MEDICAL POLICY

POLICY TITLE	RADIOIMMUNOSCINTIGRAPHY IMAGING (MONOCLONAL ANTIBODY IMAGING) WITH INDIUM-111 CAPROMAB PENDETIDE (PROSTASCINT®) FOR PROSTATE CANCER
POLICY NUMBER	MP-5.022

Original Issue Date (Created):	**August 9, 2002**
Most Recent Review Date (Revised):	**September 24, 2013**
Effective Date:	**November 1, 2013**

I. POLICY

Radioimmunoscintigraphy using indium-111 capromab pendetide (ProstaScint®) is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-Reference:
MP-5.021 Scintimammography and Other Tumor Specific Imaging of the Breast
MP-5.031 Single Photon Emission Computed Tomography (SPECT)

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

* Refer to FEP Medical Policy Manual MP-6.01.37 Radioimmunoscinitigraphy Imaging with Indium 111 for Prostate Cancer. The FEP Medical Policy manual can be found at: http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980

III. DESCRIPTION/BACKGROUND

Radioimmunoscintigraphy (RIS) 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).

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.

IV. RATIONALE

This policy regarding the use of radioimmunoscintigraphy (RIS) in patients with prostate cancer is based on a 1998 TEC Assessment (1) that was updated with a review of the literature through November 2003.

Radioimmunoscintigraphy (RIS) may be considered for use in a number of clinical indications. For the purposes of this policy, two main clinical situations will be considered:

- As part of the pretreatment workup for staging of prostate cancer. In this situation, the value of RIS is in detecting distant metastases that are not evident on other imaging studies, since detection of occult metastases is likely to alter treatment recommendations.
- In patients who have received curative treatment, but present with biochemical failure, i.e., a rising PSA without definite disease on standard imaging studies. In this situation, differentiating between local and distant recurrence is important since local recurrence may be treated with salvage radiotherapy, while distant recurrence is usually treated with androgen deprivation therapy.

Pre-treatment staging prior to curative treatment

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Based on the 1998 TEC Assessment of RIS, (1) sensitivity in detecting tumor in the pelvic lymph nodes ranged from 50–75% and specificity ranged from 72–92.6%. Pooled data from the studies reviewed in the TEC Assessment produced an estimated 61% positive predictive value (PPV). If positive RIS results were used to exclude a patient from receiving potentially curative therapy (i.e., radical prostatectomy), then 38% of patients might be harmed by inappropriately withholding the potentially curative treatment. A pooled negative predictive value (NPP) of 73% suggests that if radioimmunoscintigraphy played a key role in determining that pelvic lymph nodes were clear of tumor prior to radical prostatectomy, then 26.7% of patients with a negative RIS scan and truly positive lymph nodes might receive potentially ineffective surgery. In addition, there is debate over a potential survival benefit with performing prostatectomy in the setting of positive lymph nodes. (2, 3) Nevertheless, in terms of evaluating the pelvic nodes, the positive and negative predictive values are not sufficiently high enough to avoid pelvic lymph node dissection when necessary to determine patient management.

Since the 1998 TEC Assessment, several reports have been published that address the role of RIS in evaluating pelvic lymph node staging. (4-9) However, several of the authors of these reports appear in multiple new and prior publications, and it seems possible that some of these populations overlap with previously reported results derived from multicenter studies. Moreover, the diagnostic accuracy of RIS for evaluating pelvic lymph nodes does not appear to be substantially improved in later reports. (9)

Several of these reports use predictive modeling or cross-sectional correlation analysis to explore the value of RIS results in predicting the extent of disease in comparison to other factors such as prostate-specific antigen (PSA) level, Gleason score, and clinical stage of disease. (6, 7, 10)

In 2011, Reiter et al. (11) published a retrospective review of 197 patients who had both RIS and histopathology available at one institution over a 4-month period. For the lymph nodes, the sensitivity of RIS was 60.0% (95% confidence interval [CI]: 14.7-94.7%) and the specificity was 97.4% (95% CI: 92.3-100%). The area under the curve by receiver operating characteristic (ROC) analysis was 78.7%. Increasing Gleason score was predictive of a positive RIS scan, as was the setting of a pretreatment evaluation.

These analyses suggest that RIS provides additional and independent information that correlates with extent of disease; however, the conclusions of these studies are derived from relationships across populations and do not directly translate into how RIS results would actually be used to guide management in a manner that would improve net health outcome. Without an understanding of diagnostic accuracy and how results would influence management, it is not possible to model potential effects on health outcomes. Thus, none of the reports identified in the update support the clinical effectiveness of using RIS to evaluate pelvic lymph nodes.

