KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Positron Emission Mammography (PEM)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	*Medicare has not specifically addressed this technology in its coverage decision documents. See PET Scan criteria.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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

- Last 6 months of clinical notes from requesting provider &/or specialist

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

Breast cancer is the most common non-skin cancer among women in the United States, and one of the leading causes of cancer death among women of all races. Although the incidence rate has increased, there has been a steady decline in the breast cancer death rate since the early 1990s, mostly due to screening, better awareness, and improved treatment. Early detection and accurate staging and restaging of recurrent breast cancer are important to define appropriate therapeutic strategies and increase the chance of a cure (Bartella 2006, CDC 2010, Pan 2010).

Mammography remains the gold standard screening method for women at average risk for breast cancer. It is relatively inexpensive, requires a low dose of radiation, and reliably identifies malignant tumors especially those that are too small to feel. It can also be used to investigate breast lumps and other symptoms. Although the benefit of mammographic screening is widely accepted, its limitations and failure to detect all breast cancers are also recognized. It is reported that the false negative rate of screening mammography ranges between 20-30%. It also has a low specificity resulting in a large number of unnecessary procedures. It is reported that only 25-45% of the biopsies done based on mammographic abnormalities result in a diagnosis of carcinoma. Diagnostic mammography is commonly used to identify possible breast cancers in women with signs and symptoms and has a higher sensitivity (85-93%) compared with screening mammography (Bartella 2007).

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Ultrasound (US) imaging may be used to evaluate abnormalities detected during a breast exam or mammogram and is useful in differentiating solid tumors from fluid filled cysts. It is considered the imaging technique of choice for evaluating palpable masses in women younger than 30 years as well as in pregnant and lactating women. It can also be used for the guidance of interventional procedures and treatment planning for radiation therapy. US is easily accessible, relatively low in cost, and does not involve the use of ionizing radiation. However, it cannot detect microcalcifications, can be time consuming, and its performance is operator dependent (Ferrara 2010).

Breast MRI using a special receiver and injected contrast material is more sensitive and accurate than mammography and ultrasound in detecting invasive lobular cancer. MRI detects blood flow to lesions and does not expose the patient to radiation. The increased blood flow is indicative of vascularization frequently found in cancer. MRI however, has some disadvantages; it can lead to false positive results as both benign and malignant lesions can absorb the contrast, it is less sensitive in detecting in situ cancers, and its interpretation is challenged when the breast is under estrogen modulation during menstrual cycle or HRT use, which affects the glandular tissue of the breast. In addition, MRI is not indicated and/or tolerated by many patients due to renal disease, metallic implants, claustrophobia, large body size, or general medical condition. It is a costly test to use for screening and is not a substitute for mammography. MRI is recommended for screening women at very high risk of breast cancer especially for the BRCA1 and BRCA2 subgroups. Other accepted indications include patients presenting with axillary adenopathy and an unknown primary, patients with equivocal mammograms, the differentiation of scar versus recurrence at lumpectomy site, as well as other indications (Tafreshi 2010, Philpotts 2011, Schilling 2011).

Nuclear breast imaging refers to functional imaging of the breast through the use of radiopharmaceuticals such as 18 F-fluorodeoxyglucose (18FDG) or 99mTc-sestamibi. It takes advantage of the differences in metabolic activity between tumor and normal tissue. Functional imaging can thus show changes in cell metabolism that are due to malignancies as the majority of primary and metastatic cancers take up more glucose than the adjacent normal tissues. Positron emission tomography (PET) with the radiotracer FDG may be able to detect cancer even before vascularization as cancer cell metabolism is usually heightened prior to the stimulation of new vessel growth. It has the potential of improving detection of cancer in dense breasts, illustrating the extent of the disease for surgical planning, and distinguishing between recurrent cancer and scar tissue (Schilling 2011).

The use of whole-body PET (WB- PET) and PET/CT is limited due to the low sensitivity and positive predictive value in detecting early stage breast cancer, invasive lobular and ductal carcinoma in situ, as well regional lymphadenopathy. The reasons reported for this low sensitivity include low spatial resolution, and lower level of FDG tracer uptake in some breast malignancies compared to other cancers (Schilling 2011).

