Scintimammography/ Breast Specific Gamma Imaging (BSGI)/Molecular Breast Imaging (MBI) /Positron Emission Mammography (PEM)

Medical Policy #: 06.01.22
Original Effective Date: August 2006
Reviewed: July 2022
Revised: July 2022

NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Scintimammography, also known as nuclear medicine breast imaging, refers to the use of radiotracers with nuclear medicine imaging as a diagnostic tool for abnormalities of the breast. Breast specific gamma imaging (BSGI) also known as molecular breast imaging (MBI) refers to specific types of imaging machines that are used in conjunction with scintimammography to improve diagnostic performance.

Note: The term molecular breast imaging (MBI) may be used in different ways, sometimes for any type of breast imaging involving molecular imaging, including positron emission mammography (PEM), and sometimes is limited to imaging with a type of breast specific gamma camera.

These modalities have been proposed primarily as adjuncts to mammography and physical examination in patients who have palpable masses or suspicious mammograms as a technique to improve patient selection for biopsy. It has been suggested scintimammography has the potential to reduce unnecessary invasive biopsies by differentiating benign from malignant lesions. Breast specific gamma imaging (BSGI) or molecular breast imaging (MBI) have been suggested for evaluating suspected recurrence in patients who are at high risk, for patients in whom breast MRI is indicated but who are not candidates due to contraindications, and among patients in whom breast imaging is technically difficult, such as those with radio dense breast tissue.

Scintimammography
Scintimammography is performed while the patient is lying prone and the camera positioned laterally, which increases the distance between the breast and the camera. Scintimammography using conventional imaging modalities has relatively poor sensitivity in detecting smaller lesions (< 15 mm), because of this relatively poor resolution BSGI/MBI were developed to address this issue.

Breast Specific Gamma Imaging (BSGI)/Molecular Breast Imaging (MBI)
Breast-specific gamma imaging (BSGI) and is also sometimes referred to as "molecular breast imaging (MBI)" is a scintimammography examination that uses a special breast optimized gamma camera. This is performed while the patient is seated in a position similar to that of mammography, and the breast is lightly compressed. The detector head(s) is immediately next to the breast, increasing resolution, and images can be compared with mammographic images.

BSGI/MBI uses high-resolution gamma cameras. These cameras, specially designed to image the breast, offer improved signal-to-noise ratio and improved spatial resolution to produce high-contrast images of small lesions. The dedicated breast cameras facilitate imaging from several angles to more closely resemble the cranial-caudal and medial-lateral-oblique mammographic views.

Radiopharmaceuticals
The primary radiopharmaceutical used is technetium-sestamibi (MIBI). MIBI accumulates in tissues with increased mitochondrial activity, such as rapidly growing tumors. After intravenous injection, MIBI rapidly (within two minutes) accumulates within breast tumors and slowly, over the courses of hours is "washed out" out of the cells by P-glycoprotein receptor, allowing imaging to be performed immediately after injection, but also allowing ample time for clinicians to perform all desired views and data collection.

Positron Emission Mammography (PEM)
Positron emission mammography (PEM) is an imaging modality that has higher resolution than PET-CT and can be performed on patients unable to have an MRI scan. PEM uses a pair of dedicated gamma radiation detectors placed above and below the breast and mild breast compression to detect coincident gamma rays after administration of fluorine-18 fluorodeoxyglucose (18F-FDG), the positron-emitting radionuclide used in whole-body PET studies for the detection of metastatic disease. Whereas PEM has high imaging sensitivity for breast lesions, its clinical utility requires further investigation. PEM cannot provide the anatomical detail that is provided by MRI. The radiation dose associated with PEM is larger than with mammography and is an important consideration when using this modality. Studies are ongoing to determine the effects on sensitivity and specificity of PET when the radiation dose is reduced and to find alternate radiopharmaceutical tracers.

Patients
Screening, diagnosis, and management for individuals with breast cancer.

