Positron Emission Mammography

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.
**POLICY GUIDELINES**

There are no specific CPT codes for positron emission mammography.

**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. The 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." 14.

In 2009, the Naviscan PEM Flex™ Solo II™ High Resolution PET Scanner (Naviscan) 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 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 Compa Mexicana de Radiología SA, 15, which currently markets the Naviscan Solo II™ Breast PET Scanner in the U.S. (CMR Naviscan). FDA product code: KPS.

**RATIONALE**

**Summary of Evidence**

For individuals who are being screened for breast cancer the evidence includes a retrospective study. The relevant outcomes are overall survival (OS), disease-specific survival, test accuracy and validity, and resource utilization. It has not been demonstrated that positron emission mammography (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.

For individuals with clinically localized breast cancer undergoing presurgical evaluation, the evidence includes prospective studies. The relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. 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.

For individuals with a suspicious breast lesion on conventional breast cancer evaluation, the evidence includes prospective studies as well as a meta-analysis. The relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. 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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Practice Guidelines and Position Statements

American College of Radiology

The American College of Radiology (2017) 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 (v.1.2019) guidelines for breast cancer screening and diagnosis 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

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<td>September 2012</td>
<td>New policy</td>
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<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature search. References added. Editorial changes made to Background and Rationale. No change in policy statement.</td>
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<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 5, 8-10, 16-18, and 27 added, references 22 and 26 updated. No change to policy statement.</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 17 and 24 added. Policy statement unchanged.</td>
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<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 20, 2017; references 28-29, added. Policy statement unchanged, but “not medically necessary corrected to “investigational”.</td>
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<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 9; 2018; no references added. Policy statement unchanged.</td>
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