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

Policy #  00419
Original Effective Date:  06/18/2014
Current Effective Date:  11/13/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radioimmunoscintigraphy (RIS) using indium-111 capromab pendetide (ProstaScint®)† for the evaluation and management of individuals with prostate cancer to be investigational.*

Background/Overview
Radioimmunoscintigraphy 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 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
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

*The services of ProstaScint® are considered investigational by the Company as of the most current effective date that this policy is in effect. A medical necessity determination is required by the Company before services are provided.

†Indium-111 capromab pendetide (ProstaScint®) is an FDA approved diagnostic imaging agent.

©2019 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) With Indium-111 Capromab Pendetide for Prostate Cancer

Policy # 00419
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019

[prostate-specific antigen] 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 prostate-specific membrane antigen binding sites, are also under development.

Rationale/Source
Radioimmunoscintigraphy (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.

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.
Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) With Indium-111 Capromab Pendetide for Prostate Cancer

Policy # 00419
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019

Supplemental Information
Practice Guidelines and Position Statements

National Comprehensive Cancer Network
The National Comprehensive Cancer Network guidelines for prostate cancer (v.3.2018) do not mention ProstaScint or radioimmunoscintigraphy.

American College of Radiology
The American College of Radiology’s 2017 Appropriateness Criteria rated the appropriateness of various imaging tests in men with rising prostate-specific antigen levels after prostatectomy or radiotherapy. Indium 111 capromab pendetide (ProstaScint) scans were found to be “not routinely used in the evaluation of prostate cancer recurrence” and studies “have demonstrated no benefit with use of capromab pendetide in selection of patients for local salvage therapy.” It was also noted that for salvage therapy with a rising prostate-specific antigen, use of “ProstaScint provided no incremental value in appropriately selected patients compared to basic clinicopathologic factors alone.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in August 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

References

©2019 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) With Indium-111 Capromab Pendetide for Prostate Cancer

Policy #    00419
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019

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

Policy # 00419
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019


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

Policy # 00419
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019


Policy History
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019
06/05/2014 Medical Policy Committee review
06/18/2014 Medical Policy Implementation Committee approval. New policy.
08/06/2015 Medical Policy Committee review
08/19/2015 Medical Policy Implementation Committee approval. No change to coverage.
08/04/2016 Medical Policy Committee review
08/17/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017 Medical Policy Committee review
11/15/2017 Medical Policy Implementation Committee approval. No change to coverage.

©2019 Blue Cross and Blue Shield of Louisiana
Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 6 of 8
Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) With Indium-111 Capromab Pendetide for Prostate Cancer

Policy # 00419
Original Effective Date: 06/18/2014
Current Effective Date: 11/13/2019

11/08/2018 Medical Policy Committee review
11/07/2019 Medical Policy Committee review

Next Scheduled Review Date: 11/2020

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2018 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:
Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) With Indium-111 Capromab Pendetide for Prostate Cancer

Policy # 00419  
Original Effective Date: 06/18/2014  
Current Effective Date: 11/13/2019

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>78800, 78801, 78802, 78803, 78804</td>
</tr>
<tr>
<td>HCPCS</td>
<td>A9507</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>C61, Z85.46</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2019 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.