BlueCross BlueShield of Louisiana

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Positron Emission Mammography (PEM)

Policy # 00285
Original Effective Date: 02/16/2011
Current Effective Date: 05/05/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of positron emission mammography (PEM) to be **investigational.***

Background/Overview

Positron emission mammography (PEM) is a form of positron emission tomography (PET) that uses a high-resolution, mini-camera detection technology for imaging the breast. As with PET, PEM provides functional rather than anatomic information on the breast. This policy will address the use of PEM for pre-surgical planning and staging, monitoring response to therapy, and monitoring for recurrence of breast cancer.

PEM is a form of PET that uses a high-resolution, mini-camera detection technology for imaging the breast. As with PET, a radiotracer, usually 18F-fluorodeoxyglucose (FDG) is administered and the camera is used to provide a higher resolution image of a limited section of the body than would be achievable with FDG-PET. Gentle compression is used, and the detector(s) are mounted directly on the compression paddle(s). PEM was developed to overcome the limitations of PET for detecting breast cancer tumors. Patients usually are supine for PET procedures, and the breast tissue may spread above the chest wall, making it potentially difficult to differentiate breast lesions from other organs that take up the radiopharmaceutical. PET's resolution is generally limited to about 5 mm, which may not detect early breast cancer tumors. PEM allows for the detection of lesions smaller than 2 cm and creates images that are more easily compared to mammography, since they are acquired in the same position. Three-dimensional reconstruction of the PEM images is also possible. As with PET, PEM provides functional rather than anatomic information on the breast. In studies of PEM, exclusion criteria included some patients with diabetes (e.g., references). PET may be used for other indications for breast cancer patients, namely, detecting loco-regional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In August 2003, the PEM 2400 PET Scanner (PEM Technologies, Inc.) was cleared for marketing by the U.S. FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in "medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body." In March 2009, the Naviscan PEM Flex™‡ Solo II High Resolution PET Scanner (Naviscan, Inc.) was cleared for marketing by the FDA through the 510(k) process for the same indication. The PEM 2400 PET Scanner was the predicate device. The newer device is

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described by the manufacturer as "a high spatial resolution, small field-of-view PET imaging system specifically developed for close-range, spot, i.e., limited field, imaging."

There was a class 2 recall of the Naviscan PET Systems Inc. PEM Flex Solo II PET Scanner on September 11, 2008, due to "a report from a user indicating that the motorized compression exceeded 25 pounds of compression force during the pre-scan positioning of the patient." Software for the PEM Flex Solo I and PEM Flex Solo II PET scanners was recalled in August 2007.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination for PEM specifically; there is one for PET.

Rationale/Source

The most recent, highest quality evidence is summarized in this section. No randomized, controlled trials (RCTs) beginning with use of PEM and following up through clinical outcomes were found, nor were any meta-analyses. One single-arm, prospective study and 2 comparative, prospective studies are summarized.
In an early 4-site clinical study (NCT00484614), 94 women with suspected or proven (n=44) breast cancer were given a median dose of 13 mCi 18F FDG and imaged with PEM. Median time from injection to imaging was 99 minutes; imaging took 10 minutes per image, and median slice thickness was 5.2 mm. "Unevaluable" cases were excluded (n not reported). Eight readers had mammography and clinical breast examination (CBE) results, as well as clinical information, but not information on surgical planning or outcomes. At least 2 readers evaluated each case in random order. Median patient age was 57 years with median tumor size of 22 mm on pathology. Seventy-seven percent of the primary lesions were nonpalpable. The performance of PEM in this study is as follows:

- BIRADS 4b, c or 5 (probably malignant) assigned to 39 of 44 (89%) pathologically confirmed breast cancers. Missed lesions ranged in size from 1 to 10 mm; all were malignant, and 4 of 5 were low grade.
- Extensive ductal carcinoma in situ (DCIS) predicted in 3 cases and confirmed to be malignant; they were not detected by other imaging modalities used.
- Among the 44 patients with proven breast cancer, 5 incidental benign lesions were correctly classified and 4 of 5 incidental malignant tumors were detected, 3 of which were not detected with other imaging modalities (not evident whether MRI [magnetic resonance imaging] was performed on these specific patients).
- Correctly detected multifocality in 64% of the 31 patients evaluated for it, and correctly predicted its absence in 17 patients.
- Correctly predicted 6 of 8 patients undergoing partial mastectomy who had positive margins and 11 of 11 who had negative margins.

