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

Medical Policy

Section
Radiology

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12:2013

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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 satumomab pendetide (CYT-103, OncoScint CR/OV®) has been approved by the U.S. Food and Drug Administration (FDA) for imaging of colorectal and ovarian carcinomas.
- Technetium-99m arcitumomab (IMMU-4, CEA-Scan®) has been approved by the FDA for use in colorectal and ovarian carcinoma.

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.

Policy

Radioimmunoscintigraphy using satumomab pendetide or arcitumomab as the monoclonal antibody may be considered 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-aricutumomab (IMMU-4, CEA-Scan) are considered investigational, including, but not limited to ovarian cancer, breast cancer, medullary thyroid cancer, and lung cancer.

Policy Guidelines

PET scanning has largely replaced radioimmunoscintigraphy using satumomab pendetide or aricutomab as the as the imaging technique of choice to evaluate for suspected recurrent colorectal carcinoma.

Rationale

Colon Cancer

The policy statement regarding RIS in patients with colorectal cancer is based on a 1994 TEC Assessment (1) that concluded that the evidence was adequate to conclude that radioimmunoscintigraphy improved health outcomes in certain patients with colorectal cancer. Specifically, 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 (CEA) level, or resection of a metastasis that was incorrectly assumed to be an isolated lesion.

Additional review of the literature does not change the conclusions of the prior assessment. However, further reports have illustrated that RIS findings may yield false-positive findings such that biopsy or surgical confirmation of RIS findings may still be necessary to ensure appropriate patient management. (2-6) Furthermore, Dominguez et al. (7) reported in 15 patients with colorectal cancer that In-111 satumomab pendetide imaging had no effect on surgical management in 67%, a beneficial effect in 13%, and a negative effect in 20% of cases.

Moffat et al. (8) reported a review of the literature using various RIS agents in colorectal cancer. In a multicenter trial also by Moffat et al. (9) using Tc-99m-aricutumomab, RIS results were associated with “potential clinical benefit” in 49 of 88 patients (56%) with suspected occult colorectal cancer recurrence. In a larger analysis from this same study, RIS results provided information that could have changed treatment planning in 89 of 210 (42%) patients.

Ovarian Cancer

The policy statement regarding RIS in patients with ovarian cancer is also based on a 1994 TEC Assessment (1) that concluded that the evidence was inadequate to determine whether its use was associated with beneficial health outcomes. Specifically, RIS has been investigated as a
technique to select patients for second-look laparotomy after initial treatment for ovarian carcinoma. However, the assessment concluded that the positive predictive value of RIS was not fully reported in the available studies, and therefore it was not possible to determine whether the use of RIS was a reliable basis for making patient management decisions.

Additional review of the literature does not provide sufficient evidence to demonstrate the clinical effectiveness of RIS in ovarian cancer. (10-13) One study reviewed in the prior TEC Assessment, Surwit et al. (14), reports sensitivity of RIS with In-111 satumomab pendetide to be 68% in 103 subjects who had suspected or proven ovarian cancer before surgical management. However, when analysis was restricted to only patients with recurrent disease, sensitivity was only 59%. In the overall population, specificity was only 50%. Blend et al. (12) included 29 subjects with suspected recurrent ovarian cancer in a retrospective analysis of the impact of RIS using In-111 satumomab pendetide on management. In this study, clinical management was influenced in 19 of 299 cases (65.5%). Surgery was initiated in 3 cases, cancelled in 1 case, and limited exploration was elected in 2 cases. Chemotherapy was started in 8 cases. Several smaller studies combine reporting for results with colorectal cancer and ovarian cancer, yet the actual number of patients with ovarian cancer is very small, with only 2 in each study. (11,15)

Two studies evaluated the use of RIS prior to second-look laparotomy. (13,16) Method et al. (13) reported a prospective, blinded study in 20 subjects with ovarian cancer who had “normal CA 125 levels and no clinical evidence of disease after primary cytoreductive surgery and cytotoxic chemotherapy.” All but 2 patients underwent reassessment laparotomy. Twelve patients had true-positive findings on RIS that were confirmed on laparotomy, and RIS sensitivity was calculated to be 100%, although specificity was relatively low at 16.7%. CT scanning showed relatively poor sensitivity (16.7%) but higher specificity (66.7%). Hempling et al. (16) studied 15 patients and found that RIS had a sensitivity of 62.5% and specificity of 57.1%. In patients with macroscopically visible tumor, disease location was correctly predicted by RIS in only 57% of cases.

These preliminary results suggest that RIS may possibly be useful in detecting additional sites of ovarian tumor in some cases, although reported sensitivity is variable. Specificity may be relatively low, and confirmation of positive findings may be necessary. Despite some evidence that RIS may be helpful in some cases where occult recurrence is suspected but cannot be localized, the relatively small size of most studies and the retrospective nature of the analyses without prospectively designed confirmation studies limits the conclusions that can be made from the available data.

Breast Cancer

Gopalan et al. (17) review various nuclear medicine techniques in breast cancer imaging and summarize findings using In-111 satumomab pendetide from a Phase I study by Lamki et al. (18) in 16 patients with primary breast cancer. While RIS detected all primary cancers (ranging in size from 1.2–2.5 cm), diagnostic accuracy in evaluating axillary lymph nodes was more limited with both false negative and false positive findings observed. Goldenberg (19) also mentions the use of anti-CEA RIS in evaluating breast cancer, but little empirical data was identified.

Medullary Thyroid Cancer

Medullary thyroid cancer may express carcinoembryonic antigen (CEA), and CEA levels are
one method used to monitor disease for recurrence. Radiolabeled anti-CEA monoclonal antibodies have been applied as an adjunct to evaluate patients with medullary thyroid cancer, however, most of the identified studies (20-24) used indium- or iodine-labeled monoclonal antibodies, which are not the same as the FDA-approved technetium-labeled product. One study of 26 subjects included 1 subject who received the FDA-approved Tc-99m arcitumomab (IMMU-4; CEA-scan). In that case, RIS showed uptake in the 3 lesions that were also visible on CT.

**Lung Cancer**

The 1997 TEC Assessment (25) on radioimmunoscinintigraphy for lung cancer reviews 2 studies and 1 abstract using Tc-99m arcitumomab (IMMU-4; CEA-Scan®, Immunomedics, Inc.) for evaluation of non-small cell lung cancer (NSCLC). These reports included relatively small samples, and some studies did not provide reporting of sensitivity and specificity. One study of 17 subjects found that RIS had 67% sensitivity in demonstrating 39 malignant lesions that were known to express CEA and that had been detected on conventional imaging techniques. It is not clear from these results how RIS would be useful in improving management and health outcomes.

**Other Cancers**

Bombardieri et al. (26) note that anti-CEA RIS has been used in evaluating other malignancies including pancreatic, gastric, and esophageal cancers, but there appears to be little evidence on this use.

References:

1. 1994 TEC Assessments; Tab 5.


25. 1997 TEC Assessments; Tab 17.


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Type of Service | Radiology  
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