3D Breast Tomosynthesis
The evidence-based choice for improved annual screening

September 2017
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In the United States, approximately 1 in 8 women (about 12%) will develop invasive breast cancer over the course of her lifetime. Though the mortality rate is very low, breast cancer kills more women than almost any other type of cancer. Only lung cancer claims more lives. Approximately 85% of breast cancers occur in women who have no family history of breast cancer and 2,470 new cases of invasive breast cancer are expected to be diagnosed in men in 2017. Breast cancer affects everyone.

It is clear that preventative measures are important for everyone. Mammography is the most important tool doctors have, not only to screen for breast cancer, but also to diagnose, evaluate, and follow those who have had breast cancer. The goal of screening is to find breast cancer early before symptoms can develop and when cancer is usually easier to treat.

Fortunately, you have access to the most advanced form of mammography, three dimensional (3D) breast tomosynthesis. This paper will introduce you to the procedure, explain how it works, outline the reasons why it should be your choice for your annual screening mammography, and provide information on insurance coverage. Whether you have had your annual exams for years or are about to have your first mammogram, we encourage you to learn more.

We believe, and hope you do as well, that 3D Breast Tomosynthesis is the best option for your annual screening mammography.
What is 3D Breast Tomosynthesis?

Breast tomosynthesis, also known as three-dimensional (3-D) mammography and digital breast tomosynthesis (DBT), is the most advanced form of mammography. Images are produced using low-dose x-ray images combined with digital reconstructions to create three-dimensional views of the breasts. Breast tomosynthesis increases early detection and diagnosis of breast disease, when it is most treatable.

In breast tomosynthesis, the breast is compressed as in traditional 2D mammography. The 3D scanner moves in an arc over the compressed breast to capture a series of images, or “slices,” through the tissue. Because the resulting images are captured at varying angles, radiologists are able to more accurately identify and locate abnormalities. This technology has proven to find invasive cancer earlier while reducing false positive recall rates.3

The American College of Radiology (ACR) estimates that as of May 2017, only about 30 percent of the mammography units installed in U.S. hospitals and imaging facilities were of the 3D variety.4 Research continues to be published, focusing on the benefits of tomosynthesis with regard to cost savings, increased cancer detection rates, and lower recall rates.

How Does 3D Mammography Compare to Typical 2D Mammography?

Clearer, more precise images

Traditional 2-dimensional mammography provides your radiologist with a single image that displays all layers of breast tissue as one. By producing a series of images 3D Tomosynthesis exams deliver a series of detailed breast images, from multiple angles, creating an array of “slices” through the breast. This allows your radiologist to better evaluate your breasts layer by layer. Abnormalities, including both benign and cancerous masses, are easier to identify and precisely locate.
Studies show that the 3D exam has greater accuracy than 2D mammography for women across a variety of ages and breast densities.\textsuperscript{5,7,9,12,13,14}

C-View\textsuperscript{TM} technology is a software application exclusive to the type of equipment we use at Advanced Radiology. It allows us to produce the world’s first and only synthesized 2D images that are FDA approved to replace FFDM (Full Field Digital Mammography). C-View creates the 2D image from the 3D Tomosynthesis data.

**Increased Detection and Fewer Recalls**

Clearer and more detailed images have direct benefits for patients. 3D tomosynthesis has been proven clinically to increase invasive cancer detection rates by up to 40\%.\textsuperscript{5,5-9} Industry studies have demonstrated that the use of 3D tomosynthesis reduces patient recalls by up to 15\%.\textsuperscript{5,8,12}

Wendy B. DeMartini, MD, division chief of breast imaging and professor in the department of radiology at Stanford University School of Medicine, and president of the Society of Breast Imaging, has said, “Major benefits have been demonstrated when DBT is used for screening, including better detection of cancers and, very importantly, a reduction in false positive recalls,” she says. “These benefits directly address the current limitations of standard mammography, including the number of, and impact of, false positives.”

Vivek Kalra, MD, of Medical Center Radiology Group in Orlando, feels that “Dedicated mammographers have greater confidence in reading screening exams, and thus have lower recall rates.”\textsuperscript{14}

All Advanced Radiology breast imaging specialists are certified by the American Board of Radiology, and have had additional years of sub-specialty training.
Reduced Overall Radiation Dose

Using C-View technology to create 2D images from 3D data eliminates the need for additional 2D scans. Patients receive a radiation dose that’s comparable to conventional 2D exams, about 50% less than combined 2D and 3D scans, and well below the safe level set by the FDA.

