

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

Original Issue Date (Created):	8/9/2002
Most Recent Review Date (Revised):	9/27/2018
Effective Date:	11/1/2018

[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

Radioimmunoscinigraphy 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.

II. PRODUCT VARIATIONS

[Top](#)

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO- Refer to FEP Medical Policy Manual MP-6.01.37 Radioimmunoscinigraphy Imaging (Monoclonal Antibody Imaging) with Indium 111Capromab Pendetide (Prostascint®) for Prostate Cancer. The FEP Medical Policy manual can be found at:
<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

[Top](#)

Radioimmunoscinigraphy (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).

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

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

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

In 1996, indium 111 capromab pentetide (ProstaScint®) (also referred to as CYT-356), which targets an intracellular binding site on prostate-specific membrane antigen (PSMA), and was approved by the U.S. Food and Drug Administration through the biologics license application process 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

[Top](#)

SUMMARY OF EVIDENCE

For individuals who have prostate cancer and are undergoing staging before curative treatment who receive RIS 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, the 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 the use of RIS for pretreatment staging changes patient management or improves 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 are generally retrospective, descriptive, and do 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.

X. DEFINITIONS

[Top](#)

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

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.

V. BENEFIT VARIATIONS

[Top](#)

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 BlueCross for benefit information.

VI. DISCLAIMER

[Top](#)

Capital BlueCross'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 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 BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. CODING INFORMATION

[Top](#)

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.

Radioimmunosciintigraphy using indium-111 Capromab Pendetide is investigational; therefore, the following codes are not covered:

CPT Codes®							
78800	78801	78802	78803	78804			

Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved.

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

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

VIII. REFERENCES

[Top](#)

1. EUSA Pharma (USA). ProstaScint® Kit (capromab pendetide). Kit for the Preparation of Indium In 111 Capromab Pendetide. 2012; https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103608s5043lbl.pdf. Accessed August 8, 2018.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Radioimmunosintigraphy for Prostate Cancer – Update. TEC Assessments. 1998;13;Tab 21.
3. Lange PH. PROSTASCINT scan for staging prostate cancer. Urology. Mar 2001;57(3):402-406. PMID 11248606
4. Moul JW, Kane CJ, Malkowicz SB. The role of imaging studies and molecular markers for selecting candidates for radical prostatectomy. Urol Clin North Am. Aug 2001;28(3):459-472. PMID 11590806
5. Lau HY, Kindrachuk G, Carter M, et al. Surgical confirmation of ProstaScint abnormalities in two patients with high risk prostate cancer. Can J Urol. Feb 2001;8(1):1199-1202. PMID 11268308
6. Manyak MJ, Hinkle GH, Olsen JO, et al. Immunoscintigraphy with indium-111-capromab pendetide: evaluation before definitive therapy in patients with prostate cancer. Urology. Dec 1999;54(6):1058-1063. PMID 10604708
7. Murphy GP, Snow PB, Brandt J, et al. Evaluation of prostate cancer patients receiving multiple staging tests, including ProstaScint scintiscans. Prostate. Feb 1 2000;42(2):145-149. PMID 10617872
8. Polascik TJ, Manyak MJ, Haseman MK, et al. Comparison of clinical staging algorithms and 111indium-capromab pendetide immunoscintigraphy in the prediction of lymph node involvement in high risk prostate carcinoma patients. Cancer. Apr 1 1999;85(7):1586-1592. PMID 10193950
9. Quintana JC, Blend MJ. The dual-isotope ProstaScint imaging procedure: clinical experience and staging results in 145 patients. Clin Nucl Med. Jan 2000;25(1):33-40. PMID 10634528
10. Rosenthal SA, Haseman MK, Polascik TJ. Utility of capromab pendetide (ProstaScint) imaging in the management of prostate cancer. Tech Urol. Mar 2001;7(1):27-37. PMID 11272670

