Medical Coverage Policy | Scintimammography and Gamma Imaging of the Breast and Axilla



EFFECTIVE DATE: 01|01|2019 **POLICY LAST UPDATED:** 08|16|2023

OVERVIEW

Scintimammography refers to the use of radiotracers with nuclear medicine imaging as a diagnostic tool for abnormalities of the breast. Breast-Specific Gamma Imaging (BSGI), or Molecular Breast Imaging (MBI), refers to specific types of imaging machines that are used in conjunction with scintimammography to improve diagnostic performance.

This policy is applicable only for Scintimammography. For use of gamma detection following radiopharmaceutical administration for localization of sentinel lymph nodes in patients with breast cancer please refer to the High-Tech Radiology policy.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Scintimammography, Breast-Specific Gamma Imaging, and Molecular Breast Imaging are considered not covered in all applications, including but not limited to their use as an adjunct to mammography or in staging the axillary lymph nodes as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Scintimammography, Breast-Specific Gamma Imaging, and Molecular Breast Imaging are considered not medically necessary in all applications, including but not limited to their use as an adjunct to mammography or in staging the axillary lymph nodes as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Medicare Advantage Plans and Commercial Products

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND:

Scintimammography is a diagnostic modality using radiopharmaceuticals to detect tumors of the breast. After injection of a radiopharmaceutical, the breast is evaluated with planar imaging. Scintimammography is performed with the patient lying prone and the camera positioned laterally, which increases the distance between the breast and the camera. Scintimammography using conventional imaging modalities has relatively poor sensitivity in detecting smaller lesions (e.g., smaller than 15 mm), because of the relatively poor resolution of conventional gamma cameras in imaging the breast.

BSGI and MBI were developed to address this issue. Breast-specific gamma cameras acquire images while the patient is seated in a position similar to that in mammography, and the breast is lightly compressed. The detector head(s) is immediately next to the breast, increasing resolution, and the images can be compared with the mammographic images. Breast-Specific Gamma Imaging and Molecular Breast Imaging differ primarily in the type and number of detectors used (multi-crystal arrays of cesium iodide or sodium iodide versus semiconductor materials, such as cadmium zinc telluride, respectively). In some configurations, a detector is placed on each side of the breast and used to lightly compress it. The maximum distance between the detector and the breast is therefore from the surface to the midpoint of the breast. Much of the research on BSGI and MBI has been conducted at the Mayo Clinic. The radiotracer usually utilized is technetium Tc99m sestamibi. MBI imaging takes approximately 40 minutes.

Preoperative lymphoscintigraphy and/or intraoperative hand-held gamma detection of sentinel lymph nodes is a method of identifying sentinel lymph nodes for biopsy after radiotracer injection. Surgical removal of 1 or more sentinel lymph nodes is an alternative to full axillary lymph node dissection for staging evaluation and management of breast cancer. Several trials have compared outcomes following sentinel lymph node biopsy versus axillary lymph node dissection for managing patients with breast cancer.

For individuals who have indeterminate or suspicious breast lesions who receive scintimammography, BSGI, or MBI, the evidence includes diagnostic accuracy studies. Relevant outcomes are overall survival, Scintimammography and Gamma Imaging of the Breast and Axilla disease-specific survival, test validity, and treatment-related morbidity. In the available studies, compared with biopsy, the negative predictive value of BSGI (or MBI) varied from 83% to 94%. Given the relative ease and diagnostic accuracy of the criterion standard of biopsy, coupled with the adverse consequences of missing a breast cancer, the negative predictive value of BSGI (or MBI) would have to be extremely high to alter treatment decisions. The evidence to date does not demonstrate this level of negative predictive value. Moreover, the value of BSGI in evaluating indeterminate or suspicious lesions must be compared with other modalities that would be used, such as spot views for diagnostic mammography. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as an adjunct to mammography or in staging the axillary lymph nodes: **S8080** Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

RELATED POLICIES

High-Tech Radiology Radiopharmaceuticals

PUBLISHED

Provider Update, October 2023 Provider Update, February 2023 Provider Update, January 2023 Provider Update, January 2022 Provider Update, January 2021

REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special report: screening symptomatic women with dense breasts and normal mammograms for breast cancer. TEC Assessments. 2013;Volume 28:Tab 15.

