

## Corporate Medical Policy

# Monoclonal Antibody Imaging

**File Name:** monoclonal\_antibody\_imaging  
**Policy Number:** RAD5120  
**Origination:** 3/1994  
**Last Review:** 3/2008  
**Next Review:** 3/2010

### Description of Procedure or Service

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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).

### Policy

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**BCBSNC will provide coverage for Monoclonal Antibody Imaging when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

**Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions.**

### Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

### When Monoclonal Antibody Imaging is covered

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

- ◆ Elevated CEA (carcinoembryonic antigen) level who have no evidence of the disease on CT (or other) scans, in patients in whom a second look laparotomy is being considered
- ◆ Isolated, potentially resectable recurrent tumor on CT (or other) scan, if finding evidence of additional tumor would change the plan of surgery

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**\*\*\*Note: OncoScint CR/OV® is no longer commercially available.**

2. 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).

### When Monoclonal Antibody Imaging is not covered

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- Monoclonal antibody imaging is not covered for other cancers. There is not enough scientific evidence to substantiate that monoclonal antibody imaging is accurate for, or improves the net health outcome for the following conditions. This includes, but is not limited to the following:
  - ◆ Ovarian cancer
  - ◆ Malignant melanoma
  - ◆ Breast cancer -Scintimammography, (Technetium-99m sestamibi, Miraluma ®)
  - ◆ Lung cancer
  - ◆ Prostate cancer (Indium-111 Capromab Pendetide, ProstaScint®)
  - ◆ [Thrombosis](#)
  - ◆ Inflammatory disease
  - ◆ Lymphoma
- Other monoclonal antibody imaging agents which are considered investigational include but are not limited to the following:
  - ◆ 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.
  - ◆ OncoScint CR/OV® is no longer commercially available.
  - ◆ Technetium-99m Fanolesomab (NeuroSpec) is no longer commercially available.
  - ◆ AFP-SCAN®
  - ◆ Combidex®
  - ◆ LeukoScan
  - ◆ Lymphoscan®
  - ◆ Myoscint

### Policy Guidelines

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Except for the few indications noted as covered, 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. Several of the monoclonal antibody imaging agents are no longer available for use in the United States due to safety concerns.

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### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 78800, 78801, 78802, 78803, 78804, 78890, 78891, A4641, A4642, A9500, A9507, A9568, S8080*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Policy Key Words

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Key Words: Monoclonal Antibody Imaging, MAb, Radioimmunoscintigraphy, RIS, Antigens, Scintimammography, Indium-111 satumomab pentetide, OncoScint CR/OV, CYT-103, Technetium-99m Arcitumomab, IMMU-4, CEA-Scan, Technetium-99m Fanolesomab, NeutroSpec, Indium-111 Capromab Pentetide, ProstaScint, Indium-111 Pentetreotide, Octreoscan, Technetium-99m Nofetumomab Merpentan, Verluma, Technetium-99m Sestamibi, Miraluma, AFP-Scan, Combidex, LeukoScan, Lymphoscan, Myoscint, SPECT, RAD5120

### Medical Term Definitions

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#### **Colorectal**

pertaining to the colon and rectum.

#### **Thrombosis**

the formation of a thrombus or clot.

### Scientific Background and Reference Sources

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National Association 12/95

Zuckier LS, DeNardo GL. Trials and tribulations: oncology antibody imaging comes to the fore. *Semin Nuc Med.* 1997;27(1):10-29.

Stodee DB, Ellis RJ. Prostate cancer and prostate bed SPECT imaging with ProstaScint:semiquantitative correlation with prostatic biopsy results. *Prostate.* 1998;37(3):140-8

Medical Policy Reference Manual 1/30/98

TEC Assessment Volume 13, No. 21 February 1999

Medical Policy Advisory Group review 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

## Policy: Monoclonal Antibody Imaging

BCBSA Medical Policy Reference Manual, 4/30/00; 6.01.18  
Specialty Matched Consultant Advisory Panel - 6/2002  
BCBSA Medical Policy Reference Manual - 6.01.05, 12/18/2002  
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.36, 2/25/2004.  
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 2/25/2004.  
Specialty Matched Consultant Advisory Panel 5/2004  
BCBSA Medical Policy Reference Manual [Electronic Version]- 6.01.05, 11/9/2004.  
BCBSA Medical Policy Reference Manual [Electronic Version]- 6.01.18, 3/15/2005.  
BCBSA Medical Policy Reference Manual [Electronic Version]- 6.01.35, 8/17/2005.  
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.36, 11/9/2004.  
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 8/17/2005.  
Specialty Matched Consultant Advisory Panel - 3/2006  
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 2/15/07.  
Specialty Matched Consultant Advisory Panel - 3/2008

### Policy Implementation/Update Information

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11/93 Evaluated: Eligible for coverage using satumomab penetide for selected patients with known or suspected recurrent colorectal carcinoma. Investigational for ovarian carcinoma, malignant melanoma, breast cancer, thrombosis, inflammatory disease, lymphoma, and prostate cancer

9/94 Revised: Added FDA approval of indium 111 penetetretotide (Octeoscan®)

6/96 Evaluated: National Association reviewed 12/95. No changes.

5/99 Revised based on Medical Policy Advisory Group recommendations. Article from *Semin Nucl Med* indicates that ProstaScint® (Indium-111 capromab pendetide) has received FDA approval. TEC Assessment indicates that there are a high number of false positives with the ProstaScint®, therefore, it was not added to the policy at this time.

10/00 Specialty Matched Consultant Advisory Panel review. No change recommended in criteria. System coding changes. Medical Policy Advisory Group review. No change in criteria. Approve.

1/01 Revised. Added the term scintimammography to "When Monoclonal Antibody Imaging is not covered" section for breast cancer and added this term to the policy key words.

6/02 Specialty matched Consultant Advisory Panel. No changes. Approve.

6/04 HCPCS code S8080 added to Billing/Coding section.

6/10/04 Specialty Matched Consultant Advisory Panel review. Benefit Application and Billing/Coding Section updated for consistency. Added "Technetium-99m Nofetumomab Merpentan (Verluma) Not Applicable" under section When Monoclonal Antibody Imaging is covered. Added "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. BCBSNC does not provide coverage for investigational procedures." under section When Monoclonal Antibody Imaging is Not Covered. Added codes 78804 and A4641. References added. Notification given 6/10/2004. Effective date 8/12/2004.

3/02/06 Removed deleted CPT code 78990 from Billing/Coding Section.

## **Policy: Monoclonal Antibody Imaging**

- 4/10/06 Specialty Matched Consultant Advisory Panel review 3/15/2006. No changes to policy intent. Removed OncoScint Cr/OV® from "When covered" section and noted that "OncoScint CR/OV® is no longer commercially available." Added specific names of various noncovered monoclonal antibody imaging agents to "When not covered" section. Added rationale to "Policy Guidelines" section. Added HCPCS codes A4642, A9500, A9507 to "Billing/Coding" section. Added imaging agent names to "Key Words" section. References added.
- 1/3/07 Added new 2007 HCPCS code, A9568 to "Billing/Coding" section.
- 6/2/08 Specialty Matched Consultant Advisory Panel review 3/17/08. No change to policy statement. Reference to the Clinical Trials policy added to "Policy" section. References added.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

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