MetroPlus Health

Policy and Procedure

Title: Urinary Biomarker	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 8/29/2022	**LOB: Medicaid, Medicare, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP**
Effective Date: 8/29/2022	**Policy Number: UM-MP339**
Review Date: 8/29/2023	**Cross Reference Number:**
Retired Date:	**Page 1 of 4**

1. POLICY DESCRIPTION:

Prompt diagnosis of urothelial cell carcinoma of the bladder is dependent on recognizing its early symptomatology—hematuria. Microhematuria can be widely prevalent in urine specimens however, the associated etiologies are diverse. The incidence of genitourinary malignancies in all patients with MH is estimated at less than 1%.

The American Urologic Association's guideline on "Diagnosis, evaluation and follow-up of asymptomatic microhematuria in adults" (Davis et al, 2012) stated that "The use of urine cytology and urine markers, bladder tumor antigen and UroVysion fluorescence in situ hybridization assay is not recommended as part of the routine evaluation of the asymptomatic microhematuria patient". They also clarified in recent guidance that "Clinicians should not use urine cytology or urine-based tumor markers in the initial evaluation of patients with microhematuria as insufficient evidence exists that routine use would improve detection of bladder cancer".

Urine-based tumor markers have a role in the detection of bladder cancer recurrence as an adjunct to cytology and cystoscopy but should not be used as a screening tool for bladder malignancy.

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS:

4. POLICY:

MetroplusHealth considers urinary biomarkers (e.g., bladder tumor antigen (BTA) (e.g., BTA Stat and BTA TRAK) nuclear matrix protein (NMP22) test, the fibrin/fibrinogen degradation products (Aura-Tek FDfP) test or fluorescence in situ hybridization (FISH) (e.g., Pathnostics Bladder FISH test, UroVysion Bladder Cancer test) medically necessary in *any* of the following conditions:

a. Follow-up of treatment for bladder cancer; *or*
b. Monitoring for eradication of bladder cancer; *or*
c. Recurrences after eradication.

MetroPlusHealth considers the BTA Stat test, the NMP22 test, the Aura-Tek FDP test, or the UroVysion fluorescent in situ hybridization (FISH) test and other Urinary Biomarker tests experimental and investigational for screening of bladder cancer, evaluation of hematuria, and diagnosing bladder cancer in symptomatic individuals, and all other indications.

5. LIMITATIONS/ EXCLUSIONS:

Non- Covered ICD-10 Codes (not all-inclusive)

CODE	Description
R31.0-R31.9	Hematuria
Z12.6	Encounter for screening for malignant neoplasm of bladder

6. APPLICABLE PROCEDURE CODES:

CPT	Description
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

7. APPLICABLE DIAGNOSIS CODES:

Covered ICD-10 Codes

CODE	Description
C67.0-C67.9	Malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder

8. REFERENCES:

1. Barocas DA, Boorjian SA, Alvarez RD et al: Microhematuria: AUA/SUFU guideline. J Urol 2020; 204: 778.
2. Mariani AJ, Mariani MC, Macchioni C et al: The significance of adult hematuria: 1,000 hematuria evaluations including a risk-benefit and cost-effectiveness analysis. J Urol 1989; 141: 350.
3. Davis R, Jones JS, Barocas DA et al: Diagnosis, evaluation and follow-up of asymptomatic microhematuria (AMH) in adults: AUA guideline. J Urol, suppl., 2012; 188: 2473.
4. Jung H, Gleason JM, Loo RK et al: Association of hematuria on microscopic urinalysis and risk of urinary tract cancer. J Urol 2011; 185: 1698.
5. Loo RK, Lieberman SF, Slezak JM et al: Stratifying risk of urinary tract malignant tumors in patients with asymptomatic microscopic hematuria. Mayo Clin Proc 2013; 88: 129.

REVISION LOG:

REVISIONS	DATE
Creation date	8/29/2022
Annual Review	8/29/2023

Approved: Glendon Henry Digitally signed by Glendon Henry Date: 2023.09.07 08:56:19 -04'00' **Glendon Henry, MD** **Senior Medical Director**	**Date:**
Approved: Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.09.25 14:59:24 -04'00' **Sanjiv Shah, MD** **Chief Medical Officer**	**Date:**

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.