

**Policy terminated because Medicaid covers codes in the same manner as  
Health Choice.**

**Table of Contents**

1.0 Description of the Procedure, Product, or Service ..... 1  
1.1 Medical Term Definitions ..... 1  
2.0 Eligible Recipients ..... 1  
2.1 General Provisions ..... 1  
3.0 When the Procedure, Product, or Service Is Covered ..... 2  
3.1 General Criteria ..... 2  
3.2 Specific Criteria ..... 2  
3.3 Other Medical Policy Guidelines ..... 3  
4.0 When the Procedure, Product, or Service Is Not Covered ..... 3  
4.1 General Criteria ..... 3  
4.2 Specific Criteria ..... 4  
5.0 Requirements for and Limitations on Coverage ..... 5  
5.1 Prior Approval ..... 5  
6.0 Providers Eligible to Bill for the Procedure, Product, or Service ..... 6  
7.0 Additional Requirements ..... 6  
7.1 Compliance ..... 6  
8.0 Policy Implementation/Revision Information ..... 6  
Attachment A: Claims-Related Information ..... 7  
A. Claim Type ..... 7  
B. Diagnosis Codes ..... 7  
C. Procedure Code(s) ..... 7  
D. Modifiers ..... 7  
E. Billing Units ..... 7  
F. Place of Service ..... 7  
G. Co-payment ..... 7  
H. Reimbursement ..... 7

## **1.0 Description of the Procedure, Product, or Service**

Tumor markers are substances in the body that usually indicate the presence of cancer. These markers are usually specific to certain types of cancer and are usually found in the blood or other tissue samples. The markers are thought to be produced by the cancer cells and are a way of determining whether or not a cancer is currently present in the body. A blood sample is taken and mixed with specially shaped proteins to detect these substances. If the marker shows up in the blood, it may help determine if a recipient has cancer, or whether the recipient is responding to cancer treatment. The markers are used to do follow-up monitoring, as well as to diagnose the presence of cancer.

Two techniques for determining the serum levels and the presence of tumor markers are the radioimmunoassay and immunohistochemical assay. Both techniques rely on a system of testing antigen-antibody reactions in the body. An antigen is any substance capable of causing a specific immune response. An antigen may cause the immune response and then also react with the product of that response, i.e., with the antibodies that were produced as a result of introducing foreign proteins into the blood. Radioimmunoassay uses radioactive labelling of the antigen or antibody to detect the extent of the reaction. The immunohistochemical technique uses immunofluorescence.

### **1.1 Medical Term Definitions**

- a. Antibody: a protein that is produced by the immune system against a specific antigen.
- b. Antigen: any substance that the body regards as foreign or potentially dangerous. The body produces antibodies against this substance. Antigens may be soluble substances such as toxins and foreign protein or particulate such as bacteria and tissue cells.
- c. Biliary: pertaining to the bile, to the bile ducts, or to the gallbladder.
- d. Immunofluorescence: a technique where either the antigen or antibody is made fluorescent so that the reaction can be seen as a fluorescing occurrence. It is used to localize small amounts of the antigen or specific antibody.
- e. Immunohistochemical: a system for testing antigen-antibody interactions to histochemical techniques, as in the use of immunofluorescence.
- f. Immunofluorescence is a technique where either the antigen or antibody is made fluorescent so that the reaction can be seen as a fluorescing occurrence. It is used to localize small amounts of the antigen or specific antibody.
- g. Radioimmunoassay: a system for testing antigen/antibody reactions that uses radioactive labelling of the antigen or antibody to detect the extent of the reaction.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NCHC recipients must be enrolled on the date of service.

### 3.0 When the Procedure, Product, or Service Is Covered

#### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

#### 3.2 Specific Criteria

Tumor markers are covered under the NC Health Choice Program when they are determined to be medically necessary because the following medical criteria are met:

- a. **Cancer antigen 125 (CA-125)**: immunoassay of serum CA-125 is considered medically necessary in the following cases:
  1. In recipients with symptoms suggestive of ovarian cancer or in those with known ovarian cancer.
  2. When used as a key decision-making tool to avoid the risks of second-look surgery in recipients with suspected recurrent ovarian cancer.
  3. For monitoring response to treatment of ovarian or other gynecologic cancers, such as endometrial cancer, when used for purposes of guiding recipient management.
  4. When used to differentiate a pelvic mass when there is strong suspicion that the mass is ovarian cancer so that arrangements can be made for the GYN oncologist to be present in the operating room if necessary.
  5. For monitoring recipients diagnosed with primary peritoneal surface cancer.
- b. **CA 15-3 or CA 27.29** when used to monitor recipients with metastatic breast cancer.
- c. **Carcinoembryonic antigen (CEA)** Immunoassay of CEA is considered eligible for coverage for recipients diagnosed with breast cancer for the monitoring of treatment.
- d. **Carcinoembryonic antigen (CEA)** Immunoassay of CEA is considered eligible for coverage for recipients diagnosed with colon cancer who have had surgical resection when any of the following criteria are met:
  1. for evaluation after the surgical resection.
  2. for evaluation of recurrent colon cancer or metastatic disease when the recipient has been treated with chemotherapy.
  3. for the evaluation of response or progress for a recipient treated with chemotherapy for colon cancer.

