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

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<th>Individuals:</th>
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<td>• With prostate cancer and undergoing staging before curative treatment</td>
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<td>Comparators of interest are:  • Bone scan  • Ultrasonography  • Computed tomography  • Magnetic resonance imaging</td>
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### Interventions

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 prostate-specific 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, a 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 were generally retrospective,
descriptive, and did 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
Radioimmunoscintigraphy using indium-111 capromab pendetide (ProstaScint®) is considered investigational.

Background
Radioimmunoscintigraphy is an imaging modality that uses radiolabeled monoclonal antibodies (MAbs) 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 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 intra-cellular 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.

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.