2. O'Connor M, Rhodes D, Hruska C. Molecular breast imaging. Expert Rev Anticancer Ther. Aug 2009; 9(8): 1073-80. PMID19671027

3. Krag DN, Anderson SJ, Julian TB, et al. Sentinel-lymph-node resection compared with conventional axillary-lymph-nodedissection in clinically node-negative patients with breast cancer: overall survival findings from the NSABP B-32 randomisedphase 3 trial. Lancet Oncol. Oct 2010; 11(10): 927-33. PMID 20863759 4. Ashikaga T, Krag DN, Land SR, et al. Morbidity results from the NSABP B-32 trial comparing sentinel lymph node dissectionversus axillary dissection. J Surg Oncol. Aug 01 2010; 102(2): 111-8. PMID 20648579 5. Ram R, Singh J, McCaig E. Sentinel Node Biopsy Alone versus Completion Axillary Node Dissection in Node Positive BreastCancer: Systematic Review and Meta-Analysis. Int J Breast Cancer. 2014; 2014: 513780. PMID 25383226

6. DailyMed. Kit for the preparation of technetium TC99M sestamibi. 2019;

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8c03a854-185a-45d7-883f-9f87e4750181. Accessed August 25, 2022.

7. Hruska CB, O'Connor MK. Nuclear imaging of the breast: translating achievements in instrumentation into clinical use. MedPhys. May 2013; 40(5): 050901. PMID 23635248

8. Schillaci O, Spanu A, Danieli R, et al. Molecular breast imaging with gamma emitters. Q J Nucl Med Mol Imaging. Dec 2013;57(4): 340-51. PMID 24322791

9. GE Healthcare. Myoview (Kit for the preparation of technetium Tc99m tetrofosmin for injection). 2017 April;https://www.gehealthcare.com/-/jssmedia/918cbfdcae184f449d731d4dcffc492f.pdf?la=en-us. August 25, 2022.

10. Aarsvold JN, Alazraki NP. Update on detection of sentinel lymph nodes in patients with breast cancer. Semin Nucl Med. Apr2005; 35(2): 116-28. PMID 15765374

11. American College of Radiology (ACR). Appropriateness criteria: breast cancer screening.

2017;https://acsearch.acr.org/docs/70910/Narrative/. Accessed August 24, 2022.

 Hruska CB, O'Connor MK. Curies, and Grays, and Sieverts, Oh My: A Guide for Discussing Radiation Dose and Risk of Molecular Breast Imaging. J Am Coll Radiol. Oct 2015; 12(10): 1103-5. PMID 26435124
 Hendrick RE. Radiation doses and cancer risks from breast imaging studies. Radiology. Oct 2010; 257(1): 246-53. PMID20736332

14. Health risks from exposure to low levels of ionizing radiation: BEIR VII, Phase 2. Washington, DC: National Research Councilof the National Academies Press; 2006.

15. Berrington de Gonzalez A, Berg CD, Visvanathan K, et al. Estimated risk of radiation-induced breast cancer frommammographic screening for young BRCA mutation carriers. J Natl Cancer Inst. Feb 04 2009; 101(3): 205-9. PMID 19176458

16. Ernestos B, Nikolaos P, Koulis G, et al. Increased chromosomal radiosensitivity in women carrying BRCA1/BRCA2 mutationsassessed with the G2 assay. Int J Radiat Oncol Biol Phys. Mar 15 2010; 76(4): 1199-205. PMID 20206018

17. Food and Drug Administration (FDA). 510(k) Summary: Gamma MedicaTM Instruments: LumaGEM Scintillation Camera(K993813). 2000; https://www.accessdata.fda.gov/cdrh_docs/pdf/K993813.pdf. Accessed August 25, 2022.

18. BlueCross BlueShield Association. Breast-specific gamma imaging (BSGI), molecular breast imaging (MBI), orscintimammography with breast-specific gamma camera. Technol Eval Cent Assess Program Exec Summ. Jun 2013; 28(2): 1-4. PMID 23865107

19. Rhodes DJ, Hruska CB, Conners AL, et al. Journal club: molecular breast imaging at reduced radiation dose for supplementalscreening in mammographically dense breasts. AJR Am J Roentgenol. Feb 2015; 204(2): 241-51. PMID 25615744

20. Shermis RB, Wilson KD, Doyle MT, et al. Supplemental Breast Cancer Screening With Molecular Breast Imaging for WomenWith Dense Breast Tissue. AJR Am J Roentgenol. Aug 2016; 207(2): 450-7. PMID 27186635