Interventions
Scintimammography including Breast Specific Gamma Imaging (BSGI), Molecular Breast Imaging (MBI) and Positron Emission Mammography (PEM).

Comparators
The following tests are currently being used to make decisions for individuals with undetermined or suspicious breast lesions to assist in provider decision making:

- Mammography
- Ultrasound (US)
- Magnetic Resonance Imaging (MRI)

Outcomes
Decisions to initiate treatment which:

- Screening may improve detection of breast cancer
- May reduce the number of biopsies in individuals in need of a diagnosis of breast cancer
- Informs decision to initiate treatment
- Aids in the management of breast cancer

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Summary of Evidence
There is limited evidence on the use of scintimammography including breast specific gamma imaging (BSGI)/molecular breast imaging (MBI), and positron emission mammography (PEM) for screening individuals who have an elevated risk of breast cancer or in individuals with factors that limit the sensitivity of mammography. It has not been demonstrated that BSGI, BMI, and/or PEM provides better diagnostic accuracy compared with the current standard of care imaging which includes MRI of the breast. The evidence indicates there is a relatively high radiation dose currently associated with BSGI/MBI compared to mammography and MRI of the breast. The evidence is insufficient to determine the effects of this technology on net health outcomes.

The American College of Radiology recommends against the use of BSGI/MBI for screening. The consideration of the potential use of BSGI/MBI for screening individuals with dense breasts or at high risk of breast cancer should await the development of a lower dose regimen, and if warranted, larger higher quality studies with study populations representative of patients encountered in clinical practice. A large quality head-to-head comparison of BSGI/MBI and MRI would be needed, especially for individuals at high risk of breast cancer, because MRI, alternated with mammography, is currently the recommended screening technique.

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists (ACOG)
(2017; Reaffirmed 2021) The American College of Obstetricians and Gynecologists' practice bulletin on breast cancer screening in average-risk women provided no discussion or recommendation for scintimammography or any other gamma imaging techniques for routine screening. (*Accessed July 2022*)

American College of Radiology (ACR)
ACR: Breast Cancer Screening in Women at Higher-Than-Average Risk:
(2018) The ACR issued an updated appropriateness criteria for individuals in higher-than-average risk using Molecular Breast Imaging (MBI). This criterion states the following,

- "MBI is not recommended for screening surveillance in any higher-risk population." (*Accessed July 2022*)

ACR Appropriateness Criteria® Breast Cancer Screening
(2017) The American College of Radiology (ACR), revised their breast cancer screening guidelines to the following:

- Variant 1: Breast cancer screening. Average-risk women:15% lifetime risk of breast cancer:
    - Sestamibi MBI and FDG-PET breast dedicated: Usually not Appropriate.
        - Women with MBI and FDG-PET Breast Dedicated Supplementing mammography with molecular breast imaging (MBI) in women with dense breasts increases the cancer detection rate. However,

there have been no large population studies of MBI for screening, and the whole-body radiation dose with this technique is concerning. Positron emission tomography with fluorine18-2-fluoro-2-deoxy-D-glucose (FDG-PET) breast is similarly limited by radiation dose and lack of evidence in large screening populations.

- Variant 2: Breast cancer screening. Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer:
    - Sestamibi MBI and FDG-PET breast dedicated: Usually Not Appropriate
        - MBI and FDG-PET Breast Dedicated Supplementing mammography with MBI in women with dense breasts increases the cancer detection rate. However, there have been no large population studies of MBI for screening and whole-body radiation dose with this technique is concerning. FDG-PET breast is similarly limited by radiation dose and lack of evidence in large screening populations.
- Variant 3: Breast cancer screening. High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, women with 20% or greater lifetime risk of breast cancer:
    - Sestamibi MBI and FDG-PET breast dedicated: Usually Not Appropriate
        - MBI and FDG-PET Breast Dedicated Supplementing mammography with MBI in women with dense breasts increases the cancer detection rate. However, there have been no large population studies of MBI for screening and the whole-body radiation dose with this technique is concerning. FDG-PET breast is similarly limited by radiation dose and lack of evidence in large screening populations.
- Summary of Recommendations
    - For average-risk women, annual screening mammography or DBT (Digital Breast Tomosynthesis) (with accompanying planar or synthesized 2-D images) is recommended beginning at age 40. For women with dense breasts, US may also be considered, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision.
    - For intermediate-risk women, breast mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended. MRI may be considered as an adjunct to mammography or DBT (with accompanying planar or synthesized 2-D images) depending upon risk factors. For women with dense breasts, US may be an option, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision. For high-risk women, mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended. MRI is recommended as an