The results from this pilot study are reported in detail to illustrate the potential uses of PEM that were being considered.

A follow-up article on the same trial (NCT00484614) reported on 77 patients. This article also indicated that patients with type I or II diabetes were excluded (apparently because FDG is glucose based, so diabetic patients must have well-controlled glucose for the test to work). Readers had access to the mammographic

and clinical findings, as it was assumed they would in clinical practice. The median dose of FDG was 12 mCi (range: 8.2-21.5 mCi). Of the 77 patients, 33 had suspicious findings on core biopsy prior to PEM, 38 had abnormalities on x-ray mammograms, and 6 had suspicious findings on CBE. Five women had personal histories of breast cancer, one of whom had had reconstructive surgery. The median age was 53 years. Forty-two of 77 cases were malignant, and 2 had atypical ductal hyperplasia. The sensitivity and specificity of PEM was 93% and 85%, respectively, for index lesions and 90% and 86%, respectively, for index and incidental lesions. These values were similar or higher if lesions were clearly benign on conventional imaging and diabetic patients were excluded. Adding PEM to x-ray mammography and ultrasound (when available) yielded sensitivity and specificity of 98% and 41%, respectively.

At a single site, a prospective study comparing PEM and magnetic resonance imaging (MRI) (1.5 T) was conducted to assist in presurgical planning. The performance of PEM, MRI, and whole-body positron emission tomography (WBPET) were compared with final surgical histopathology among women with newly diagnosed, biopsy-proven breast cancer. For PEM and WBPET (performed consecutively), the median FDG dose was 432.9 MBq (equivalent to 11.7 mCi). Patients' 4-6 hour fasting glucose had to be less than 7.8 mmol/L. One of 6 readers evaluated the PEM, x-ray mammography, and MRI images with access to conventional imaging (mammography or ultrasound) results "but without influence of the alternative (PEM or MRI) imaging modality"; WBPET images were interpreted by a nuclear physician. For evaluating PEM images, readers used a proposed PEM lexicon based on MRI BI-RADS. Patients underwent surgery approximately 3 weeks after PEM and WBPET imaging. Of 250 patients approached to participate in this study, 31 were disqualified, and 26 were ineligible because they underwent PEM or MRI before study entry; the analysis therefore includes 182 patients. Almost half (45.6%) of lesions were clinically palpable. On pathology, 77.5% of patients had invasive disease; 20.9% DCIS; and 1.6% Paget's disease. For index lesions, both PEM and MRI had a sensitivity of 92.8% (95% confidence interval [CI]: 88%, 96%; p=not significant), which was greater than the WBPET sensitivity of 67.9% (95% CI: 60%, 70%; p<0.001). The specificity was not reported, since only malignant index lesions were analyzed. The sensitivity of PEM and MRI were not affected by breast density, menopausal status, or use of hormone replacement therapy. PEM tended to overestimate the size of the largest lesion, compared to surgical pathology and MRI (120 mm for PEM vs. 95 mm for pathology and MRI); however, the Spearman's correlation coefficient between size on histopathology versus size on either PEM or MRI was the same at 0.61. Twelve lesions were missed on both PEM and MRI; 3 of them were not in the PEM field of view due to patient positioning. For the 67 additional ipsilateral lesions detected (40 malignancies), the sensitivity of PEM and MRI were 85% (95% CI: 70%, 94%) and 98% (95% CI: 89%, 100%; p=0.074), respectively; and the specificity of PEM and MRI, were 74% (95% CI: 54%, 89%) and 48% (95% CI: 29%, 68%; p=0.096), respectively. Further investigation is needed to determine whether these are 2 points along the same operating curve (i.e., whether PEM is being read to emphasize specificity compared to MRI). Additional larger studies are also warranted.

The results of a trial that compared PEM and MRI were reported at the 2010 Annual Meeting of the Radiological Society of North American (RSNA) and simultaneously published in the journal *Radiology.* The study was funded in part by Naviscan, which manufactures the FDA-cleared PEM device, and by the National Institutes of Health. The first author is a consultant to Naviscan; other authors include a former employee and a current employee.