- e. **Carcinoembryonic antigen (CEA)** Immunoassay of CEA is considered eligible for coverage for recipients diagnosed with non small cell lung cancer to monitor response to treatment.
- f. **Prostate specific antigen (PSA):** Immunoassay (a process that measures and identifies a specific biological substance such as an antigen) of serum PSA is considered eligible for coverage for the following purposes:
  - 1. for monitoring response to treatment of prostate cancer when used for purposes of guiding management;
  - 2. for staging to determine the need for a bone scan in recipients with prostate cancer; or
  - 3. for screening/diagnostic evaluation for prostate cancer.
- g. **Bladder Cancer Tumor antigen such as BTA stat or NMP-22** may be medically necessary in the diagnosis and monitoring of bladder cancer only in conjunction with surveillance with cystoscopy in recipients with a history of bladder cancer.
- h. **ImmunoCyte:** The bladder tumor markers using immunohistochemistry test ImmunoCyte may be considered medically necessary in the monitoring of bladder cancer only when used with cystoscopy and cytology.
- i. **CA 19-9** when used to monitor treatment for recipients diagnosed with pancreatic or biliary cancer.
- j. **Chromogranin A (CgA)** may be medically necessary when used to assist in the diagnosis and management of neuroendocrine/carcinoid tumors, neuroblastoma, and small cell lung cancer.
- k. **Human Epididymis Protein 4 (HE4)** may be medically necessary for monitoring recipients with an existing diagnosis of epithelial ovarian cancer.

### 3.3 Other Medical Policy Guidelines

Assays of alpha- fetoprotein (AFP) and carcinoembryonic antigen (CEA) were developed prior to the enactment of the 1976 Food, Drug, and Cosmetic Act, and have not been evaluated. For additional information on CEA, see Common Diagnostic Tests, American College of Physicians, 1987, pp. 257-275.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

## 4.2 Specific Criteria

Tumor markers are not covered under the NC Health Choice Program in the following situations:

### a. Breast Cancer

1. The use of tumor markers for screening in asymptomatic recipients is not covered. It is considered investigational. The NC Health Choice Program does not cover investigational procedures.
2. The following tumor markers for breast cancer are not covered for the differential diagnosis of breast cancer, or for monitoring a recipient's response to treatment. They are considered investigational.
  - a. MCA
  - b. CA549
  - c. CAM26
  - d. CAM29
  - e. Cathespin-D
  - f. DNA Flow Cytometrically Derived Parameters
  - g. p53
  - h. TPA
  - i. MSA
- b. **Immunoassay of serum CA-125:** using tumor markers to screen asymptomatic (without symptoms) women for ovarian disease is considered investigational.
- c. **Tumor Markers for Colorectal Cancer:** The following tumor markers are not covered for the screening, diagnosis, staging, surveillance, or monitoring treatment of recipients with colorectal cancer.
  1. LASA - lipid-associated sialic acid
  2. CA 19-9
  3. DNA Ploidy or Flow Cytometric Proliferation Analysis
  4. p53
  5. ras oncogene
- d. **ImmunoCyte:** The bladder tumor markers using immunohistochemistry test ImmunoCyte is considered investigational in the diagnosis of bladder cancer or for screening for bladder cancer in asymptomatic recipients.
- e. **NMP-22 or BTA stat** is considered investigational for screening for bladder cancer in asymptomatic recipients.
- f. **Other Tumor Markers:** Immunoassays of the following chemicals are considered investigational as tumor markers for screening asymptomatic subjects for cancer, for the differential diagnosis of cancer, and for monitoring the response to treatment including, but not limited to:
  1. oa2-PAG - pregnancy-associated alpha-2 glycoprotein

2. BCM - breast cancer mucin
3. CA50 - cancer antigen 50
4. CA72- 4 - cancer antigen 72- 4
5. CA195 - cancer antigen 195
6. CA242 - cancer antigen 242
7. CA549 - cancer antigen 549
8. CA-SCC - squamous cell carcinoma antigen
9. CAM17- 1 - monoclonal antimucin antibody 17- 1
10. CAM-26 - monoclonal antimucin antibody 26
11. CAM-29 - monoclonal antimucin antibody 29
12. CAR-3 - antigenic determinant recognized by monoclonal antibody AR-3
13. DMSA - dimercaptosuccinic acid
14. DU-PAN-2 - sialylated carbohydrate antigen DU- PAN- 2
15. MCA - mucin- like carcinoma associated antigen
16. MSA - mammary serum antigen
17. NSE - neuron specific enolase
18. P- LAP - placental alkaline phosphatase
19. PNA/ELLA - peanut lectin bonding assay
20. SLEX - sialylated Lewis X-1 antigen
21. SLX - sialylated SSEA - 1 antigen
22. SPAN- 1 - sialylated carbohydrate antigen SPAN- 1
23. ST- 439 - sialylated carbohydrate antigen ST- 439
24. TAG12 - tumor- associated glycoprotein 12
25. TAG72 - tumor-associated glycoprotein 72
26. TAG72.3 - tumor-associated glycoprotein 72.3
27. TATI-tumor - associated trypsin inhibitor
28. TNF- a - tumor necrosis factor alpha
29. TPA - tissue polypeptide antigen
30. TPS - a marker of epithelial cells

## **5.0 Requirements for and Limitations on Coverage**

### **5.1 Prior Approval**

Prior approval is not required for tumor markers.

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** July 1, 2010

**Revision Information:**

Date	Section Revised	Change
April 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 <b>“NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”</b>
February 29, 2012	Throughout	Policy Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

CPT Code(s)				
82378	84152	84153	84154	86294
86300	86301	86304	86305	88316
88365				

HCPCS Code
G0103

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Outpatient Hospital and Office

### G. Co-payment

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.