FDA) approved bladder tumor detection tests are:

- BTA (Bladder Tumor Antigen) Stat test by BARD Diagnostic - this test was the first approved by the FDA in 1995 as a class II device. It could be used in the physician office or at home. The BTA TRAK test is done in the laboratory.

- NMP22 test (nuclear matrix protein) – the FDA approved this Class II device in 2002. This test could be used in the doctor’s office or at home.
- AccuDx by Intracel (formerly called AuraTek) (fibrin/fibrinogen degradation products) is a rapid urine dipstick immunoassay lab test. This lab test is categorized by the FDA as part of their clinical laboratory improvements amendments (CLIA).
- UroVysion fluorescent in situ hybridization (FISH) test by Abbott – in 2005 the FDA granted premarket approval for this Class II test as an aid for initial diagnosis of bladder cancer in patients with hematuria in conjunction with cystoscopy and in 2001 also for monitoring tumor recurrence in patients with a history of bladder cancer.
- There are other tumor marker tests which are under investigation – CYFRA21-1, Sialyl LewisX, BLCA-4, Cangen test (in clinical trials).

B. Indications

Bladder tumor antigen testing is **only** indicated for the following:

- Follow-up treatment for bladder cancer
- Monitoring for the eradication of bladder cancer **or**
- Recurrence after eradication.

C. Limitations

Bladder tumor antigen testing is considered experimental/investigational for the screening of bladder cancer.

D. Variations

N/A

F. Quality Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan’s Technology Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

H. References

1. Centers for Medicare & Medicaid Services, LCD 1303 - *Bladder Tumor Antigen*, revision date 09/01/2008
2. Highmark Medical Policy Bulletin Number L-28, *Tumor Markers*, Issued Date 01/01/2009
3. Cigna HealthCare, *Tumor Markers for Diagnosis and Management of Cancer*, Coverage position Number 0172, Effective date 12/15/2008
4. ECRI, Health Technology Forecast, *Molecular screens for bladder cancer*, 11/14/2006
5. *Bladder Cancer Highlights* from AUA 2006 meeting by Cathy Lee MD, American Urological Association, www.medscape.com/viewarticle/537508
6. Aetna, Clinical Policy Bulletin 0352, *Tumor Markers*, 12/19/2008
7. *Prostate and Bladder Cancer Screening*, Journal of the American College of Surgeons, Martin Goldstein MD and Edward Messing MD, Special Article for Urology, 10/28/1997,
8. World Journal of Urology, *The use of the BTA Test in the detection of persistent or recurrent transitional cell cancer of the bladder*, 1997
9. U.S. Food and Drug Administration Center for Devices and Radiologic Health, BARD Diagnostic Sciences BARD BTA Test Kit
10. *A comparison of BTA stat, hemoglobin dipstick and UroVysion assays for the detection of urothelial carcinoma in urine*, Journal of Urology, May 2002
11. *Diagnostic value of urinary molecular markers in bladder cancer*, Anticancer Research Sept-Oct 2003
12. *Can urine bound diagnostic tests replace cystoscopy in the management of bladder cancer*, Journal of Urology, June 1998
13. *Rapid detection of bladder cancer: a comparative study of point of care tests*, Journal of Urology 1997; 158(6):2098-101, Queen's University, Kingston, Ontario, Canada
14. *Multicenter Trial of the Quantitative BTA TRAK Assay in the Detection of Bladder Cancer*, Clinical Chemistry 45:4, 1999, 472-477

Disclaimer:

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