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The study was conducted at 6 sites among 388 women with newly diagnosed breast cancer detected at core-needle or vacuum-assisted biopsy and who were eligible for breast-conserving surgery. The median age was 58 years. Among 427 women originally enrolled, 18 were ineligible and 66 were excluded. The latter 66 patients were statistically significantly more likely than the women included in the analysis to have larger invasive tumor components, to be less likely to have 1 ipsilateral malignancy at study entry, and to be more likely to have known axillary node metastases (and more missing data). Among study participants included in the trial, tumor size was limited to 4 cm or less, or to 5 cm for women with large breasts. PEM and MRI were performed in random order without regard to timing in the menstrual cycle. The mean FDG dose used with PEM was 10.9 mCi, and the mean blood glucose level was 91 g/dL. PEM and MRI were read by different investigators; some but not all readers were blinded to results of the other test. PEM results with a BIRADS score of 4a or higher or a score of 3 with a recommendation for biopsy were considered a positive result. Negative cases included those with negative pathology or follow-up of at least 6 months with no suspicious change.

Prior to surgery, 404 malignancies were detected in 388 breasts. After surgery, 386 lesion sites in 3710 breasts were confirmed. This difference is presumably due to biopsies that removed all malignant tissue. Among the 386 lesion sites confirmed during surgery, there was no statistically significant difference in the sensitivity of PEM (92.5%) and MRI (89.1%) when only tumor sites were included " (p=0.79, nonsignificant difference)." When tumors and biopsy sites were visualized, MRI had a higher sensitivity than PEM (98.2% vs. 94.5%, respectively; p=0.004). There were no visible tumor or biopsy site changes in 7 breasts on MRI and in 19 cases on PEM; however, there was residual tumor on surgery in all of these breasts.

Twenty-one percent (82) of the 388 women had additional foci of tumor after study entry. The sensitivity in identifying breasts with these lesions was 60% (95% CI: 48%, 70%) for MRI and 51% for PEM (95% CI: 40%, 62%; p=0.24). Of the 82 additional lesions, 21 (26%) were detected only with MRI, 14 (17%) only with PEM (p=0.31), and 7 (8.5%) only with conventional imaging. Adding PEM to MRI increased the sensitivity from 60% to 72% (p<0.01). Twelve women with additional foci in the breast with the primary tumor were not identified by any of the imaging techniques. Among women with an index tumor and no additional lesions in the ipsilateral breast, PEM was more specific than MRI (91.2% vs. 86.3%, respectively, p=0.032). There was no statistically significant difference between PEM and MRI area under the receiver operating characteristic (ROC) curve. Again, the question arises whether the differences in specificity and sensitivity between the two tests are due to selecting different operating points along the ROC curve.

Of the 116 malignant lesions unknown at study entry, 53% were reported as suspicious on MRI versus 41% on PEM (p=0.04). There is no difference between PEM and MRI in detecting DCIS in this study (41% vs. 39%; p=0.83). Adding PEM to MRI would increase the sensitivity for detecting DCIS from 39% with MRI alone to 57% combined (p=0.001); another 7 DCIS foci were seen only on conventional imaging. MRI is more sensitive than PEM in detecting invasive cancer (64% vs. 41%; p=0.004), but the two combined would still have a higher sensitivity than MRI alone (73% vs. 64%, p=0.025). MRI is more sensitive than PEM in dense breasts (57% vs. 37%; p=0.031).

In a second article based on the same study, the performance of PEM and MRI were compared in detecting lesions in the contralateral breast among the same study population. In this case, readers were blinded to

the results of the other test but knew the conventional imaging and pathology results from prestudy biopsies. After recording results for a single modality, the reader then assessed the results across all modalities. The readers had 1 to 15 years of experience in interpreting contrast-enhanced breast MRI and underwent training in interpreting PEM results; 5 of the 30 readers had prior experience in interpreting PEM images. The final sample size was 367. Nine patients were excluded because the highest scored lesion was a BIRADS 3 (probably benign) based on all imaging, and no follow-up or histopathology was performed. The contralateral breast could not be assessed in 12 women, e.g., due to prior mastectomy or lumpectomy and radiotherapy.