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

11. Sodee DB, Malguria N, Faulhaber P, et al. Multicenter ProstaScint imaging findings in 2154 patients with prostate cancer. *The ProstaScint Imaging Centers. Urology.* Dec 20 2000;56(6):988-993. PMID 11113745
12. Rieter WJ, Keane TE, Ahlman MA, et al. Diagnostic performance of In-111 capromab pendetide SPECT/CT in localized and metastatic prostate cancer. *Clin Nucl Med.* Oct 2011;36(10):872-878. PMID 21892036
13. Elgamal AA, Troychak MJ, Murphy GP. ProstaScint scan may enhance identification of prostate cancer recurrences after prostatectomy, radiation, or hormone therapy: analysis of 136 scans of 100 patients. *Prostate.* Dec 1 1998;37(4):261-269. PMID 9831223
14. Kahn D, Williams RD, Haseman MK, et al. Radioimmunoscintigraphy with In-111-labeled capromab pendetide predicts prostate cancer response to salvage radiotherapy after failed radical prostatectomy. *J Clin Oncol.* Jan 1998;16(1):284-289. PMID 9440754
15. Murphy GP, Elgamal AA, Troychak MJ, et al. Follow-up ProstaScint scans verify detection of occult soft-tissue recurrence after failure of primary prostate cancer therapy. *Prostate.* Mar 1 2000;42(4):315-317. PMID 10679761
16. Petronis JD, Regan F, Lin K. Indium-111 capromab pendetide (ProstaScint) imaging to detect recurrent and metastatic prostate cancer. *Clin Nucl Med.* Oct 1998;23(10):672-677. PMID 9790041
17. Raj GV, Partin AW, Polascik TJ. Clinical utility of indium 111-capromab pendetide immunoscintigraphy in the detection of early, recurrent prostate carcinoma after radical prostatectomy. *Cancer.* Feb 15 2002;94(4):987-996. PMID 11920467
18. Seltzer MA, Barbaric Z, Belldegrun A, et al. Comparison of helical computerized tomography, positron emission tomography and monoclonal antibody scans for evaluation of lymph node metastases in patients with prostate specific antigen relapse after treatment for localized prostate cancer. *J Urol.* Oct 1999;162(4):1322-1328. PMID 10492189
19. Khan A, Caride VJ. Indium-111 capromab pendetide (ProstaScint) uptake in neurofibromatosis. *Urology.* Jul 1 2000;56(1):154. PMID 10869655
20. Michaels EK, Blend M, Quintana JC. 111Indium-capromab pendetide unexpectedly localizes to renal cell carcinoma. *J Urol.* Feb 1999;161(2):597-598. PMID 9915456
21. Scott DL, Halkar RK, Fischer A, et al. False-positive 111 indium capromab pendetide scan due to benign myelolipoma. *J Urol.* Mar 2001;165(3):910-911. PMID 11176508
22. Liauw SL, Weichselbaum RR, Zagaja GP, et al. Salvage radiotherapy after postprostatectomy biochemical failure: does pretreatment radioimmunoscintigraphy help select patients with locally confined disease? *Int J Radiat Oncol Biol Phys.* Aug 1 2008;71(5):1316-1321. PMID 18234446

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

23. Nagda SN, Mohideen N, Lo SS, et al. Long-term follow-up of 111In-capromab pentetide (ProstaScint) scan as pretreatment assessment in patients who undergo salvage radiotherapy for rising prostate-specific antigen after radical prostatectomy for prostate cancer. *Int J Radiat Oncol Biol Phys.* Mar 1 2007;67(3):834-840. PMID 17293236
24. Proano JM, Sodee DB, Resnick MI, et al. The impact of a negative (111)indium-capromab pentetide scan before salvage radiotherapy. *J Urol.* May 2006;175(5):1668-1672. PMID 16600726
25. Mouraviev V, Madden JF, Broadwater G, et al. Use of 111in-capromab pentetide immunoscintigraphy to image localized prostate cancer foci within the prostate gland. *J Urol.* Sep 2009;182(3):938-947. PMID 19616259
26. Tsivian M, Wright T, Price M, et al. 111-In-capromab pentetide imaging using hybrid-gamma camera-computer tomography technology is not reliable in detecting seminal vesicle invasion in patients with prostate cancer. *Urol Oncol.* Mar-Apr 2012;30(2):150-154. PMID 20189846
27. Schuster DM, Nieh PT, Jani AB, et al. Anti-3-[(18)F]FACBC positron emission tomography-computerized tomography and (111)In-capromab pentetide single photon emission computerized tomography-computerized tomography for recurrent prostate carcinoma: results of a prospective clinical trial. *J Urol.* May 2014;191(5):1446-1453. PMID 24144687
28. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 3.2018. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 8, 2018.
29. American College of Radiology. ACR Appropriateness Criteria: Post-Treatment Followup of Prostate Cancer. 2017; <https://www.guidelinecentral.com/summaries/acr-appropriateness-criteria-post-treatment-follow-up-of-prostate-cancer/#section-society>. Accessed August 9, 2018.
30. Blue Cross Blue Shield Association Medical Policy Reference Manual. 6.01.37, Radioimmunoscintigraphy (Monoclonal Antibody Imaging) With Indium 111 Capromab Pentetide for Prostate Cancer. September 2018.

IX. POLICY HISTORY

[Top](#)

MP 5.022	CAC 7/29/03
	CAC 5/31/05
	CAC 6/28/05
	CAC 7/25/06
	CAC 9/26/06

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

	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
	CAC 9/24/13 Consensus. No change to policy statements. Rationale section added. Added FEP variation to reference the policy manual. References updated.
	CAC 9/30/14 Consensus review. References and rationale updated. No change to the policy statement.
	CAC 2/29/15 Consensus review. No change to policy statements. References and rationale reviewed.
	CAC 09/29/15 Consensus review. Coding reviewed and unchanged.
	CAC 9/27/16 Consensus review. No change to policy statements. References and rationale reviewed. Variation reformatted. Coding Reviewed.
	CAC 11/28/17 Consensus. No change to policy statements. References and rationale updated. Title changed from Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) with Indium-111 Capromab Pendetide (ProstaScint®) for Prostate Cancer to Radioimmunoscintigraphy (Monoclonal Antibody Imaging) With Indium 111 Capromab Pendetide for Prostate Cancer”. Coding Reviewed.
	9/20/18 Consensus review. No change to the policy statement. References updated. Rationale revised.

[Top](#)

Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies