

**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..... 1
3.1 General Criteria..... 1
3.2 Specific Criteria 1

4.0 When the Procedure, Product, or Service Is Not Covered..... 2
4.1 General Criteria..... 2
4.2 Specific Criteria 2
4.3 Policy Guidelines 3

5.0 Requirements for and Limitations on Coverage 3
5.1 Prior Approval 3

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 3

7.0 Additional Requirements 3
7.1 Compliance 3

8.0 Policy Implementation/Revision Information..... 4

Attachment A: Claims-Related Information 5
A. Claim Type 5
B. Diagnosis Codes 5
C. Procedure Code(s)..... 5
D. Modifiers..... 5
E. Billing Units..... 5
F. Place of Service 5
G. Co-payments 5
H. Reimbursement 5

1.0 Description of the Procedure, Product, or Service

Antigens are substances which the body views as foreign or harmful. The body makes antibodies to fight them. Antibodies are proteins that are shaped exactly to fit the target cell or the antigen. Certain antibodies have been manufactured to determine whether certain cancers have spread or metastasized in the patient's body. These radioactive antibodies are injected into the patient. A special type of X-ray study, called a SPECT (single-photon emission computed tomography), is done about 2 to 7 days after the antibodies have been injected. The SPECT uses a "gamma camera" to take pictures of the body. The antibodies will light up in areas where the cancer has spread because they are radioactive. Monoclonal means that the antibodies are all targeted against one type of cancer cell. This procedure is called Monoclonal Antibody Imaging (MAbs) or radioimmunosciintigraphy (RIS).

1.1 Medical Term Definitions:

- a. Colorectal: pertaining to the colon and rectum.
- b. Thrombosis: the formation of a thrombus or clot.

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

Monoclonal antibody imaging is covered under the NC Health Choice Program when it is determined to be medically necessary because the following medical criteria are met:

- a. Monoclonal antibody imaging with Indium-111 satumomab pentetide (CYT- 103) or Technetium-99m (Tc-99m) arcitumomab (IMMU-4, CEA-Scan®) as the monoclonal antibody may be considered medically necessary in recipients with known or suspected recurrent colorectal carcinoma in the following situations:

1. Elevated CEA (carcinoembryonic antigen) level who have no evidence of the disease on CT (or other) scans, in recipients in whom a second look laparotomy is being considered.
 2. Isolated, potentially resectable recurrent tumor on CT (or other) scan, if finding evidence of additional tumor would change the plan of surgery.
- b. Monoclonal antibody imaging using Indium- 111 pentetreotide (Octreoscan®) as the monoclonal antibody may be considered medically necessary for locating the primary and metastatic neuroendocrine tumors that have somatostatin receptors. These tumors usually occur in the pancreas or adrenal glands (such as pheochromocytoma).

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

- a. Monoclonal antibody imaging is not covered for conditions other than those listed in **Subsection 3.2**. There is not enough scientific evidence to substantiate that monoclonal antibody imaging is accurate for, or improves the net health outcome for certain conditions. This list includes the following:
 1. Ovarian cancer
 2. Malignant melanoma
 3. Breast cancer -Scintimammography, (Technetium-99m sestamibi, Miraluma ®)
 4. Lung cancer
 5. Prostate cancer (Indium-111 Capromab Pendetide, Prostascint®)
 6. Thrombosis
 7. Inflammatory disease
 8. Lymphoma
- b. Other monoclonal antibody imaging agents which are considered investigational include but are not limited to the following:
 1. Technetium-99m Nofetumomab Merpentan (Verluma) is considered investigational for all malignancies, including but not limited to lung, colorectal, breast, ovary, gastroesophageal, pancreas, renal, bladder, or cervical cancer. This agent is no longer marketed in the United States.

2. Technetium-99m Fanolesomab (NeuroSpec) is no longer commercially available.
3. AFP-SCAN®
4. Combidex®
5. LeukoScan
6. Lymphoscan®
7. Myoscint

4.3 Policy Guidelines

Except for the few indications noted as covered in **Subsection 3.2**, monoclonal antibody imaging for all other conditions is considered investigational due to insufficient scientific evidence that the results of the test would affect patient management and/or improve health outcomes.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for monoclonal antibody imaging.

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 but not limited to 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
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
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 Codes				
78800	78801	78802	78803	78804

HCPCS Codes				
A4641	A4642	A9500	A9507	A9568

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

One unit = one global procedure.

F. Place of Service

Inpatient Hospital, Outpatient Hospital and Office

G. Co-payments

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

H. Reimbursement

Providers must bill their usual and customary charges.