Positron emission mammography (PEM) is a modification of PET that allows for a much more spatial resolution by putting the photon detectors directly on the breast. PEM uses similar principles as PET but is a breast specific imaging tool. Both work through the introduction and detection of a positron-emitting glucose analog 18F-FDG as the imaging radiotracer. The 18F-FDG analog decays by emitting a positron that is annihilated within a few millimeters resulting in emission of two gamma rays that radiate in opposite directions and are detected by the PET instrument. The resolution of PEM is increased by allowing the detectors to be directly placed on the breast. Gentle compression provides the advantage of spreading out the breast tissue for imaging. PEM devices use 2 moving detector heads mounted on compression paddles, with a similar configuration and size as a traditional mammography system. This allows direct correlation of the initial and recurrence images obtained by both devices. PEM images can also be reconstructed into 3D for localization of abnormalities. It is reported that the technique used allows capturing sharp detailed images of breast lesions as small as 2 mm, and the detection of small foci of ductal carcinoma in situ without depending on the presence of calcification for its identification. The whole-body radiation dose the patient receives from PEM is approximately three times higher than that of a mammogram, which may be a barrier to using it as a screening modality in the general population. PEM also cannot take the place of breast cancer staging performed with whole-body PET because PEM is limited to breast views only. It is reported that the same benign conditions that cause high FDG uptake in PET (e.g. infection, inflammation and fat necrosis) may cause false positive results in PEM. Glucose control is another problem with PEM as it is with PET; women with inadequately controlled diabetes cannot undergo either procedure (Tafreshi 2010, Ferrara 2010, Moadel 2011).

PEM 2400 PET scanner and PEM Flex devices have received FDA clearance to perform PET imaging of the breast under gentle compression for patients with confirmed breast cancer.

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08/15/2011: MTAC REVIEW

Evidence Conclusion: Berg et al (2006) study (Evidence table 1) evaluated PEM diagnostic performance in 77 women with 77 index and 15 incidentally discovered lesions, all histologically proven breast cancer. PEM identified 91% of DCIS, and had an overall sensitivity of 93% for the index cancers, and 90% when incidental cancers were included. Combined with conventional imaging (mammography and ultrasonography) the sensitivity of PEM improved to 98%, but with a reduced specificity. The study had its limitations and used nonstandard method for calculating the standardized uptake value (SUV). Berg et al, 2011 (Evidence table 2) examined the diagnostic performance of PEM and its impact on surgical management compared with MRI in 388 women with newly diagnosed, histologically proven breast cancer. The results of the study showed that PEM and MRI had an overall similar accuracy. MRI was more sensitive and less specific than PEM at the lesion level and in detecting incidental additional cancers. MRI was also more accurate than PEM in assessing disease extent and need for mastectomy. Still, as the authors indicate, "the combination of both MRI and PEM did not fully depict the disease extent, particularly in cases with extensive intraductal component, multifocal disease, or multicentric disease, the patient population that would benefit from accurate assessment of the disease extent". Schilling et al, 2011 (Evidence table 3) also compared the performance of FDG-PEM vs. MRI, including their effect on presurgical planning in 208 patients with newly diagnosed, biopsy proven breast cancer. Only 76% or the participants were included in the analysis. Overall, the results show that PEM and MRI had similar sensitivities of 92.8% in depiction of index cancerous lesions. Similar to the Berg's study, MRI was more sensitive and less specific than PEM in detecting additional unsuspected ipsilateral lesions but, the difference was statistically insignificant. However, the authors did not discuss if they performed any power analysis to determine the appropriate sample size. The study did not examine whether PEM results alone influenced surgical treatment as all imaging results were available to the surgeons prior to surgery treatment.

Articles: The literature search revealed around two hundred articles on PET exams for the breast. Many were review articles, technical reports, or studies on the diagnostic accuracy of FDG-PET rather than PEM which is the focus of the review. There were a limited number of studies that compared the accuracy of PEM with mammography or MRI, and most were conducted by one PEM working group. The following studies were selected for critical appraisal: Berg WA, Weinberg IN, Narayanan D, et al. High resolution fluorodeoxyglucose positron emission tomography with compression ("positron emission mammography") is highly accurate in depicting primary breast cancer. *Breast J.* 2006;12:309-323. See Evidence Table. Berg WA, Madsen KS, Schilling K, et al. Breast cancer: comparative effectiveness of positron emission mammography and MR imaging in presurgical planning for the ipsilateral breast. *Radiology.* 2011;25:59-72. See Evidence Table. Schilling K, Narayanan D, Kalinyak JE, et al. Positron emission mammography in breast cancer: presurgical planning f comparison with magnetic resonance imaging. *Eur J Nucl Med Mol Imaging* 2011;25:23-36. See Evidence Table.

The use of Positron Emission Mammography (PEM) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***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**.

Date Created	Date Reviewed	Date Last Revised
09/05/2011	09/06/2011[MDCRPC], 07/03/2012 [MDCRPC], 05/07/2013[MDCRPC], 03/04/2014[MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 06/05/2018[MPC],	09/06/2011

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	06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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