



Radiological Society of New Jersey

A Chapter of the American College of Radiology

26 Eastmans Road • Parsippany, New Jersey 07054
(973) 597-0938 Fax: (973)597-0241 www.rsnj.org

November 11, 2014

Glenn Pomerantz, MD
VP & Chief Medical Director
Horizon Blue Cross Blue Shield of New Jersey
Three Penn Plaza East, PP-14M
Newark, NJ 07105-2200

Via email: glenn_pomerantz@horizonblue.com

Dear Dr. Pomerantz:

The Radiological Society of New Jersey represents over 800 diagnostic radiologists and radiation oncologists practicing in New Jersey. We are a chapter of the American College of Radiology. We are writing to respectfully request that Horizon Blue Cross Blue Shield provide benefit coverage of digital breast tomosynthesis (DBT), also known as 3D mammography.

Breast cancer affects one woman in eight in the United States and is the most common cancer diagnosed in women worldwide. It is estimated that in the United States more than 230,000 women will be diagnosed and nearly 40,000 women will die of breast cancer in 2014 alone¹. Conventional digital 2D mammography has successfully improved early detection of breast cancer, resulting in an improvement of long-term survival rates. This earlier stage at diagnosis has decreased the mortality of breast cancer by as much as 50%².

Unfortunately, standard 2D digital mammography produces only two dimensional images. As such, there are limitations in interpretation due to superimposed or overlapping breast tissue. The challenge of overlapping breast tissue may result in unnecessary callbacks and missed cancers.

Approximately 10-20%^{3,4,5} of women called back on a screening mammogram will have false positive results with 2D mammography created by an area of overlapping tissue that can mimic a lesion. These false positives generate unnecessary follow-up tests such as diagnostic

¹ American Cancer Society: Cancer Facts and Figures 2014. Atlanta, Ga: American Cancer Society, 2014

² Kopans DB. The Most Recent Breast Cancer Screening Controversy About Whether mammographic Screening benefits Women at Any Age: Nonsense and Nonsense. *AJR* 2003;180:21-26

³ Rauscher GH, Murphy AM, Orsi JM, Dupuy DM, Grabler PM, Weldon CB. Beyond the mammography quality standards act: measuring the quality of breast cancer screening programs. *AJR Am J Roentgenol*. 2014 Jan;202(1):145-51.

⁴ Rosenberg RD, Yankaskas BC, Abraham LA, Sickles EA, Lehman CD, Geller BM, Carney PA, Kerlikowske K, Buist DS, Weaver DL, Barlow WE, Ballard-Barbash R. Performance benchmarks for screening mammography. *Radiology*. 2006 Oct;241(1):55-66. Erratum in: *Radiology*. 2014 May;271(2):620.

⁵ Schell MJ, Yankaskas BC, Ballard-Barbash R, Qaqish BF, Barlow WE, Rosenberg RD, Smith-Bindman R. Evidence-based target recall rates for screening mammography. *Radiology*. 2007 Jun;243(3):681-9.

mammograms, ultrasound, MRI and in some cases biopsies. This in turn causes significant patient anxiety. Tissue overlap may also obscure true lesion, resulting in as many as 20% of cancers being missed by conventional 2D mammography^{6,7}.

The latest advancement in mammography – digital breast tomosynthesis (DBT) also known as 3D mammography – has demonstrated the ability to address the limitation of tissue superimposition posed by 2D mammography. This greatly reduces the challenges to accurate interpretation. DBT was approved by the U.S. Food & Drug Administration (FDA) on February 11, 2011 for the same indications as 2D mammography including breast cancer screening, diagnosis and intervention. It has proven itself clinically superior to 2D mammography alone.

DBT is a mammography system that acquires images of the breast at multiple angles during a short scan time. The individual images are then reconstructed into a series of thin, high-resolution 1 mm slices. These slices can be displayed individually or in a dynamic cine mode. This allows for the internal architecture of the breast to be clearly visualized by eliminating the obstacle of over lapping tissue.

Since FDA approval, there have been numerous published studies in and outside the U.S. demonstrating the clinical benefits of 3D mammography. Clinical studies report that it decreases the recall rate and increases the cancer detection rate (CDR) for breast cancer screening. The first prospective screening trial to compare DBT to 2D mammography (a.k.a. Full Field Digital Mammography- FFDM) was published by Skaane et al⁸. Researchers reviewed 12,631 screening examinations in order to compare FFDM+DBT to FFDM alone. In this interim analysis, the researchers found that the addition of DBT resulted in a:

- 40% increase in the detection of invasive breast cancers.
- 27% increase in the detection of all cancers (invasive and in situ cancers combined)
- 15% decrease in false-positive rates.

Skaane's study demonstrated that FFDM+DBT increased sensitivity and detection of true breast disease without compromising specificity or increasing the rate of false positive results. The authors concluded that the addition of DBT to FFDM in a screening population resulted in a significant increase in cancer detection rates, particularly for invasive cancers and a simultaneous significant decrease in the false positive rate. This increase was observed across all breast densities.

