FEP 6.01.52 Positron Emission Mammography

**Effective Date:** January 15, 2019

**Related Policies:**
- 6.01.18 Scintimammography and Gamma Imaging of the Breast and Axilla
- 6.01.26 Oncologic Applications of Positron Emission Tomography Scanning

### Description
Positron emission mammography (PEM) is a form of positron emission tomography that uses high-resolution, mini-camera detection technology for imaging the breast. As with positron emission tomography, PEM provides functional rather than anatomic information about the breast. PEM has been studied primarily for use in presurgical planning and evaluation of breast lesions.

### OBJECTIVE
The objective of this evidence review is to determine whether the use of positron emission mammography improves the net health outcome in individuals being screened for breast cancer or undergoing presurgical evaluation for diagnosed breast cancer.

### POLICY STATEMENT
The use of positron emission mammography is considered **investigational** for all indications.

### BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

### FDA REGULATORY STATUS
In 2003, the PEM 2400 PET Scanner (PEM Technologies) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for “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 2009, the Naviscan PEM Flex™ Solo II™ High Resolution PET Scanner (Naviscan) was cleared for marketing by FDA through the 510(k) process for the same indication. The PEM 2400 PET Scanner was

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the predicate device. The newer device has been described by the manufacturer as "a high spatial resolution, small field-of-view PET imaging system specifically developed for close-range, spot, ie, limited field, imaging."

In 2013, Naviscan was acquired by Compañía Mexicana de Radiología SA, which currently markets the Naviscan Solo II™ Breast PET Scanner in the United States (CMR Naviscan). FDA product code: KPS.

RATIONALE

Summary of Evidence
For individuals who are being screened for breast cancer, have clinically localized breast cancer undergoing presurgical evaluation, or have a suspicious breast lesion on conventional breast cancer evaluation who receive PEM, the evidence includes prospective and retrospective studies as well as a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and resource utilization. For each indication, it has not been demonstrated that PEM provides better diagnostic accuracy than the relevant comparators nor has PEM been shown to provide clinical utility. In addition, without demonstrated advantages in clinical utility, the relatively high radiation dosage associated with PEM does not favor its use given that alternative tests deliver lower doses. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Radiology
The American College of Radiology has included positron emission mammography (PEM) in its criteria on breast screening. PEM was rated as “usually not appropriate” for screening women at average or high risk for breast cancer. The College has also assigned a relative radiation level (effective dose) of 10 to 30 mSv to PEM and stated that PEM is limited “by radiation dose and lack of evidence in large screening population”.

National Comprehensive Cancer Network
Current National Comprehensive Cancer Network guidelines for breast cancer screening and diagnosis (v.2.2018) do not include PEM.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force recommendations for PEM have been identified.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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**POLICY HISTORY**

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New Policy</td>
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<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search. References added. Editorial</td>
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