adjunct to screening mammography or DBT (with accompanying planar or synthesized 2-D images). US is recommended when the patient cannot tolerate MRI.

The American College of Radiology (ACR) criteria for breast cancer screening does not indicate the use of scintimammography, BSGI, MBI, and/or PEM in breast cancer screening. (*Accessed July 2022*)

ACR Appropriateness Criteria® Breast Imaging of Pregnant and Lactating Women
(2018) The American College of Radiology (ACR), guidelines state the following:

- Tc-99m Sestamibi MBI.
    - There is no role for molecular breast imaging (MBI) in breast cancer screening during lactation. (*Accessed July 2022*)

ACRs Breast Microcalcifications – Initial Diagnostic Workup
(2009) The American College of Radiology issued a guideline for initial diagnostic workup for breast microcalcifications:

- Diagnostic mammographic workup (including spot magnifications views in the craniocaudal and 90 ml projections) remains the optimal initial procedure for evaluating screening-detected calcifications that are not typically benign.
- Ultrasound should only be performed if the diagnostic mammographic workup demonstrates suspicious microcalcifications with an associated mass/focal asymmetry or in cases of suspicious calcifications with an extensive distribution. This may be useful in determining the method of biopsy guidance, diagnosing invasive disease, and facilitating a single-step surgery (excision and lymph node dissection).
- Currently, short-term follow-up or biopsy of calcifications directly from screening mammography is not recommended.
- In addition, the utility of PEM, BSGI, or MRI for the initial evaluation of screening detected microcalcifications has not been established. (*Accessed July 2022*)

National Comprehensive Cancer Network (NCCN)

- Breast Cancer Screening and Diagnosis Version 1.2022
    - There is emerging evidence that breast scintigraphy enhanced mammography may improve detection of early breast cancers among women with mammographically dense breasts, current evidence does **not** support their routine use as alternative screening procedures.
    - While there is emerging evidence that molecular imaging (breast-specific gamma imaging, or sestamibi scan as screening procedures may improve detection, whole-body effective radiation dose with these tests is substantially higher than that of mammography. (*Accessed July 2022*)

Regulatory Status
Several scintillation (gamma) cameras have been cleared for marketing by the FDA through the 510(k) process for "measuring and imaging the distribution of radionuclides in the human body by means of photon detection." Examples of gamma cameras used in BSGI are the Dilon 6800® (Dilon Technologies) and single-head configurations of Discovery NM750b (GE Healthcare). Dual-head cameras used in MBI include LumaGEM™ (Gamma Medical) (FDA product code IYX) and Discovery NM750b (GE Healthcare).

Tc-99m sestamibi (Sun Pharmaceutical Industries, Lantheus Medical Imaging, Cardinal Health 414, AnazaoHealth, Curium US, Jubilant Draximage) has been approved by the FDA with the following labeling: "Breast Imaging: Technetium TC 99M Sestamibi is indicated for planar imaging as a second-line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass. Technetium TC 99M Sestamibi is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy."

In 2013, Tc 99m tilmanocept (Lymphoseek; Cardinal Health) was approved by the FDA for use in breast cancer and melanoma as a radioactive diagnostic imaging agent to help localize lymph nodes.

