

Corporate Medical Policy

Monoclonal Antibody Imaging for Prostate Cancer

File Name: monoclonal_antibody_imaging_for_prostate_cancer
Origination: 5/2011
Last CAP Review: 4/2012
Next CAP Review: 4/2013
Last Review: 4/2012

Description of Procedure or Service

Radioimmunoscinigraphy 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).

Radioimmunoscinigraphy 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).

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

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

Benefits Application

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

Not applicable

When Monoclonal Antibody Imaging for Prostate Cancer is not covered

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

Policy Guidelines

Radioimmunoscinigraphy (RIS) imaging with Indium-111 capromab pendetide (ProstaScint) is an alternative imaging modality for patients with prostate cancer that is intended to assist in determining the extent and location of disease. For determining whether disease is present in the lymph nodes, RIS has a modest sensitivity, estimated at 50-75% and a moderate to high specificity, estimated at 72-93%. Because other imaging modalities have a suboptimal sensitivity for disease in the lymph nodes, RIS has been proposed to be used for staging prior to curative treatment. However, no studies have demonstrated that use of RIS for this purpose changes management, and therefore the evidence is insufficient to determine whether RIS improves health outcomes when used to stage prostate cancer pre-treatment.

For patients with biochemical failure following curative treatment, RIS has been proposed to help differentiate between local and distant recurrence. There are numerous small case series that evaluate RIS in this population, and describe rates of positivity for local and distant disease. However, none of these studies demonstrate a change in management as a result of RIS. As a result, it is not possible to determine whether use of RIS in this population improves outcomes.

Version 1:2011 of the NCCN Guidelines for prostate cancer notes a number of changes in the Guideline. These changes include removing ProstaScint® as a recommendation in the workup of patients with recurrence after prostatectomy, and with recurrence after radiation therapy.

Billing/Coding/Physician Documentation Information

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. 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

Monoclonal Antibody Imaging for Prostate Cancer

specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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

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

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

Policy Implementation/Update Information

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)

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.