CLINICAL MEDICAL POLICY	
Policy Name:	Breast Scintimammography
Policy Number:	MP-105-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2024; 11/01/2023; 12/01/2022; 11/19/2021; 11/23/2020; 01/20/2020
Effective Date:	12/01/2024; 12/01/2023; 01/01/2023; 12/20/2021; 12/21/2020; 01/20/2020
Next Annual Review:	09/2025
Revision Date:	09/18/2024; 09/20/2023; 09/21/2022; 09/15/2021; 09/16/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
12/01/2024	Provider Effective date
10/07/2024	PARP Approval
09/18/2024	QI/UM Committee review
09/18/2024	Annual Review: No changes to Experimental/Investigational stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2023	Provider Effective date
10/11/2023	PARP Approval
09/21/2023	QI/UM Committee review
09/21/2023	Annual Review: No changes. Updated 'Summary of Literature' and 'Reference Sources' sections.
01/01/2023	Provider Effective date
11/15/2022	PARP Approval
09/21/2022	QI/UM Committee review
09/21/2022	Annual Review: No changes to clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/20/2021	Provider effective date
10/18/2021	PARP Approval
09/15/2021	QI/UM Committee review
09/15/2021	Annual Review: No changes to clinical criteria. Added TAG determination information. Updated Summary of Literature and Reference Sections.
08/26/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage in the Company's Medicaid products for breast scintimammography. The service is considered experimental and investigational in all applications, including but not limited to use as an adjunct to mammography or in staging the axillary lymph nodes.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Scintimammography - A noninvasive supplemental diagnostic testing technology that requires the use of radiopharmaceuticals in order to detect tissues within the breast that accumulate higher levels of radioactive tracer that emit gamma radiation. This technology is also known as molecular breast imaging (MBI) and/or breast specific gamma imaging (BSGI).

Procedures

1. Breast scintimammography, also known as molecular breast imaging (MBI), or breast-specific gamma imaging (BSGI) are services used as an adjunct for screening and diagnosing cancer is considered experimental and investigational and therefore, not medically necessary due to insufficient evidence of effectiveness.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for breast scintimammography is outpatient.

Governing Bodies Approval

In 1990, the FDA had approved the Cardiolite Kit for the preparation of Technetium Tc00m Sestamibi for injection for cardiac imaging. The drug was also known as Cardiolite and Miraluma. The prescribing information for Cardiolite lists Miraluma as the drug name for the breast imaging indication. In September 2008, the FDA approved Tc 99 Sestamibi injection for diagnostic purposes for both cardiac and breast-imaging indications. The FDA indicated that this drug was substantially equivalent to the Cardiolite Kit.

The Centers for Medicare and Medicaid Services (CMS) has no current published guidelines addressing breast scintimammography.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

In April 2009, the TAG workgroup assigned breast scintimammography an Option # 4, specifically for HCPCS code S8080.

Summary of Literature

Breast cancer is one of the most common cancers in women in the United States. It accounts for about 30% of all new female cancers each year. The average risk of a woman in the U.S. developing breast cancer sometime in her life is about 13% (ACS, 2024).

Mammography is the most commonly used breast cancer screening tool. Magnetic resonance imaging (MRI) may be used to screen women who have a high risk of breast cancer. Whether a woman should be screened for breast cancer and the screening test to use depends on certain factors. Other screening tests such as thermography, tissue sampling, and scintimammography have been or are being studied in clinical trials (NCI, 2021).

Scintimammography is a relatively new imaging method to demonstrate cancer tissue in the breast. A radiopharmaceutical agent (Tc-99m Sestamibi) is administered intravenously and images of the breast are taken under a Gamma Camera. There is no need for any manipulation like compression of the breast as required to be done during mammography. The radiopharmaceutical accumulates in the breast in the presence of cancer tissue which can easily be seen in the images. The affinity of the cancer tissue to this radiopharmaceutical is up to 9 times in comparison to normal breast tissue. Scintimammography is not to be used as a primary screening tool, therefore not replacing mammography (Das, Biswal, Bhavaraju, 2006).