Technetium-99m-sulfur colloid was approved by the FDA through the new drug application (NDA; GE Healthcare, NDA 017456; Mallinckrodt, NDA 017724) process although these products appear to be marketed no longer. In addition, in 2011, Technetium Tc 99m Sulfur Colloid Kit (Sun Pharmaceutical Industries) was approved by the FDA through the NDA process (NDA 017858) for use as an injection to localize lymph nodes in breast cancer patients.

In 2018, the FDA granted approval to Northstar Medical Radioisotopes for its RadioGenix™ System, which produces molybdenum 99, the material used to generate Tc 99m. Previously, molybdenum 99 was only produced from enriched uranium in facilities outside of the United States.

PRIOR APPROVAL

Not applicable.

POLICY

Scintimammography including Breast Specific Gamma Imaging (BSGI), Molecular Breast Imaging (MBI), and Positron Emission Mammography (PEM) is considered **investigational** for all indications, because the evidence is insufficient to determine the effects of this technology on net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 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 (e.g., 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 (eg, abdomen and pelvis, head and chest), 1 or more days imaging or single area imaging over 2 or more days
- 78999 Unlisted miscellaneous procedure, diagnostic nuclear medicine
- A9500 Technetium tc-99m sestamibi, diagnostic, per study dose
- S8080 Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

SELECTED REFERENCES

- Bongers V et al. The Use of Scintimammography for Detecting the Recurrence of Loco-regional Breast Cancer: Histopathologically Proven Results. Nucl Med Comm 2004 F000000eb;25(2):145-9.
- Coover LR et al. Scintimammography with dedicated breast camera detects and localizes occult carcinoma. J Nucl Med 2004 Apr;45(4):553-8.
- Papantoniou V et al. 99mTc-(V)DMSA scintimammography in the assessment of breast lesions: comparative study with 99mTc-MIBI. Eur J Nucl Med 2001 Jul;28(7):923-8.
- Chiou JF, Lin MC, Chen DR et al. Usefulness of thallium-201 SPECT scintimammography to differentiate benign from malignant breast masses in mammographically dense breasts. Cancer Invest 2003; 21(6):863-8.
- Blue Cross Blue Shield Association. Technology Evaluation Center. Scintimammography. Technology Evaluation Center Assessments. 1997; Vol.12, Tab 19.
- Fondrinier E et al. Clinical experience with 99mTc MIBI scintimammography in patients with breast microcalcifications. Breast. 2004 Aug; 13(4):316-20.
- Bone B et al. Comparison of 99mTC sestamibi scintimammography and dynamic MR imaging as adjuncts to mammography in the diagnosis of breast cancer. Acta Radiol. 2003 Jan;44(1):28-34.
- Agency for Healthcare Research and Quality. Effectiveness of Noninvasive Diagnostic Tests for Breast Abnormalities. March 2006.
- Brem RF, Rapelyea JA, Zisman G et al. Occult Breast Cancer: Scintimammography with High-Resolution Breast-specific Gamma Camera in Women at High-Risk for Breast Cancer. Radiology 2005; 237:274-280.

