Medical Policy

Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) Using In-111 Satumomab Pendetide (OncoScint) or Tc-99m Arcitumomab (IMMU-4, CEA-Scan)

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

Policy Number: 638
BCBSA Reference Number: 6.01.36A

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Radioimmunoscintigraphy using satumomab pendetide or arcitumomab as the monoclonal antibody may be MEDICALLY NECESSARY in patients with known or suspected recurrent colorectal carcinoma under the following conditions:
- In patients with an elevated carcinoembryonic antigen level, who have no evidence of disease with other imaging modalities (i.e., CT), in whom a second-look laparotomy is under consideration, or
- In patients with an isolated, potentially resectable recurrence identified with conventional imaging modalities (i.e., CT), for whom the detection of additional occult lesions would alter the surgical plan.

Other applications of radioimmunoscintigraphy using In-111 satumomab pendetide (OncoScint) or Tc-99m-arcitumomab (IMMU-4, CEA-Scan) are INVESTIGATIONAL, including, but not limited to:
- Ovarian cancer
- Breast cancer
- Medullary thyroid cancer, and
- Lung cancer.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>No</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>No</td>
</tr>
<tr>
<td>Medicare PPO Blue℠</td>
<td>No</td>
</tr>
</tbody>
</table>

**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>
</tr>
</thead>
<tbody>
<tr>
<td>78800</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area</td>
</tr>
<tr>
<td>78801</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas</td>
</tr>
<tr>
<td>78803</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT)</td>
</tr>
<tr>
<td>78804</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging</td>
</tr>
</tbody>
</table>

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4642</td>
<td>Supply of satumomab pendetide, radiopharmaceutical diagnostic imaging agent, per dose</td>
</tr>
</tbody>
</table>

**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).

Examples of RIS agents for imaging of colorectal and ovarian carcinomas include Indium-111 satumomab pendetide (CYT-103, OncoScint CR/OV®) and Technetium-99m arcitumomab (IMMU-4, CEA-Scan®). All RIS agents are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

These RIS agents have also been used in an off-label use to evaluate other malignancies including, but not limited to, breast cancer, lung cancer, and thyroid cancer.
OncoScint is no longer commercially available.

Summary
Positive findings on radioimmunoscintigraphy can affect the surgical management of patients with suspected occult cancer who would otherwise undergo second-look laparotomy due to a rising carcinoembryonic antigen level, or resection of a metastasis that was incorrectly assumed to be an isolated lesion. Radioimmunoscintigraphy may be considered medically necessary in these circumstances.

The relatively small size of most studies and/or the retrospective nature of the analyses without prospectively designed confirmation studies limits the conclusions that can be made from the available data on other cancer types. Therefore, radioimmunoscintigraphy is investigational for these cancers.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
</table>
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |

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
1. 1994 TEC Assessments; Tab 5.
25. 1997 TEC Assessments; Tab 17.