Fifteen (4.1%) of the 367 participants had contralateral cancer. PEM detected cancer in 3 of these women and MRI in 14. The sensitivity of PEM and MRI was 20% (95% CI: 5.3%, 45.8%) and 93% (95% CI: 66%, 94%), respectively ($p<0.001$), while the specificity was 95.2% (95% CI: 92.2%, 97.0%) and 89.5% (95% CI: 85.7%, 92.4%), respectively ($p=0.002$). The area under the receiver operating characteristic curve was 68% (95% CI: 54%, 82%) for PEM and 96% (95% CI: 94%, 99%) for MRI ($p<0.0001$). There was no statistically significant differences across modalities in the positive predictive value for women undergoing biopsies (21% for PEM vs. 28% for MRI; $p=0.58$). There were more benign biopsies based on MRI results (39 biopsies in 34 of 367 women) than for PEM results (11 biopsies in 11 of 367 women) ($p<0.001$). The authors discussed possible improvements in interpreting PEM, based in part on results of having the lead investigators reread the PEM images. They determined that 7 of 12 false-negative PEM results were due to investigator error. This could only be confirmed through further study. They also noted that a substantial proportion of contralateral lesions may be effectively treated by chemotherapy and that PEM cannot optimally evaluate the extreme posterior breast. For additional articles on the same study that focus on identifying malignant characteristics on PEM and on training and evaluating readers of PEM, see references.

Another factor that should be taken into account is the radiation dose associated with PEM. The label recommended dose of FDG for PEM is 370 MBq (10 mCi). An article published online in August 2010 calculated mean glandular doses, and from those, lifetime attributable risk of cancer (LAR) for film mammography, digital mammography, breast-specific gamma imaging (BSGI), and PEM. The author, who is a consultant to GE Healthcare and a member of the medical advisory boards of Koning (which is working on dedicated breast computed tomography [CT]) and Bracco (MR contrast agents), used BEIR VII Group risk estimates to gauge the risks of radiation-induced cancer incidence and mortality from breast imaging studies. The estimated lifetime attributable risk of cancer for a patient with the average-sized compressed breast during mammography of 5.3 cm (it would be higher for larger breasts) for a single breast procedure at age 40 years is:

- 5 per 100,000 for digital mammography (breast cancer only),
- 7 per 100,000 for screen film mammography (breast cancer only),
- 55-82 per 100,000 for BSGI (depending on the dose of Technetium Tc 99m Sestamibi), and
- 75 per 100,000 for PEM.

The corresponding LAR of cancer mortality at age 40 years is:

- 1.3 per 100,000 for digital mammography (breast cancer only),
- 1.7 per 100,000 for screen film mammography (breast cancer only),

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- 26-39 per 100,000 for BSGI, and
- 31 per 100,000 for PEM.

A major difference in the impact of radiation between mammography, on the one hand, and BSGI or PEM, on the other, is that for mammography, the substantial radiation dose is limited to the breast, whereas with BSGI and PEM, all organs are irradiated. Furthermore, as one ages, the risk of cancer induction from radiation exposure decreases more rapidly for the breast than for other radiosensitive organs. The organs at highest risk for cancer are the bladder with PEM and the colon with BSGI; these cancers, along with lung cancer, are also less curable than breast cancer. Thus, the distribution of radiation throughout the body adds to the risks associated with BSGI and PEM. Hendrick concludes that "The results reported herein indicate that BSGI and PEM are not good candidate procedures for breast cancer screening because of the associated higher risks for cancer induction per study compared with the risks associated with existing modalities such as mammography, breast US [ultrasound], and breast MR imaging. The benefit-to-risk ratio for BSCI and PEM may be different in women known to have breast cancer, in whom additional information about the extent of disease may better guide treatment."

