

Protocol

Radioimmunoscinigraphy (Monoclonal Antibody Imaging) With Indium 111 Capromab Pendetide for Prostate Cancer

(60137)

Medical Benefit		Effective Date: 04/01/15	Next Review Date: 11/19
Preauthorization	No	Review Dates: 11/14, 11/15, 11/16, 11/17, 11/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With prostate cancer and undergoing staging before curative treatment	Interventions of interest are: <ul style="list-style-type: none">• Radioimmunoscinigraphy with indium 111 capromab pendetide	Comparators of interest are: <ul style="list-style-type: none">• Bone scan• Ultrasonography• Computed tomography• Magnetic resonance imaging	Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Disease-specific survival• Test accuracy• Test validity
Individuals: <ul style="list-style-type: none">• With prostate cancer with biochemical failure after curative treatment	Interventions of interest are: <ul style="list-style-type: none">• Radioimmunoscinigraphy with indium 111 capromab pendetide	Comparators of interest are: <ul style="list-style-type: none">• Bone scan• Ultrasonography• Computed tomography• Magnetic resonance imaging	Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Disease-specific survival• Test accuracy• Test validity

DESCRIPTION

Radioimmunoscinigraphy (RIS) involves the administration of radiolabeled monoclonal antibodies, 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 the prostate-specific membrane antigen.

SUMMARY OF EVIDENCE

For individuals who have prostate cancer and are undergoing staging before curative treatment who receive RIS 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, 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 pendetide, 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.

POLICY

Radioimmunosциntigraphy using indium-111 capromab pendetide (ProstaScint®) is considered **investigational** for the evaluation and management of individuals with prostate cancer.

BACKGROUND

Radioimmunosциntigraphy is an imaging modality that uses radiolabeled monoclonal antibodies to target specific tissue types. Monoclonal antibodies 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 two to seven-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.

REGULATORY STATUS

In 1996, indium 111 capromab pendetide (ProstaScint®) (also referred to as CYT-356), which targets an intracellular binding site on prostate-specific membrane antigen, 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 high-risk for pelvic lymph node metastases... [It] is also indicated ... in post-prostatectomy patients with a rising PSA [prostate-specific antigen] and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.”¹ Other monoclonal antibodies, directed at extracellular prostate-specific membrane antigen binding sites, are also under development.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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). Radioimmunoscintigraphy 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 111 indium 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 1127267011.
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, Beldegrun 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
23. Nagda SN, Mohideen N, Lo SS, et al. Long-term follow-up of 111In-capromab pendetide (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 pendetide 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 pendetide 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 pendetide 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 pendetide 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.