- O"Connor MK, Phillips SW, Hruska CB et al. Molecular Breast Imaging: Advantages and Limitations of a Scintimammographic Technique in Patients with Small Breast Tumors. Breast J. 2007 Jan-Feb; 13(1):3-11.
- Brem RF, Petrovitch I, Rapelyea JA et al. Breast-specific gamma imaging with 99mTc-Sestamibi and magnetic resonance imaging in the diagnosis of breast cancer-a comparative study. Breast J 2007 Sep-Oct; 13(5):465-9.
- Schillaci O, Cossu E, Roman P et al. High-resolution gamma-camera for molecular breast imaging: First clinical results. Phys Med. 2006;21S1:121-124.
- Brem RF, Fishman M, Rapelyea JA. Detection of ductal carcinoma in situ with mammography, breast-specific gamma imaging, and magnetic resonance imaging: a comparative study. Acad Radiol. 2007 Aug;14(8):945-50.
- Brem RF, Floerke AC, Rapelyea JA et al. Breast-specific gamma imaging as an adjunct imaging modality for the diagnosis of breast cancer. Radiology. 2008 Jun;247(3):651-7.
- Zhou M, Johnson N, Blanchard D et al. Real-world application of breast-specific gamma imaging, initial experience at a community breast center and its potential impact on clinical care. Am J Surg. 2008 May;195(5):631-5;discussion 635.
- ECRI Institute. Breast-specific Gamma Imaging for Diagnosis and Screening of Breast Cancer. Plymouth Meeting (PA): ECRI Institute; 2010 January 18. 7p. [ECRI hotline response]. Also available: http://www.ecri.org.
- Hendrick RE. Radiation doses and Cancer risks from breast imaging studies. Radiology. 2010 Aug 24. [Epub ahead of print].
- ECRI Institute. Dual-head CZT Gamma Cameras for Molecular Imaging of Breasts. Plymouth Meeting (PA): Health Technology Assessment Information Service; 2012 September. [Hotling Response]. Available at http://www.ecri.org.
- Bruening W, Uhl S, Fontanarosa J, Reston J, et al. Noninvasive Diagnostic Tests for Breast Abnormalities: Update of a 2006 Review. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Feb. Report No.: 12-EHC014-EF. AHRQ Comparative Effectiveness Reviews.
- ECRI: Evidence Report, Breast Specific Gamma Imaging for Breast Cancer, March 2013
- National Comprehensive Cancer Network. NCCN Guidelines Version 1.2022. Breast Cancer Screening and Diagnosis. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf
- American College of Radiology, ACR Appropriateness Criteria, 2009, Breast Microcalcifications-Initial Diagnostic Work-Up
- Society of Breast Imaging, Use of Alternative Imaging Approaches to Detection of Breast Cancer
- American College of Radiology, 2010; 7:18-27, Breast Cancer Screening with Imaging: Recommendations from the Society of Breast Imaging and the ACR on the use of Mammography, Breast MRI, Breast Ultrasound, and other Technologies for the Detection of Clinically Occult Breast Cancer
- Society of Nuclear Medicine, 2010, SNM Practice Guidelines for Breast Scintigraphy with Breast Specific y-Cameras 1.0

