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NCCN Guidelines Panel: Breast Cancer Screening and Diagnostics

We kindly request the NCCN Breast Cancer Screening and Diagnostics panel to review the enclosed peer reviewed clinical data/papers for considering the inclusion of the breast-specific gamma imaging (BSGI), also referred to as molecular breast imaging (MBI), procedure in patients for whom breast MRI would be indicated but not possible (pacemakers, ferromagnetic implants etc.), and when an alternative is needed for patients who meet MRI diagnostic screening criteria.
BSGI is performed with a high-resolution, small-field-of-view, breast-optimized gamma camera after intravenous administration of Tc-99m-sestamibi and is not affected by breast density [1].

Specific Changes: Where breast MRI is recommended/indicated, add, "BSGI may be used when the breast MRI is not available or is contraindicated."

FDA Clearances:
1. Pharmaceuticals: *Tc99m-Sestamibi* is indicated for planar breast imaging.
2. Detector Systems: *Dilon 6800 Series Gamma Camera(s), Gamma Medica LumaGem, General Electric Discovery NM750b.*

Rationale: BSGI is a molecular breast imaging procedure capable of detecting breast malignancies that are either occult or underestimated by mammography and ultrasound. When mammography encounters radiodense breast and cannot reach conclusive diagnosis results (BI-RADS 0), compound with other high risk factors, adjunct diagnostic imaging modality is needed to further assists this group of population to early detect and early treatment [1, 2, 3, 4]. Like breast MRI, BSGI has demonstrated the ability to improve patient management, but in contrast, BSGI has no known contraindications for use and can therefore be utilized in situations where breast MRI is unavailable or in patients unable to undergo MRI [1, 5, 6]. Clinical publications report that BSGI has similar sensitivity but better specificity than breast MRI and is not affected by the density of breasts [1, 5, 7, 8].

Clinical Publications:

1. Rechtman LR, Lenihan MJ, Lieberman JH, Teal CB, Torrente J, Rapelyea JA, Brem RF. Breast-specific gamma imaging for the detection of breast cancer in dense versus nondense breasts. Am J Roentgenol 2014 Feb; 202(2):293-8.
2. Sun Y, Wei W, Yang HW, Liu JL, Clinical usefulness of breast-specific gamma imaging as an adjunct modality to mammography for diagnosis of breast cancer: a systemic review and meta-analysis. Eur J Nucl Med Mol Imaging 2013 Feb; 40(3):450-63
3. Society of Nuclear medicine - SNM Guideline for Breast Scintigraphy with Breast-Specific Gamma Cameras 1.0. June 2010.
4. Silverstein M, Recht, A, Lagios MD, Bleiweiss I, Blumencranz PW, Gizienski T, Harms SE, Harness J, Jackman R, Klimberg S, Kuske R, Levine G, Linver M, Rafferty E, Rugo H, Schilling K, Tripathy D, Whitworth PW, Willey SC. Image-Detected Breast Cancer: State-of-the-Art Diagnosis and Treatment. American College of Surgeons Consensus III. 2009. ISSN 1072-7515/09
5. Johnson N, Sorenson L, Bennetts L, Winter K, Bryn S, Johnson W, Glissmeyer M, Garreau J, Blanchard D. Breast-specific gamma imaging is a cost effective and efficacious imaging modality when compared with MRI. Am J Surg 2014 May; 207, 698-701
6. Sun Y, Wei W, Yang HW, Liu JL. Clinical usefulness of breast-specific gamma imaging as an adjunct modality to mammography for diagnosis of breast cancer: a systemic review and meta-analysis. Eur J Nucl Med Mol Imaging 2013 Feb; 40(3):450-63.
7. Park JY, Yi SY, Park HJ, et al. Breast-Specific Gamma Imaging: Correlations With Mammographic and Clinicopathologic Characteristics of Breast Cancer. Am J Roentgenol 2014; 203:223–228
8. Tadwalkar RV, McSwain AP, Rapelyea JA, et al. Breast-specific gamma imaging as an adjunct modality for the diagnosis of invasive breast cancer with correlation to tumour size and grade. Br J Radiol 2012; 85, e212–e216