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Evaluating patients with biochemical failure following prostatectomy or radiotherapy

Patients who experience a rising PSA following curative treatment for prostate cancer are considered to have a recurrence; however, the location of the recurrence is sometimes not evident for a period of time after biochemical failure. Localized recurrence is typically treated with salvage radiotherapy, whereas distant recurrence, i.e. metastatic disease, is usually treated with androgen deprivation therapy.

In terms of evaluating recurrent or residual disease, there are limited data showing that the use of RIS in this patient group can detect additional sites of disease and would result in different management decisions compared to decisions based on usual care. (6, 8-10, 12-17) Imaging evaluation may be useful in suspected recurrence due to rising PSA to localize recurrent tumor and to determine whether recurrent tumor is local to the prostate area, involves distant sites, or both. When residual or recurrent disease is only local, patients may undergo postoperative radiation therapy (RT), whereas, when the recurrence includes distant sites, hormonal therapy would be considered. Distant hematogenous metastasis from prostate cancer most frequently involves bone but can infrequently involve other soft tissue sites. Bone scan is generally considered to be more sensitive than RIS for detecting bone metastases. (9) Positive RIS findings have been reported anecdotally in abnormalities other than prostate cancer, so biopsy confirmation of unexpected distant findings may be necessary to ensure proper patient management. (18-20)

The available studies are generally retrospective, descriptive reports of patterns of RIS uptake in patients with suspected recurrence. These studies, however, do not provide consistent verification of disease status, and thus the rate of false-positive and false-negative RIS studies is not well established. While some studies report what percent of cases had associated changes in management, it is frequently difficult to specifically determine how RIS results affected management and to determine whether these changes resulted in an improvement in net health outcome.

A retrospective study by Raj et al. (16) included 252 patients with biochemical failure following radical prostatectomy (PSA $\leq$0.4 ng/mL) who had RIS performed to localize recurrence. In this study, 72% of subjects had a positive scan. A localized (prostatic fossa only) uptake pattern was seen in 30.6%, regional uptake pattern (regional lymph nodes plus or minus prostatic fossa and no distant disease) in 42.8%, and distant uptake noted in 29.4%. This study did not report the proportion of subjects in whom patient management was altered by RIS findings. Only a minority of patients (<20%) had also received a computed tomography (CT) scan or bone scan showing positive findings, making comparisons across technologies subject to potential bias. A uniform reference standard was not applied in this study, and detailed follow-up was available for only an approximately half of the patients (132 of 255). The study reports sensitivity and specificity in a small subset of subjects (i.e., 95 of 252 total or 38% of subjects) who had some degree of verification of disease status. Reported

sensitivity was 73% and specificity was 53%. However, due to the selected nature of the small subset analysis, these estimates are subject to potential verification bias and may not be considered valid measures of expected performance.

Sodee et al. (10) performed a retrospective analysis on a large multicenter study including 2,290 RIS scans in 2,154 patients with prostate cancer, either before or after treatment. This study reports the rates of positive RIS scans in local, regional, and distant sites but does not provide detailed verification of results and thus, sensitivity and specificity cannot be determined. When analysis was stratified by whether primary treatment had been surgery, radiation, or hormonal therapy, RIS showed uptake limited to extrapelvic nodes in 8.5% to 15.1% of patients and uptake in both pelvic and extrapelvic nodes in 22.1% to 33.2% of patients. Relatively few patients had also undergone CT scanning (n=146). When CT was compared with RIS, CT did not detect pelvic or extrapelvic nodes that were detected by RIS in 73% of CT cases. In contrast, in a separate study of 45 subjects, RIS did not perform as well as CT in detecting metastatic disease. (17)

Kahn et al. (13) reported results in 32 patients who received salvage pelvic radiation for suspected recurrence and had received RIS imaging. The authors reported that RIS had 50% sensitivity, 89% specificity, 78% positive predictive value (PPV), and 70% negative predictive value (NPV) for detecting patients who would develop tumor recurrence after irradiation. Thomas and colleagues reported on the results of RIS in a case series of 30 men with recurrent prostate cancer treated with radiation therapy. (21) This study found no correlation between the results of RIS and tumor control, as assessed by serial PSA levels. Further studies would be necessary to demonstrate that long-term outcomes after radiation therapy are improved when RIS is used to select patients.

