Monoclonal Antibody Imaging for Prostate Cancer

Description of Procedure or Service

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

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

Not applicable

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

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

**Policy Guidelines**

For individuals who have prostate cancer and are undergoing staging before curative treatment who receive Radioimmunoscintigraphy (RIS) imaging with Indium-111 capromab pendetide 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 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. For these reasons, RIS with In-111 capromab pendetide is considered investigational.

**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 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*


Monoclonal Antibody Imaging for Prostate Cancer


Policy Implementation/Update Information

See Previous Policy Entitled Monoclonal Antibody Imaging


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)

2/25/14 Reference added. (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)
Monoclonal Antibody Imaging for Prostate Cancer

5/26/17  Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)

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.