The Screening with Tomosynthesis OR Standard Mammography (STORM) trial⁹ was a prospective comparative study which enrolled 7292 women in two institutions. Cancer detection rate and the rate of false positive recalls were compared between FFDM alone and FFDM + DBT. The cancer detection rate was 51% higher for FFDM+DBT than FFDM alone, while FFDM+DBT was also associated with a 17% reduction in false positive recalls.

⁶ Pisano, ED et al. Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening. *N Engl J Med* 2005 353: 1773-1783.

⁷ Schell MJ et al. Evidence-based Target Recall Rates for Screening Mammography. *Radiology*, June 2007; 243: 681 – 689.

⁸ Skaane P, Bandos AI, Gullien R, et al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. *Radiology* 2013, Apr; 267(1): 47-56.

⁹ Ciatto S, Houssami N, Bernardi D, Caumo F, Pellegrini M, Brunelli S, Tuttobene P, Bricolo P, Fantò C, Valentini M, Montemezzi S, Macaskill P. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. *Lancet Oncol.* 2013 Jun;14(7):583-9.

Haas et al.,¹⁰ in a study of 6100 women receiving FFDM + DBT, recently reported a 30% reduction in recall rate with DBT screening. Rose et al.¹¹, in a study of 9499 women receiving FFDM + DBT, reported a 53% increase in the detection of invasive cancers and a significant increase in the positive predictive value for screening recalls (PPV1) with 3D DBT compared with 2D DM alone.

The largest study to date was recently published this year in the Journal of the American Medical Association by Friedewald et al.¹² This study compared 281,187 conventional mammograms to 173,663 DBT exams. The study reported the following findings:

- A 41% increase in the detection of invasive breast cancers (p<.001).
- A 29% increase in the detection of all breast cancers (p<.001).
- A 15% decrease in women recalled for additional imaging (p<.001).
- A 49% increase in Positive Predictive Value (PPV) for a recall (p<.001).
- A 21% increase in PPV for biopsy (p<.001).

In conclusion, the Radiological Society of New Jersey acknowledges the following:

- DBT addresses the limitations of 2D mammography in reducing tissue superimposition and presents an advanced imaging technology in the screening and diagnosis of breast cancer.
- Published clinical benefits of population-based screening using DBT include increased detection of invasive breast cancer and a significant reduction in unnecessary call backs from screening mammography. These benefits have direct value in decreasing patient anxiety and reducing costs associated with call backs.
- DBT has the potential to change the clinical pathway of care, eliminating subsequent diagnostic services and abbreviating the call back pathway^{13,14}.
- DBT is becoming more common in clinical practice with approximately 1,100 digital breast tomosynthesis systems currently available in the U.S. (all 50 states), with over 50 facilities in New Jersey with DBT capability.

Therefore, the RSNJ **recommends** coverage of digital breast tomosynthesis as a medically necessary screening and diagnostic mammography service for the detection of breast cancer. Please note that the American College of Radiology (ACR) has released a position statement requesting that all insurers cover this service. We have attached a copy of that statement for your review.

¹⁰ Haas BM, Kaira V, Geisel J, Raghy M, Durand M, Philpotts LE. Comparison of tomosynthesis plus digital mammography and digital mammography alone for breast cancer screening. *Radiology* 2013; 269:694–700

¹¹ Rose SL, Tidwell AL, Bujnoch LJ, Kushwaha AC, Nordmann AS, Sexton R. Implementation of breast tomosynthesis in a routine screening practice: an observational study. *AJR* 2013; 200:1401–1408

¹² Friedewald S M, Rafferty E A, Rose S L, Durand M A, Plecha D M, Greenberg J S, Hayes M K, Copit D S, Carlson K L, Cink T M, Barke L D, Greer L N, Miller D P, Conant E F Breast Cancer Screening Using Tomosynthesis in Combination with Digital Mammography, *JAMA*. 2014;311(24):2499-2507

¹³ Greenberg J S, Javitt M C, Katzen J, Michael S, Holland A E. Mammography for Breast Cancer Screening in Community Practice. *AJR*:203, September 2014.

¹⁴ Lourenco AP, Barry-Brooks M, Baird G, Tuttle A, Mainero MB. Changes in recall type and patient treatment following implementation of screening digital tomosynthesis. *Radiology* 2014; Epub ahead of print. Posted online 22 Sept. 2014.

Thanks you for your consideration and please let me know if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Mitchell Miller, MD". The signature is written in black ink and is positioned above the typed name and title.

Mitchell Miller, MD
President, Radiological Society of New Jersey

CC:

Daniel Halevy, MD
Daniel_Halevy@horizonblue.com

Nathan Negin, MD
Nathan_Negin@horizonblue.com

Neil Sullivan
Assistant Commissioner, Life and Health
Neil.sullivan@doh.state.nj.us