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### **Contractor's Policy Number**

03-08

### **Contractor's Name**

CareFirst of Maryland Inc., Medicare Part A

### **Contractor Number**

00190

### **Contractor Type**

Fiscal Intermediary

### **LMRP Title**

Bladder Tumor Antigen

### **AMA CPT Copyright Statement**

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### **CMS National Coverage Policy**

- Establishment of national policy supersedes all previous contractor policy

statements, including Local Medical Policy coverage guidelines.

- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically 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, Section 1833(e). This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.

## **Primary Geographic Jurisdiction**

Maryland

Washington, DC

## **Secondary Geographic Jurisdiction**

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

## **CMS Region**

Region III

## **CMS Consortium**

Northeast

## **Original Policy Effective Date**

04/28/1997

**Original Policy Ending Date**

11/24/2002

**Revision Effective Date**

04/21/2003

**Revision Ending Date**

**LMRP Description**

Bladder tumor antigen (BTA) is a latex agglutination assay for the qualitative detection of bladder tumor antigen in the urine. The antigen is composed of basement membrane complexes that have been isolated and characterized from the urine of patients with bladder cancer. The test may be performed rapidly on a voided urine specimen and requires minimal technical expertise.

Bladder tumor antigen may be used as a method of surveillance for patients with previously diagnosed bladder cancer. The predictive value of the test increases when the stage and grade of the tumor advances (i.e., it is more predictive for stage T1 grade 2 than for stage TA grade 1.

**Indications and Limitations of Coverage and/or Medical Necessity**

BTA testing, e.g., the Mentor Accu-Dx Recurrent Bladder Cancer Test, is indicated for patients with biopsy proven bladder cancer. It is used as a surveillance technique to detect recurrent invasive bladder cancer. Active infections of the genitourinary tract, renal or bladder calculi and/or a positive leukocyte reading on a urinalysis test strip may cause false positive results. The

BTA test should not be used for screening.

Medicare would not expect to see this test performed more than four times in a 12-month period.

Benefits of this test may include making a decision whether:

- to perform a flexible versus a rigid cystoscopy; or,
- to avoid local cystoscopy and move directly to the highly probable biopsy/resection/upper tract evaluation which would be performed when there was a negative cystoscopy, but positive voided urine cytology in the past.

The rapid determination of the BTA test result may allow this decision to be made while the patient is being prepared for cystoscopy. This may reduce the number of cystoscopies performed.

### **CPT/HCPCS Section & Benefit Category**

Laboratory/Pathology

### **Type of Bill Code**

13X, 83X

### **Revenue Codes**

30X, 31X

### **CPT/HCPCS Codes**

The AMA and CMS require the use of short descriptors for policies published on the Web. Refer to the CPT book for the long description of the following code:

86294©      Immunoassay, tumor qual

**Not Otherwise Classified (NOC)****ICD-9 Codes that Support Medical Necessity**

Medicare is establishing the following limited coverage for HCPCS 86294:

**Covered for:**

- 188.0 Malignant neoplasm of bladder, trigone of urinary bladder
- 188.1 Malignant neoplasm of bladder, dome of urinary bladder
- 188.2 Malignant neoplasm of bladder, lateral wall of urinary bladder
- 188.3 Malignant neoplasm of bladder, anterior wall of urinary bladder
- 188.4 Malignant neoplasm of bladder, posterior wall of urinary bladder
- 188.5 Malignant neoplasm of bladder, bladder neck
- 188.6 Malignant neoplasm of bladder, ureteric orifice
- 188.7 Malignant neoplasm of bladder, urachus
- 188.8 Malignant neoplasm of bladder, other specified sites of bladder
- 188.9 Malignant neoplasm of bladder, bladder part unspecified
- 198.1 Secondary malignant neoplasm of other urinary organs
- 233.7 Carcinoma in situ of the bladder
- 239.4 Neoplasm of unspecified nature of the bladder
- V10.51 Personal history of malignant neoplasm of the bladder
- V67.2 Follow-up examination following chemotherapy

## **Diagnoses that Support Medical Necessity**

As listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy

## **ICD-9 Codes that DO NOT Support Medical Necessity**

Any diagnosis codes not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy

## **Diagnoses that DO NOT Support Medical Necessity**

Conditions not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

## **Reasons for Denial**

- All other indications not listed in the "Indications and Limitations of Coverage" section of this policy,
- The service is for screening purposes,
- The service is not medically necessary,
- The medical record does not verify that the service described by the HCPCS code was provided, and;
- The service does not follow the guidelines of this policy.

## **Non-covered ICD-9 Codes**

Any diagnosis codes not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

## **Non-covered Diagnoses**

Conditions not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

## **Coding Guidelines**

- To report this service, use the appropriate HCPCS code,
- All of the coverage criteria must be met before this service can be reimbursed by Medicare,
- Diagnosis (es) must be present on any claim submitted, and be coded to the highest level of specificity, and;
- The diagnosis codes(s) must be representative of the patient's condition.

## **Documentation Requirements**

- Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and available to Medicare upon request.

## **Utilization Guidelines**

Medicare will monitor the utilization of this laboratory test through the Medical Review process.

## **Other Comments**

### **Financial Responsibility:**

#### **Provider Liable**

The provider of the service or the ordering physical must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

#### **Beneficiary Liable**

If there is clear evidence that the beneficiary was issued and signed an Advanced Beneficiary Notice (ABN) prior to the service, the liability rests with the beneficiary. Claims for dates of service prior to January 1, 2003 should contain the condition code 20 and occurrence code 32, with date to signify that an ABN was issued to the beneficiary. Absence of these codes will result in a provider liable determination

Claims for dates of service beginning January 1, 2003 should contain the occurrence code 32 with date to signify that an ABN was issued to the beneficiary. Absence of this code will result in a provider liable determination.

Reference: PM AB-02-168, CR 2415

### **Sources of Information and Basis for Decision**

- CareFirst, Inc., Medicare Part A, LMRP for Immunoassay for Tumor Antigen
- TrailBlazer LMRP for Bladder Tumor Antigen

### **Advisory Committee Notes**

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups , which includes representatives from the appropriate specialty(ies).

Advisory Committee Meeting Date:

**Start Date of Comment Period**

**End Date of Comment Period**

**Start Date of Notice Period****Revision History**

<b>Number</b>	<b>Date</b>	<b>Change</b>
03-08	04/21/2003	Information on bladder tumor antigen (86294) extracted from archived LMRP for Immunoassay for Tumor and placed in policy of its own. No new information included, just revised it into its own policy with policy number.
97-04-R4	11/24/2002	LMRP for Immunoassay for Tumor Antigen which contained this code was archived due to implementation of Lab NCD.

**THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1, 1999 ARE AVAILABLE FROM OUR WEBSITE AT [www.marylandmedicare.com](http://www.marylandmedicare.com)**

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