Another study estimated the lifetime attributable risk of cancer and cancer mortality from use of digital mammography, screen film mammography, PEM, and MBI. Only the results for digital mammography and PEM are reported here. The study concludes that in a group of 100,000 women at age 80 years, a single digital mammogram at age 40 would induce 4.7 cancers with 1.0 cancer deaths, 2.2 cancers with 0.5 cancer deaths for a mammogram at age 50, 0.9 cancers with 0.2 cancer deaths for a mammogram at age 60, and 0.2 cancers with 0.0 cancer deaths for a mammogram at age 70. Comparable numbers of PEM would be 36 cancers and 17 cancer deaths for PEM at age 40; 30 and 15 for PEM at age 50, 22 and 12 for PEM at age 60, and 9.5 and 5.2 for PEM at age 70. The authors also analyze the cumulative effect of annual screening between ages 40 and 80, as well as between ages 50 and 80. For women at age 80 who were screened annually from ages 40 to 80, digital mammography would induce 56 cancers with 15 cancer deaths; for PEM, the analogous numbers are 800 cancers and 408 cancer deaths. For women at age 80 who were screened annually from ages 50 to 80, digital mammography would induce 21 cancers with 6 cancer deaths; for PEM, the analogous numbers are 442 cancers and 248 cancer deaths. However, background radiation from age 0 to 80 is estimated to induce 2,174 cancers and 1,011 cancer deaths. These calculations, as all estimates of the health effects of radiation exposure, are based on a number of assumptions. Comparing digital mammography and PEM, two conclusions are clear: Many more cancers are induced by PEM than by digital mammography; and for both modalities, adding annual screening from 40 to 49 roughly doubles the number of induced cancers. In a benefit/risk calculation performed for digital mammography but not for PEM, the authors nevertheless report that the benefit/risk ratio of annual screening is still about 3 to 1 for women in their 40s, although it is much higher for women 50 and older. Like Hendrick, the authors conclude "…that if molecular imaging techniques [including PEM] are to be of value in screening for breast cancer, then the administered doses need to be substantially reduced to better match the effective doses of mammography."

The American College of Radiology assigns a relative radiation level of 10 to 30 mSv. They also state that because of the radiation dose, PEM and breast-specific gamma imaging in their present form are not indicated for screening.

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Since the use of BSGI or molecular breast imaging (MBI) has been proposed for women at high risk of breast cancer, it should be mentioned that there is controversy and speculation over whether some women, such as those with BRCA mutations, have a heightened radiosensitivity. Of course, if women with BRCA mutations are more radiosensitive than the population as a whole, the above estimates may underestimate the risks they face from breast imaging with ionizing radiation (i.e., mammography, BSGI, MBI, PEM, [single-photon emission computed tomography] SPECT/CT, breast-specific CT, and tomosynthesis; ultrasound and MRI do not involve the use of radiation). More research will be needed to resolve this issue. Also, the risk associated with radiation exposure will be greater for women at high risk of breast cancer, whether or not they are more radiosensitive, because they start screening at a younger age when the risks associated with radiation exposure are larger.

Summary
Three principal studies on PEM were reviewed. The first single-arm study provided preliminary data on sensitivity. Given that there are one or more imaging tests for each potential use in breast cancer, any new or newly disseminating technology must be compared to the existing modalities. The two studies (3 articles) comparing the use of PEM and MRI in presurgical planning are therefore important. However, each has its limitations, e.g., single site, lack of full blinding to results of alternate test, lack of adjustment for multiple comparisons. It is also possible that the apparent differences between PEM and MRI, e.g., possibly higher sensitivity for MRI and potentially higher specificity for PEM, are due in part to selection of different operating points on the receiver operating characteristic (ROC) curve. Furthermore, ignoring the timing of testing in the newer Berg et al. study might bias the results against MRI. One study reports that PEM provides some new information in the form of higher sensitivity for detecting DCIS. But this finding needs to be confirmed in additional studies. The Berg et al. study includes a number of comparisons on subsets of the population (for example, women with no sign of multicentric or multifocal disease). This could be avoided by comparing MRI and PEM in women prior to biopsy and following them through to treatment, and ideally afterward, as well to gauge patient outcomes. A companion article reports that MRI is far more sensitive than PEM in detecting contralateral cancer, although it is somewhat less specific. However, there is no statistical difference in the positive predictive value among women undergoing biopsy of the contralateral lesions. Finally, even if the addition of PEM to MRI improves accuracy, this finding must be weighed against the potential risk from radiation exposure associated with PEM and the lack of a full chain of evidence for some of these findings—e.g., that improved accuracy for some uses results in better patient outcomes. Thus, since the impact on net health outcome is uncertain, PEM is considered investigational.

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Code Type	Code
CPT	78811, 78999

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HCPCS	No codes
ICD-9 Diagnosis	All relative codes
ICD-9 Procedure	No codes

Policy History

Original Effective Date: 02/16/2011
Current Effective Date: 05/05/2014
02/03/2011 Medical Policy Committee review
05/02/2011 Medical Policy Implementation Committee approval. New Policy.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2013 Medical Policy Committee review
02/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014 Medical Policy Committee review
02/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 02/2015

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B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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