21. Brem RF, Ruda RC, Yang JL, et al. Breast-Specific -Imaging for the Detection of Mammographically Occult Breast Cancer inWomen at Increased Risk. J Nucl Med. May 2016; 57(5): 678-84. PMID 26823569

22. Zhang Z, Wang W, Wang X, et al. Breast-specific gamma imaging or ultrasonography as adjunct imaging diagnostics in womenwith mammographically dense breasts. Eur Radiol. Nov 2020; 30(11): 6062-6071. PMID 32524221

23. Rhodes DJ, Hruska CB, Phillips SW, et al. Dedicated dual-head gamma imaging for breast cancer screening in women withmammographically dense breasts. Radiology. Jan 2011; 258(1): 106-18. PMID 21045179

24. Brem RF, Rapelyea JA, Zisman G, et al. Occult breast cancer: scintimammography with high-resolution breast-specific gammacamera in women at high risk for breast cancer. Radiology. Oct 2005; 237(1): 274-80. PMID 16126919

25. Cho MJ, Yang JH, Yu YB, et al. Validity of breast-specific gamma imaging for Breast Imaging Reporting and Data System 4lesions on mammography and/or ultrasound. Ann Surg Treat Res. Apr 2016; 90(4): 194-200. PMID 27073789

26. Meissnitzer T, Seymer A, Keinrath P, et al. Added value of semi-quantitative breast-specific gamma imaging in the work-up of suspicious breast lesions compared to mammography, ultrasound and 3-T MRI. Br J Radiol. Jul 2015; 88(1051): 20150147.PMID 25882690

27. Tan H, Jiang L, Gu Y, et al. Visual and semi-quantitative analyses of dual-phase breast-specific gamma imaging with Tc-99m-sestamibi in detecting primary breast cancer. Ann Nucl Med. Jan 2014; 28(1): 17-24. PMID 24142630

28. Spanu A, Sanna D, Chessa F, et al. The clinical impact of breast scintigraphy acquired with a breast specific -camera (BSGC)in the diagnosis of breast cancer: incremental value versus mammography. Int J Oncol. Aug 2012; 41(2): 483-9. PMID22641247

29. Hruska CB, Phillips SW, Whaley DH, et al. Molecular breast imaging: use of a dual-head dedicated gamma camera to detectsmall breast tumors. AJR Am J Roentgenol. Dec 2008; 191(6): 1805-15. PMID 19020253 30. Spanu A, Chessa F, Meloni GB, et al. The role of planar scintimammography with high-resolution dedicated breast camera inthe diagnosis of primary breast cancer. Clin Nucl Med. Nov 2008; 33(11): 739-42. PMID 18936602

31. Brem RF, Petrovitch I, Rapelyea JA, et al. Breast-specific gamma imaging with 99mTc-Sestamibi and magnetic resonanceimaging in the diagnosis of breast cancer--a comparative study. Breast J. Sep-Oct 2007; 13(5): 465-9. PMID 17760667

32. Guo C, Zhang C, Liu J, et al. Is Tc-99m sestamibi scintimammography useful in the prediction of neoadjuvant chemotherapyresponses in breast cancer? A systematic review and meta-analysis. Nucl Med Commun. Jul 2016; 37(7): 675-88. PMID26974314

33. Lee HS, Ko BS, Ahn SH, et al. Diagnostic performance of breast-specific gamma imaging in the assessment of residual tumorafter neoadjuvant chemotherapy in breast cancer patients. Breast Cancer Res Treat. May 2014; 145(1): 91-100. PMID24671359

34. Edwards C, Williams S, McSwain AP, et al. Breast-specific gamma imaging influences surgical management in patients withbreast cancer. Breast J. Sep-Oct 2013; 19(5): 512-9. PMID 23848225 35. Xu HB, Li L, Xu Q. Tc-99m sestamibi scintimammography for the diagnosis of breast cancer: meta-

analysis and meta-regression. Nucl Med Commun. Nov 2011; 32(11): 980-8. PMID 21956488

36. Taillefer R. The role of 99mTc-sestamibi and other conventional radiopharmaceuticals in breast cancer diagnosis. Semin NuclMed. Jan 1999; 29(1): 16-40. PMID 9990681