Liauw et al. reported on 82 patients with adenocarcinoma of the prostate treated with salvage RT for an elevated prostate-specific antigen (PSA) level after prostatectomy. (22) The median pre-RT PSA level was 0.63 ng/mL. Of the 82 patients, 47 (57%) had a pre-RT RIS ProstaScint scan, which was used for both patient selection and target delineation. Patients with a pre-RT RIS scan had a lower preoperative PSA level (p=.0240) and shorter follow-up (p=.0221) than those without RIS. With a median follow-up of 44 months, the biochemical control rate was 56% at 3 years and 48% at 5 years. Margin status was the only factor associated with biochemical control on univariate (p=.0055) and multivariate (p=.0044) analysis. Patients who had prostate bed-only uptake on RIS (n=38) did not have improved outcomes, with biochemical control rates of 51% at 3 years and 40% at 5 years. These data support the conclusion that patients who were selected for treatment with RIS did not have better biochemical outcomes.

Nagda et al. reported on a series of 58 patients who had ProstaScint scans as part of an assessment of rising PSA after prostatectomy who were then treated with prostate bed radiation therapy. (23) The 4-year biochemical relapse-free survival (bRFS) rates for patients

with negative ProstaScint scans (53%), positive in the prostate bed alone (45%), or positive elsewhere (74%) scan findings did not differ significantly (p=.51). The capromab pendetide scan status had no effect on bRFS. Those with a pre-radiation therapy (RT) PSA level of less than 1 ng/mL had improved bRFS (p=.003). The authors concluded that the capromab pendetide scan has a low PPV in patients with positive elsewhere uptake and the 4-year bRFS was similar to that for those who did not exhibit positive elsewhere uptake.

Proano et al. (24) reported "early experience" on outcomes among a group of 44 patients with biochemical recurrence after radical prostatectomy who underwent a ProstaScint scan immediately before salvage radiotherapy. They noted an improved prognosis (mean follow-up of 22 months) in patients who had a negative pre-radiotherapy scan but also noted that this finding was not necessarily independent of pre-radiotherapy PSA level.

Two publications raise questions about the accuracy (including sensitivity and specificity) of immunoscintigraphy, co-registered with CT, in imaging localized prostate cancer within the prostate gland and in detecting seminal vesicle invasion. (25, 26)

Use of RIS scanning to direct "image-guided" radiotherapy

One trial was identified that used the results of ProstaScint to change management. Wong et al. (27) prospectively enrolled 71 patients with localized prostate cancer and performed capromab pendetide scans on all prior to initiating intensity-modulated radiation therapy (IMRT) treatment. Areas of increased uptake within the prostate gland on RIS scanning were given an additional "boost" of radiation in addition to the baseline dose given to the entire gland. Grade 2 urinary and gastrointestinal toxicity was common, affecting up to 50% of patients, but grade 3 or higher toxicity was less frequent, with 4% of patients exhibiting grade 2 urinary toxicity. At a median of 66 months' follow-up, biochemical control was 94%. No attempt was made in this study to compare outcomes of "image-guided" IMRT with standard treatment.

Summary

Radioimmunoscintigraphy (RIS) imaging with Indium-111 (In-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.

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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 the above reasons, RIS with In-111 capromab pendetide is considered investigational.

Practice Guidelines and Position Statements

Version 1:2011 of the National Comprehensive Cancer Network (NCCN) Guidelines for prostate cancer note a number of changes in the Guideline; this includes removing ProstaScint as a recommendation in the workup of a patient with recurrence after prostatectomy and with a recurrence after RT. (28) No other comments were found in these guidelines when searching for the term ProstaScint.

V. DEFINITIONS

RADIOPHARMACEUTICAL is a radioactive chemical or drug that has a specific affinity for a particular body tissue or organ. It can be used in nuclear medicine to obtain images of structures, or to treat radiation-sensitive diseases.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider

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and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

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IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Radioimmunoscintigraphy using indium-111 capromab pendetide (ProstaScint®) is investigational; therefore the following codes are not covered:

CPT Codes®								
78800	78801	78802	78803	78804				

HCPCS Code	Description
A9507	Indium In-111 capromab pendetide, diagnostic, per study dose, up to 10 millicuries

X. POLICY HISTORY

MP 5.022	CAC 7/29/03
	CAC 5/31/05
	CAC 6/28/05
	CAC 7/25/06

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	CAC 9/26/06
	CAC 9/25/07
	CAC 9/30/08
	CAC 9/29/09 Consensus
	CAC 4/26/11 Adopt BCBSA, Removed information regarding radioimmunoscintigraphy for all indications other than prostate cancer. Revised policy criteria from medically necessary to investigational.
	CAC 6/26/12 Consensus, Background/Description revised to match BCBSA changes. Policy statements unchanged.
	7/24/13 Admin coding review complete--rsb
	CAC 9/24/13 Consensus. No change to policy statements. Rationale section added. Added FEP variation to reference the policy manual. References updated.