Medical Policy

Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) with Indium-111 Capromab Pendetide (Prostascint®) for Prostate Cancer

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

Policy Number: 639
BCBSA Reference Number: 6.01.37

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members
Radioimmunoscintigraphy using indium-111 capromab pendetide (Prostascint®) is INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO BlueSM
This is NOT a covered service.

Medicare Members: PPO BlueSM
This is NOT a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>78800</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area</td>
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<tr>
<td>78801</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas</td>
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<tr>
<td>78802</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging</td>
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<tr>
<td>78803</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging</td>
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**HCPCS Codes**

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<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tr>
<td>A9507</td>
<td>Indium In-111 capromab pendetide, diagnostic, per study dose, up to 10 millicuries</td>
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**Description**

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. 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 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.

**Summary**

Radioimmunoscintigraphy (RIS) imaging with Indium-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.
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.

Policy History

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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>2/2009</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References
