KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Scintimammography

- Breast Scintigraphy
- Breast-Specific Gamma Imaging (BSGI)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **Scintimammography** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Scintimammography (A-0071) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider and/or specialist (general surgery, oncology)
- Most recent imaging reports

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Mammography is the standard tool used for breast cancer imaging. Community screening programs have found that mammography has an overall sensitivity of 75% and a specificity of 92%. The sensitivity of mammography in randomized trials is in the range of 68-88% (Elmore 2005). However, mammography is less sensitive in women younger than 50 and in women with dense breasts (Brem 2008; Killela 2009). Breast-specific gamma imaging (BSGI) is intended for use when post-mammography evaluation is indicated. Other technologies currently used for post-mammography evaluation include ultrasound and magnetic resonance imaging (MRI). Each of these technologies has its advantages and limitations. Ultrasound is well tolerated, it does not use ionizing radiation or require intravenous contrast administration, and it is able to identify small non-palpable masses in dense breast tissue; however, it is time consuming to perform and increases the risk of false-positive results (Le-Petross 2011). MRI of the breast offers high sensitivity (93-100%), but it has a low specificity (65-79%), which leads to a high

Back to Top

number of false-positive results (Zhou 2009). Additionally, MRI is not suitable for all patients; women with pacemakers, who are claustrophobic, and who cannot lie prone for the required length of the exam may not be suitable candidates for MRI (Ferrara 2010).

Imaging modalities can be roughly classified as either anatomical imaging or functional imaging. Anatomical imaging techniques, such as mammography and MRI, identify structural abnormalities in the body. Functional imaging techniques, such as BSGI, illustrate a physiological behavior. Functional imaging evaluates the metabolic activity of breast lesions through uptake of radioactive tracers. To conduct BSGI, patients are given an intravenous injection with a small dose of a tracing agent (Technicium Tc99m) that emits gamma rays. The tracer is absorbed by the cells in the body. Cancer cells absorb more of the tracing agent due to their higher metabolic activity and increased blood supply. Thus, cancerous areas show up as “hot spots” on BSGI imaging. When used for screening, functional imaging techniques have an advantage over anatomical imaging techniques because they can usually reliably differentiate between an active tumor and scar tissue (Ferrara 2010). BSGI is not without limitations; it is limited by its inability to reliably image cancers smaller than 1 cm. The sensitivity of BSGI is also low (35%-65%). The advent of high-resolution breast-specific gamma cameras is thought to have increased the sensitivity of BSGI and its ability to detect cancers smaller than 1 cm (Brem 2008).

BSGI uses a specialized high-resolution, small field-of-view gamma camera. The cameras are compact and maneuverable, and they can be placed close to the chest to image deep within the breast. Two camera manufacturers were identified. One camera is the Dilon 6800 made by Dilon Technologies of Newport News, VA. An earlier version of this camera, the Dilon 2000, was approved by the FDA in 1999, but the Dilon 6800 was not identified in the FDA database. The second technology is the LumaGem camera developed by Gamma Medica. A version of the LumaGem scintillation camera was cleared by the FDA in 2000. As with the Dilon camera, the breast-specific model described on the manufacturer’s Web site, the LumaGem 3200S, was not identified in the FDA database (Ferrara 2010).

Medical Technology Assessment Committee (MTAC)

Breast Specific Gamma Imaging

02/05/2007: MTAC REVIEW

Evidence Conclusion: No published studies were identified that compared the diagnostic accuracy of breast-specific gamma cameras and standard techniques for post-mammographic imaging such as MRI and ultrasound. In addition, there were no studies that evaluated change in clinical practice if the breast-specific gamma camera were used instead of, or in addition to, MRI or ultrasound. Two studies (Brem et al., 2005; Coover et al., 2004) were evaluated that examined the ability of a breast-specific gamma camera to identify cancers in high-risk women not identified by mammography or physical examination. Both studies were small and had industry funding, and only one included an independent blind comparison of the gamma cameras findings to a reference standard for all patients (Brem et al., 2005). The reference standard in the Brem study was biopsy of positive findings and one-year follow-up for negative cases. In the Brem study, there were 14 false-positives (specificity=85%) and 2 true positives (sensitivity=100%) in 94 women. The confidence interval for sensitivity was very wide due to the small sample size (the 95% CI varied from 22% to 100%) so it is difficult to draw conclusions about accuracy from this study. The Coover study, which was weaker methodologically, identified 3 cancers with the breast-specific gamma camera in 37 women who had had negative mammograms. Although results from these studies are promising, additional appropriately designed studies with a larger number of women are needed to evaluate the accuracy of the breast-specific gamma cameras.