- American Cancer Society, Mammograms and other Breast Imaging Procedures.www.cancer.org
- American Cancer Society. What's New in Breast Cancer Research and Treatment? Last Revised 9/11/13. www.cancer.org
- American Cancer Society. Experimental and Other Breast Imaging Methods. Last reviewed 12/12/12.
- Carole Mathelin et. al., Case Report Optimization of Sentinel Lymph Node Biopsy in Breast Cancer Using an Operative Gamma Camera, World Journal of Surgical Oncology 2007, 5:132. Also available www.wjso.com/content/5/1/132
- Khaldoun Kerrou, et. al. The Usefulness of a Preoperative Compact Imager, a Hand-Held y-Camera for Breast Cancer Sentinel Node Biopsy: Final Results of a Prospective Double-Blind, Clinical Study, Journal of Nuclear Medicine. Available at jnm.snmjournals.org/content/52/9/1346
- National Cancer Institute. Clinical Trials PDQ. Intraoperative Gamma Camera for Breast Cancer Surgery. October 17, 2013. www.cancer.gov
- American College of Radiology (ACR) 2013 Appropriateness Criteria Breast Cancer Screening. J Am Coll Radiol 2016; Abstract
- ACR-SPR Practice Parameter for the Performance of Tumor Scintigraphy (with Gamma Cameras). Amended 2014.
- UpToDate. MRI of the Breast and Emerging Technologies. Priscilla J. Slanetz, M.D., MPH, FACR. Topic last updated July 2, 2014. www.uptodate.com
- MD Consult. Nuclear Medicine Imaging of the Breast: A Novel, Physiologic Approach to Breast Cancer Detection and Diagnosis. Rachel F. Bren M.D., Laren R. Rechtman, MA. www.mdconsult.com
- American Cancer Society. What's New in Breast Cancer Research and Treatment? Topic last revised 1/31/2014. www.cancer.org
- American Cancer Society. Experimental and Other Breast Imaging Methods. Tope last revised 6/10/2014. www.cancer.org
- Hendrick RE. Radiation doses and cancer risks from breast imaging studies. Radiology. 2010;257(1):246–253.
- Glass SB, Shah ZA. Clinical utility of position emission mammography. Proc (Bayl Univ Med Cent). 2013 Jul; 26(3): 314–319.
- Reiter M. U.S. team finds favor with new PEM unit. 8/7/2015. Auntminnie.com. Presented at AAPM annual meeting, Anaheim, CA.
- Brem RF, Floerke AC, Rapelyea JA, Teal C, Kelly T, Mathur V. Breast-specific gamma imaging as an adjunct imaging modality for the diagnosis of breast cancer. Radiology. 2008;247(3):651.
- Slanetz P., Chagpar A, Elmore J, et al. MRI of the breast and emerging technologies. UptoDate June 2016. Uptodate.com.
- Guo C, Zhang C, Liu J, et al. Is Tc-99m sestamibi scintimammography useful in the prediction of neoadjuvant chemotherapy responses in breast cancer? A systematic review and meta-analysis. Nucl Med Commun. Jul 2016;37(7):675-688. PMID 26974314

- Cho MJ, Yang JH, Yu YB, et al. Validity of breast-specific gamma imaging for Breast Imaging Reporting and Data System 4 lesions on mammography and/or ultrasound. Ann Surg Treat Res. Apr 2016;90(4):194-200. PMID 27073789
- Brem RF, Ruda RC, Yang JL, et al. Breast-specific gamma-imaging for the detection of mammographically occult breast cancer in women at increased risk. J Nucl Med. May 2016;57(5):678-684. PMID 26823569
- Shermis RB, Wilson KD, Doyle MT, et al. Supplemental breast cancer screening with molecular breast imaging for women with dense breast tissue. AJR Am J Roentgenol. Aug 2016;207(2):450-457. PMID 27186635
- Muller FH, Farahati J, Muller AG, et al. Positron emission mammography in the diagnosis of breast cancer. Is maximum PEM uptake value a valuable threshold for malignant breast cancer detection? Nuklearmedizin. 2016;55(1):15-20. PMID 26627876
- Yamamoto Y, Tasaki Y, Kuwada Y, et al. A preliminary report of breast cancer screening by positron emission mammography. Ann Nucl Med. Feb 2016;30(2):130-137. PMID 26586370
- American College of Radiology. ACR Guideline for Breast Microcalcifications – Initial Diagnostic Workup. Last review date 2009.
- American College of Radiology. ACR Appropriateness Criteria Breast Cancer Screening. Last review date 2017.
- American College of Radiology. ACR Breast Cancer Screening in Women at Higher-Than-Average Risk. Last review date 2018.
- BCBS Association Evidence Positioning System.
- Spanu A, Sanna D, Chessa F, et al. The clinical impact of breast scintigraphy acquired with a breast specific gamma-camera (BSGC) in the diagnosis of breast cancer: incremental value versus mammography. Int J Oncol. Aug 2012;41(2):483-489.
- Practice Bulletin Number 179: Breast Cancer Risk Assessment and Screening in Average-Risk Women. Obstet Gynecol. Jul 2017; 130(1): e1-e16. PMID 28644335
- Bruening W, Uhl S, Fontanarosa J, et al. Noninvasive Diagnostic Tests for Breast Abnormalities: Update of a 2006 Review. Comparative Effectiveness Review No. 47. (Prepared by the ECRI Institute Evidence-based Practice Center under Contract No. 290-02-0019.) AHRQ Publication No. 12-EHC014EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2012. www.effectivehealthcare.ahrq. gov/reports/final.cfm. Available at: https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/breast-abnormalities-tests-update_executive.pdf
- American College of Obstetricians and Gynecologists (ACOG). Breast Cancer Risk Assessment and Screening in Average-Risk Women. Practice Bulletin. Number 179. July 2017. Reaffirmed 2021. Available at: https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/07/breast-cancer-risk-assessment-and-screening-in-average-risk-women#:~:text=The%20American%20College%20of%20Obstetricians%20and%

