

## Corporate Medical Policy

### Monoclonal Antibody Imaging for Prostate Cancer

**File Name:** monoclonal\_antibody\_imaging\_for\_prostate\_cancer  
**Origination:** 5/2011  
**Last CAP Review:** 4/2020  
**Next CAP Review:** 4/2021  
**Last Review:** 4/2020

#### Description of Procedure or Service

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Radioimmunoscintigraphy involves the administration of radiolabeled monoclonal antibodies (MAbs), which are directed against specific molecular targets, followed by imaging with an external gamma camera. Indium-111 capromab pendetide (ProstaScint®) is a monoclonal antibody directed against a binding site on prostate specific antigen (PSA).

Radioimmunoscintigraphy is an imaging modality that uses radiolabeled monoclonal antibodies to target specific tissue types. MAbs that react with specific cellular antigens are conjugated with a radiolabeled isotope. The labeled antibody-isotope conjugate is then injected into the patient and allowed to localize to the target over a 2- to 7-day period. The patient then undergoes imaging with a nuclear medicine gamma camera, and radioisotope counts are analyzed. Imaging can be performed with planar techniques or by using single-photon emission computed tomography (SPECT).

#### Regulatory Status

Indium-111 capromab pendetide (ProstaScint®) (also referred to as CYT-356) targets an intracellular binding site on prostate-specific membrane antigen (PSMA) and has been approved by the U.S. Food and Drug Administration (FDA) for use as a “diagnosing imaging agent in newly diagnosed patients with biopsy-proven prostate cancer, thought to be clinically localized after standard diagnostic evaluation, who are at risk for pelvic lymph node metastases and in post-prostatectomy patients with a rising prostate-specific antigen (PSA) and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.” Other monoclonal antibodies, directed at extracellular PSMA binding sites, are also under development.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**Monoclonal antibody imaging for prostate cancer is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

# Monoclonal Antibody Imaging for Prostate Cancer

## **When Monoclonal Antibody Imaging for Prostate Cancer is covered**

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Not applicable

## **When Monoclonal Antibody Imaging for Prostate Cancer is not covered**

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Radioimmunoscintigraphy (Monoclonal Antibody Imaging) using indium-111 capromab pentetide (Prostascint®) is considered investigational.

## **Policy Guidelines**

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For individuals who have prostate cancer and are undergoing staging before curative treatment who receive Radioimmunoscintigraphy (RIS) imaging with Indium-111 capromab pentetide the evidence includes diagnostic accuracy studies and a systematic review (TEC Assessment). Relevant outcomes are overall survival, disease specific survival, test accuracy, and test validity. For pretreatment staging before curative treatment, a TEC Assessment found that RIS has a modest sensitivity, estimated at 50% to 75% and a moderate to high specificity, estimated at 72% to 93%. No studies have demonstrated that use of RIS for pre-treatment staging changes patient management or health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have prostate cancer and have biochemical failure after curative treatment who receive RIS with indium 111 capromab pentetide, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. The available case series were generally retrospective, descriptive, and did not provide consistent verification of disease status. Thus, the studies do not permit accurate estimation of the false-positive and false-negative rates with RIS. There is a lack of published evidence demonstrating an association between RIS findings and change in patient management or health outcomes in this population of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **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 service codes: 78800, 78801, 78802, 78803, 78804, A9507*

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.

## **Scientific Background and Reference Sources**

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### **Policy Entitled Monoclonal Antibody Imaging Separated Out and Archived**

National Comprehensive Cancer Network. Prostate Cancer. V.1.2011.NCCN Clinical practice guidelines in oncology: prostate cancer. Retrieved 3/1/2011 from [http://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf)

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 2/10/2011

# Monoclonal Antibody Imaging for Prostate Cancer

Specialty Matched Consultant Advisory Panel – 4/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 2/9/2012

Specialty Matched Consultant Advisory Panel 4/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 2/14/2013

Specialty Matched Consultant Advisory Panel – 4/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 1/9/2014

Specialty Matched Consultant Advisory Panel – 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 1/15/2015

Specialty Matched Consultant Advisory Panel- 4/2015

Specialty Matched Consultant Advisory Panel- 4/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 9/8/2016

Specialty Matched Consultant Advisory Panel- 4/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 9/14/2017

Specialty Matched Consultant Advisory Panel- 4/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 9/13/2018

Specialty Matched Consultant Advisory Panel- 4/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.37, 9/12/2019

Specialty Matched Consultant Advisory Panel- 4/2020

Medical Director review 4/2020

## **Policy Implementation/Update Information**

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### **See Previous Policy Entitled Monoclonal Antibody Imaging**

5/24/11 Previously discussed in policy entitled; Monoclonal Antibody Imaging. Monoclonal Antibodies developed into separate policies. Specialty Matched Consultant Advisory Panel review 4/27/2011. “Radioimmunoscinigraphy (Monoclonal Antibody Imaging) using indium-111 capromab pendetide (Prostascint®) is considered investigational.” Notification given 5/24/2011. Policy effective 8/30/2011. (btw)

5/15/12 Specialty Matched Consultant Advisory Panel review 4/18/2012. No change to policy intent. Description section revised. Policy Guidelines updated. Reference added. (btw)

4/1/13 Reference added. (btw)

4/30/13 Specialty Matched Consultant Advisory Panel review 4/17/2013. No change to policy. (btw)

# Monoclonal Antibody Imaging for Prostate Cancer

- 2/25/14 Reference added. (btw)
- 5/13/14 Specialty Matched Consultant Advisory Panel review 4/29/2014. No change to policy. (btw)
- 2/24/15 Reference added. (lpr)
- 5/26/15 Specialty Matched Consultant Advisory Panel review 4/29/2015. No change to policy. (lpr)
- 5/31/16 Specialty Matched Consultant Advisory Panel review 4/27/2016. No change to policy. (lpr)
- 10/25/16 Reference added. Policy Guidelines updated. No change to policy statement. (lpr)
- 5/26/17 Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)
- 5/11/18 Specialty Matched Consultant Advisory Panel review 4/25/2018. Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 4/16/19 Specialty Matched Consultant Advisory Panel review 3/20/2019. Reference added. No change to policy statement. (lpr)
- 5/26/20 Specialty Matched Consultant Advisory Panel review 4/15/2020. Reference added. No change to policy statement. (lpr)

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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.