37. Schillaci O, Scopinaro F, Spanu A, et al. Detection of axillary lymph node metastases in breast cancer with Tc-99m tetrofosminscintigraphy. Int J Oncol. Mar 2002; 20(3): 483-7. PMID 11836558

Spanu A, Dettori G, Nuvoli S, et al. (99)mTc-tetrofosmin SPET in the detection of both primary breast cancer and axillary lymphnode metastasis. Eur J Nucl Med. Dec 2001; 28(12): 1781-94. PMID 11734916
 Pesek S, Ashikaga T, Krag LE, et al. The false-negative rate of sentinel node biopsy in patients with breast cancer: a meta-analysis. World J Surg. Sep 2012; 36(9): 2239-51. PMID 22569745

40. Thongvitokomarn S, Polchai N. Indocyanine Green Fluorescence Versus Blue Dye or Radioisotope Regarding Detection Rateof Sentinel Lymph Node Biopsy and Nodes Removed in Breast Cancer: A Systematic Review and Meta-Analysis. Asian Pac JCancer Prev. May 01 2020; 21(5): 1187-1195. PMID 32458621 41. Goonawardena J, Yong C, Law M. Use of indocyanine green fluorescence compared to radioisotope for sentinel lymph nodebiopsy in early-stage breast cancer: systematic review and meta-analysis. Am J Surg. Sep 2020; 220(3): 665-676. PMID32115177

42. van der Vorst JR, Schaafsma BE, Verbeek FP, et al. Randomized comparison of near-infrared fluorescence imaging usingindocyanine green and 99(m) technetium with or without patent blue for the sentinel lymph node procedure in breast cancerpatients. Ann Surg Oncol. Dec 2012; 19(13): 4104-11. PMID 22752379

43. Johnson CB, Boneti C, Korourian S, et al. Intraoperative injection of subareolar or dermal radioisotope results in predictableidentification of sentinel lymph nodes in breast cancer. Ann Surg. Oct 2011; 254(4): 612-8. PMID 21918427

44. Martin RC, Edwards MJ, Wong SL, et al. Practical guidelines for optimal gamma probe detection of sentinel lymph nodes inbreast cancer: results of a multi-institutional study. For the University of Louisville Breast Cancer Study Group. Surgery. Aug2000; 128(2): 139-44. PMID 10922983

45. Unkart J, Wallace A. Use of lymphoscintigraphy with Tc-99m tilmanocept does not affect the number of nodes removed duringsentinel node biopsy in breast cancer [abstract]. J Nucl Med. 2016;57(Suppl 2):615.
46. Sun X, Liu JJ, Wang YS, et al. Roles of preoperative lymphoscintigraphy for sentinel lymph node biopsy in breast cancerpatients. Jpn J Clin Oncol. Aug 2010; 40(8): 722-5. PMID 20430775

47. Mathew MA, Saha AK, Saleem T, et al. Pre-operative lymphoscintigraphy before sentinel lymph node biopsy for breast cancer.Breast. Feb 2010; 19(1): 28-32. PMID 19913418

48. Practice Bulletin Number 179: Breast Cancer Risk Assessment and Screening in Average-Risk Women. Obstet Gynecol. Jul2017; 130(1): e1-e16. PMID 28644335

49. American College of Radiology (ACR). Appropriateness criteria: palpable breast masses.

2016;https://acsearch.acr.org/docs/69495/Narrative/. Accessed August 22, 2022.

50. American College of Radiology (ACR). Appropriateness criteria: breast pain.

2018;https://acsearch.acr.org/docs/3091546/Narrative/. Accessed August 23, 2022.

 Monticciolo DL, Newell MS, Moy L, et al. Breast Cancer Screening in Women at Higher-Than-Average Risk: RecommendationsFrom the ACR. J Am Coll Radiol. Mar 2018; 15(3 Pt A): 408-414. PMID 29371086
 American College of Radiology (ACR). Appropriateness criteria: Supplemental breast cancer screening based on breastdensity. 2021; https://acsearch.acr.org/docs/70910/Narrative/. Accessed August 25, 2022.
 Lyman GH, Somerfield MR, Giuliano AE. Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: 2016American Society of Clinical Oncology Clinical Practice Guideline Update Summary. J Oncol Pract. Mar 2017; 13(3): 196-198.PMID 28118104

54. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 24, 2022.

55. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screeningand Diagnosis. Version 1.2022. 2022;

https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf. Accessed August 25, 2022.

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