Articles: One published study with the Dilon 6800 camera was identified (Brem et al., 2005). This study included 94 patients and was critically appraised. An earlier study by the same lead author (Brem RF) evaluated a prototype of the Dilon gamma camera and was not evaluated further. There also appears to be unpublished data that were presented at a professional meeting in 2005 comparing the performance of the Dilon 6800 camera to breast MRI.

One published study was identified that stated it used the LumaGem gamma camera to detect breast cancer in women with normal mammograms and clinical examinations (Coover et al., 2004). This study included 37 women and was critically appraised. A second, more recent study with 40 patients (Rhodes, 2005) may have used this or a similar technology, but the authors only stated that they used a prototype gamma camera. The Coover study was critically appraised. No studies were identified that used commercially available cameras to image patients in situations suggested by a manufacturer including patients dense breast tissue, multiple suspicious lesions or clusters of microcalcifications. *The studies reviewed were:* Brem RF et al. Occult breast cancer: Scintimammography with high-resolution breast-specific gamma camera in women at high risk for breast cancer. *Radiology* 2005; 237: 274-280. See Evidence Table. Coover LR, Caravaglia G, Kuhn P. Scintimammography with dedicated breast camera detects and localizes occult carcinoma. *J Nucl Med* 2004; 45: 553-558. See Evidence Table.

Back to Top

The use of breast-specific gamma imaging in the diagnosis of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/19/2010: MTAC REVIEW
Breast Specific Gamma Imaging
Evidence Conclusion: There is limited evidence regarding the accuracy of BSGI compared to MRI. The best available evidence was the Brem et al. study (2007), which compared the sensitivity and specificity of BSGI, using a high-resolution breast-specific gamma camera with MRI in patient with indeterminate breast findings. In this study, 23 patients with indeterminate breast findings underwent both a BSGI scan and a MRI. The results were confirmed with pathological findings. The study found that compared to MRI, BSGI had a statistically significantly higher specificity (71% vs. 25%), and a lower sensitivity (89% vs. 100%). The authors indicated that this is not statistically significant; however, they used a qualitative rather than a quantitative approach to determine significance. Although an 11% difference in sensitivity may be of clinical relevance. This study compared BSGI to MRI using pathology as a gold standard; however, there were several limitations: the study had a small sample size, patient selection criteria were unclear, and it is not stated if reviewers were blinded to the results from the other imaging technique. There were no published studies that compared BSGI with MRI in high risk women or in younger women with dense breast tissue. Kaiser also reviewed this technology on March 23, 2009 and came to similar conclusions. Conclusion: There is insufficient evidence to date to determine whether BSGI improves diagnostic accuracy compared to MRI in patients with indeterminate breast findings.
Articles: The literature search revealed five relevant studies. Three were retrospective and two were prospective. All of the studies had methodological limitations. One of the prospective studies included a comparison group and was selected for review. Brem RF, Petrovitch I, Rapelyea JA et al. Gamma Imaging with 99mTc-Sestamibi and Magnetic Resonance Imaging in the Diagnosis of Breast Cancer-A Comparative Study. The Breast Journal 2007; 13: 456-469. See Evidence Table.

The use of breast-specific gamma imaging in the diagnosis of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/19/2011: MTAC REVIEW
Breast Specific Gamma Imaging
Evidence Conclusion: Since the 2010 review, the literature search revealed only one small observational study that addressed the diagnostic accuracy of BSGI. This study was not selected for review due to methodological limitations (small sample size, patient selection criteria and baseline characteristic were not addressed, and confidence intervals were not provided) (Ozulker 2010). Conclusion: There is insufficient evidence to determine whether BSGI improves diagnostic accuracy when used as an adjunct to mammogram.
Articles: Since the 2010 review, the literature search revealed only one small observational study that addressed the diagnostic accuracy of BSGI. This study was not selected for review due to methodological limitations (small sample size, patient selection criteria and baseline characteristic were not addressed, and confidence intervals were not provided) (Ozulker 2010).

The use of breast-specific gamma imaging in the diagnosis of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Back to Top

Date Created	Date Reviewed	Date Last Revised
03/21/2007	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 10/04/2011 MDCRPC, 01/03/2012 MDCRPC, 11/06/2012 MDCRPC ,09/03/2013 MPC,11/05/2013MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC,12/07/2021MPC,12/06/2022MPC	12/07/2021

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD Non-Covered Services L34886 and L35008
12/07/2021	Removed reference to retired Non-Covered Services LCD (L35008).

Back to Top