20Gynecologists'%20recommendation%20to%20offer,Table%201%203%204%2023.
- Rhodes DJ, Hruska CB, Conners AL, et al. Journal club: molecular breast imaging at reduced radiation dose for supplemental screening in mammographically dense breasts. AJR Am J Roentgenol. Feb 2015; 204(2): 241-51
- Zhang Z, Wang W, Wang X, et al. Breast-specific gamma imaging or ultrasonography as adjunct imaging diagnostics in women with mammographically dense breasts. Eur Radiol. Jun 10 2020.
- Spanu A, Sanna D, Chessa F, et al. The clinical impact of breast scintigraphy acquired with a breast specific gamma-camera (BSGC) in the diagnosis of breast cancer: incremental value versus mammography. Int J Oncol. Aug 2012;41(2):483-489.
- Tan H, Jiang L, Gu Y, et al. Visual and semi-quantitative analyses of dual-phase breast-specific gamma imaging with Tc-99m-sestamibi in detecting primary breast cancer. Ann Nucl Med. Jan 2014;28(1):17-24.
- Meissnitzer T, Seymer A, Keinrath P, et al. The added value of semiquantitative breast-specific gamma imaging in the work-up of suspicious breast lesions compared to mammography, ultrasound and 3T MR Imaging. Br J Radiol. Apr 17 2015:20150147.
- Lee HS, Ko BS, Ahn SH, et al. Diagnostic performance of breast-specific gamma imaging in the assessment of residual tumor after neoadjuvant chemotherapy in breast cancer patients. Breast Cancer Res Treat. May 2014;145(1): 91-100.
- Edwards C, Williams S, McSwain AP, et al. Breast-specific gamma imaging influences surgical management in patients with breast cancer. Breast J. Sep-Oct 2013;19(5):512-519.
- Schillaci O, Scopinaro F, Spanu A, et al. Detection of axillary lymph node metastases in breast cancer with Tc-99m tetrofosmin scintigraphy. Int J Oncol. Mar 2002;20(3):483-487.
- Spanu A, Dettori G, Nuvoli S, et al. (99)mTc-tetrofosmin SPET in the detection of both primary breast cancer and axillary lymph node metastasis. Eur J Nucl Med. Dec 2001;28(12):1781-1794.
- Xu HB, Li L, Xu Q. Tc-99m sestamibi scintimammography for the diagnosis of breast cancer: meta-analysis and meta-regression. Nucl Med Commun. Nov 2011;32(11):980-988.
- diFlorio-Alexander, R., Slanetz P., & Moy L., et al. ACR Appropriateness Criteria® Breast Imaging of Pregnant and Lactating Women. (2018). Journal of the American College of Radiology. 15. S263-S275. 10.1016/j.jacr.2018.09.013.

POLICY HISTORY		
Date	**Reason**	**Action**
July 2022	Annual Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Renewed
July 2019	Annual Review	Policy Renewed
July 2018	Annual Review	Policy Renewed
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
August 2015	Annual Review	Policy Revised
October 2014	Annual Review	Policy Revised
October 2013	Annual Review	Policy Renewed
June 2013	Interim Review	Policy Revised
December 2012	Annual Review	Policy Renewed
December 2011	Annual Review	Policy Renewed
June 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.