



MASSACHUSETTS

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Medical Policy

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

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Policy Number: 638

BCBSA Reference Number: 6.01.36A

NCD/LCD: N/A

Related Policies

None

Policy

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

Radioimmunosciintigraphy 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 radioimmunosciintigraphy 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

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

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

CPT codes:	Code Description
78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day imaging
78801	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day imaging
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day imaging
78804	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, requiring 2 or more days imaging

HCPCS Codes

HCPCS codes:	Code Description
A4642	Supply of satumomab pentetide, radiopharmaceutical diagnostic imaging agent, per dose

Description

Radioimmunosintigraphy (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 pentetide (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 radioimmunoscinigraphy 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. Radioimmunoscinigraphy 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, radioimmunoscinigraphy is investigational for these cancers.

Policy History

Date	Action
4/2020	Policy updated with literature review through March 27, 2020, no references added. Policy statements unchanged.
1/2020	Clarified coding information.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2009	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
2/2009	BCBSA National medical policy review. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
9/2007	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2007	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. 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.
2. Su WT, Brachman M, O'Connell TX. Use of OncoScint scan to assess resectability of hepatic metastases from colorectal cancer. *Am Surg* 2001; 67(12):1200-3.
3. Bhatia M, Baron PL, Alderman DF et al. False-positive imaging of In-111 labeled monoclonal antibody conjugate CYT-103 in a patient with metastatic colorectal carcinoma. *Clin Nucl Med* 1995; 20(11):979-80.
4. Muxi A, Pons F, Vidal-Sicart A et al. Radioimmunoguided surgery of colorectal carcinoma with a 111In-labelled anti-TAG72 monoclonal antibody. *Nucl Med Commun* 1999; 20(2):123-30.
5. Volpe CM, Abdel-Nabi HH, Kulaylat MN et al. Results of immunoscintigraphy using a cocktail of radiolabeled monoclonal antibodies in the detection of colorectal cancer. *Ann Surg Oncol* 1998; 5(6):489-94.
6. Wegener WA, Petrelli N, Serafini A et al. Safety and efficacy of arcitumomab imaging in colorectal cancer after repeated administration. *J Nucl Med* 2000; 41(6):1016-20.
7. Dominguez JM, Wolff BG, Nelson H et al. 111In-CYT-103 scanning in recurrent colorectal cancer – does it affect standard management? *Dis Colon Rectum* 1996; 39(5):514-9.
8. Moffat FL, Gulec SA, Serafini AN et al. A thousand points of light or just dim bulbs? Radiolabeled antibodies and colorectal cancer imaging. *Cancer Invest* 1999; 17(5):322-34.
9. Moffat FL, Pinsky CM, Hammershaimb L et al. Clinical utility of external immunoscintigraphy with the IMMU-4 technetium-99m Fab' antibody fragment in patients undergoing surgery for carcinoma of the colon and rectum: results of a pivotal phase III trial. *J Clin Oncol* 1996; 14(8):2295-305.
10. Kalofonos HP, Karamouzis MV, Epenetos AA. Radioimmunoscintigraphy in patients with ovarian cancer. *Acta Oncol* 2001; 40(5):549-57.
11. Pinkas L, Robins PD, Forstrom LA et al. Clinical experience with radiolabelled monoclonal antibodies in the detection of colorectal and ovarian carcinoma recurrence and review of the literature. *Nucl Med Commun* 1999; 20(8):689-96.
12. Blend MJ, Bhadkamkar VA. Impact of radioimmunoscintigraphy on the management of colorectal and ovarian cancer patients: a retrospective study. *Cancer Invest* 1998; 16(7):431-41.
13. Method MW, Serafini AN, Averette HE et al. The role of radioimmunoscintigraphy and computed tomography scan prior to reassessment laparotomy of patients with ovarian carcinoma. A preliminary report. *Cancer* 1996; 77(11):2286-93.
14. Surwit EA, Childers JM, Krag DN et al. Clinical assessment of 111In-CYT-103 immunoscintigraphy in ovarian cancer. *Gynecol Oncol* 1993; 48(3):285-92.
15. Bohdiewicz PJ, Scott GC, Juni JE et al. Indium-111 OncoScint CR/OV and F-18 FDG in colorectal and ovarian carcinoma recurrences. Early observations. *Clin Nucl Med* 1995; 20(3):230-6.
16. Hempling RE, Piver MS, Baker TR et al. Immunoscintigraphy using 111InCyt103 prior to second look laparotomy in ovarian cancer. A pilot study. *Am J Clin Oncol* 1994; 17(4):331-4.
17. Gopalan D, Bomanji JB, Costa DC et al. Nuclear medicine in primary breast cancer imaging. *Clin Radiol* 2002; 57(7):565-74.
18. Lamki LM, Buzdar AU, Singletary SE et al. Indium-111-labeled B72.3 monoclonal antibody in the detection and staging of breast cancer: a phase I study. *J Nucl Med* 1991; 32(7):1326-32.
19. Goldenberg DM. Perspectives on oncologic imaging with radiolabeled antibodies. *Cancer* 1997; 80(12 Suppl):2431-5.
20. Barbet J, Peltier P, Bardet S et al. Radioimmunodetection of medullary thyroid carcinoma using indium-111 bivalent hapten and anti-CEA x anti-DTPA-indium bispecific antibody. *J Nucl Med* 1998; 39(7):1172-8.
21. Vuillez JP, Peltier P, Caravel JP et al. Immunoscintigraphy using 111-In-labeled F(ab')₂ fragments of anticarcinoembryonic antigen monoclonal antibody for detecting recurrences of medullary thyroid carcinoma. *J Clin Endocrinol Metab* 1992; 74(1):157-63.
22. Zanin DEA, van Dongen A, Hoefnagel CA et al. Radioimmunoscintigraphy using iodine-131 anti-CEA monoclonal antibodies and thallium-201 scintigraphy in medullary thyroid carcinoma: a case report. *J Nucl Med* 1990; 31(11):1854-5.
23. Riva P, Moscatelli G, Paganelli G et al. Antibody-guided diagnosis: an Italian experience on CEA-expressing tumours. *Int J Cancer Suppl* 1988; 2:114-20.

24. Juweid M, Sharkey RM, Behr T et al. Improved detection of medullary thyroid cancer with radiolabeled antibodies to carcinoembryonic antigen. *J Clin Oncol* 1996; 14(4):1209-17.
25. 1997 TEC Assessments; Tab 17.
26. Bombardieri E, Aliberti G, de Graaf C et al. Positron emission tomography (PET) and other nuclear medicine modalities in staging gastrointestinal cancer. *Semin Surg Oncol* 2001; 20(2):134-46.