Breast scintimammography, also known as molecular breast imaging (MBI), or breast-specific gamma imaging (BSGI) is a test that is being studied as a way to follow up breast problems, such as a lump or abnormal mammogram, or to help determine the extent of breast cancer that has previously been diagnosed. The test is also being used as a screening test for use along with mammograms to detect cancer in women with dense breasts. However, this test can possibly expose the whole body to radiation (ACS, 2022).

The U.S. Preventative Services Task Force (USPSTF) concludes that the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. An 'I' rating was assigned to this statement. The USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined (USPSTF, 2024).

The American College of Radiology (ACR) Appropriateness Criteria Breast Screening document recommendations did not include breast scintimammography for routine screening. The ACR screening document does issue a recommendation for Sestamibi technetium, the primary radiopharmaceutical agent used with breast nuclear imaging. The use of Sestamibi for breast cancer is listed under the 'usually not appropriate' category. The 'usually not appropriate' category is defined as: the imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios; or the risk-benefit ration for patients is likely to be unfavorable. Relative radiation level was documented as 1-10 mSv (the amount of radiation a typical patient may be exposed to during this specific procedure). This is approximately 15 to 30 times greater than the dose for a digital mammogram. It is important to note that the radiation dose is given to the entire body and for traditional mammography the dose is limited to the breast. This radiation level is similar to abdomen CT or a nuclear medicine bone scan (ACR, 2021).

The American College of Obstetricians and Gynecology (ACOG) documented that current published evidence does not demonstrate meaningful outcomes (e.g., reduction in breast cancer mortality) with supplemental tests (e.g., ultrasonography and MRI) to screening mammography or with alternative screening modalities (e.g., breast tomosynthesis or thermography) in women with dense breasts who do not have additional risk factors. Evidence is lacking to advocate for additional testing until there are clinically validated density as recorded in a mammogram report (ACOG, 2019).

Initial studies on scintimammography were performed using the high radiation technique. However, a newer very low-dose technique has been developed and early studies demonstrate detection of breast cancer with only a small decrease in specificity. (Rhodes et al. 2015)

According to the ACS, molecular breast imaging, also known as scintimammography or breast-specific gamma imaging, is still being studied. One potential drawback is that the testing exposes the whole body to radiation and it is unlikely the testing would be appropriate for yearly screening. The impact of radiation with mammography is the substantial dose is limited to the breast. With scintimammography, all organs are irradiated increasing the risks associated with radiation exposure (ACS, 2019).

The National Comprehensive Cancer Network (NCCN) provides that molecular breast imaging (MBI) is an option for high-risk breast cancer screening in those who cannot undergo breast MRI. There is emerging evidence that MBI may improve detection of early breast cancers among women with mammographically

dense breasts, but may increase recalls and benign breast biopsies. MBI has a whole-body effective radiation dose higher than that of traditional mammography (NCCN, 2024).

Coding Requirements

Non-covered Procedure Codes
These procedure codes will not be reimbursed without Medical Director approval.

HCPCS Code	Description
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical
CPT Code	
78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (leg, head, neck, chest, pelvis), single day imaging
78801	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, 2 or more areas (leg, abdomen, and pelvis, head , chest) 1 or more days imaging or single area imaging over 2 or more days

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: OPS # 05/2009-014. May 8, 2009. Accessed on August 17, 2023.

U.S. Preventive Services Task Force (USPSTF). Breast Cancer: screening. April 30, 2024. Accessed on August 27, 2024.

American College of Radiology (ACR). ACR appropriateness criteria: breast cancer screening. American College Radiology. Revised 2021. Accessed on September 2, 2021.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion: Management of women with dense breasts diagnosed by mammography. Number 625, March 2015. Reaffirmed 2020. Accessed on September 2, 2021.

Freer PE, Slantez PJ. Breast density and screening for breast cancer. UpToDate. Last updated August 4. 2023. Literature review current through July 2019. Accessed on August 17, 2023.

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National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis. Version 2.2024. April 9, 2024. Accessed on August 27, 2024.

National Cancer Institute (NCI). Breast Cancer Screening (PDQ®)–Patient Version. August 4, 2021. Accessed on September 2, 2022.

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