![MQSA Limit: 3.0 mGy]

Well within MQSA (Mammography Quality Standards Act) limit and comparable to a conventional 2D mammogram when using low dose software. A millisievert (mSv) is defined as the average accumulated background radiation dose to an individual for 1 year, exclusive of radon, in the U.S. One mSv is the dose produced by exposure to one milligray (mGy) of radiation. Source: Hologic

<table>
<thead>
<tr>
<th>FFDM</th>
<th>FFDM + DBT</th>
<th>Synthesized 2D + DBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall rate</td>
<td>7.8%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Cancer detection rate (per 1,000 exams)</td>
<td>5</td>
<td>5.7</td>
</tr>
<tr>
<td>Invasive cancer detection rate (per 1,000 exams)</td>
<td>3.9</td>
<td>3.4</td>
</tr>
<tr>
<td>In situ cancer detection rate (per 1,000 exams)</td>
<td>1.2</td>
<td>1.8</td>
</tr>
<tr>
<td>Minimal cancers found (≤ 10 mm)</td>
<td>57.6%</td>
<td>50.9%</td>
</tr>
<tr>
<td>PPV1</td>
<td>6.2%</td>
<td>8.1%</td>
</tr>
</tbody>
</table>


Improved Patient Experience

The patient experience of 3D breast tomosynthesis is virtually identical to that of traditional 2D Mammography. In fact, a patient can receive either exam using the same equipment. And a scan time of less than four seconds (the fastest available) is designed to minimize compression time and maximize patient comfort.

In a study published in the American Journal of Roentgenology, Dr. Kalra concluded that adding screening DBT to annual mammography is also cost-effective for patients of all ages and breast densities, especially in women ages 40 to 49.
3D tomosynthesis (right) provides multiple, layered images with greater detail vs. standard 2D Mammography (left). Combined with C-View technology, 3D tomosynthesis increases detection of invasive cancers by as much as 40%. Source: Hologic.

“Our analysis proves that adding [DBT] to 2D mammography starting at the age of 40 is cost-effective versus 2D mammography by itself,” says Kalra. However, it is even more significant that three times greater net monetary benefits were found in women ages 40 to 49 compared with those ages 50 to 59.”

Julie Kessel, Cigna’s senior medical director, says that in enabling earlier detection and fewer false positive callbacks, DBT supports “better-quality care, at a lower cost.”

Advanced Radiology understands that a positive patient experience involves far more than reduced cost. However, reduced costs over time, combined with a 40% reduction in false positive recalls and lower overall radiation dose will help reduce anxiety and increase peace of mind for patients and their families.

**Cost Savings of 3D Breast Tomosynthesis**

Per patient, per decade

- **40-49**: $1,598
- **50-59**: $546
- **60-69**: $535
- **70+**: $501


“Many patients are beginning to understand that they have a choice, and given a choice between what is presented as the more thorough option and the less thorough option, they will take the former.”

Garnetta Morin-Ducote, MD, medical director of The University Breast Center at the University of Tennessee Medical Center in Knoxville, Tennessee.
Who Should Have a Screening Mammogram?

Advanced Radiology would like to remind everyone, specifically women age 40 and above, who have not had their initial, baseline mammogram, of the importance of screening mammography. Approximately 1 in 8 women will develop breast cancer and 8 out of 9 of those diagnosed have no family history of breast cancer. In addition, early detection continues to provide a five-year survival rate of almost 100%. Below is a comparison of recommendations from American College of Radiology and the Society of Breast Imaging vs. American Cancer Society vs. U.S. Preventative Task Force.

Advanced Radiology supports the ACR recommendation and believes that detection and survival rates will continue to improve with advances in imaging technology and treatment.

With the implementation of tomosynthesis, Advanced Radiology has been able to update our imaging protocol for breast cancer survivors. Since October 2016 we have recommended that patients who have been treated for breast cancer with breast conservation obtain a diagnostic mammogram for the initial five years after their treatment. After five years, patients can return to screening mammography. We hope to spark continuing discussion between women and their physicians about mammography and its potential to deliver the life-saving care they both desire and deserve.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Annual screening starting at 40 (ACR, SBI)</th>
<th>Annual screening, 45-54; biennial screening, 55-79 (ACS)</th>
<th>Biennial screening, 50-74 (USPSTF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent mortality reduction</td>
<td>39.6%</td>
<td>30.8%</td>
<td>23.2%</td>
</tr>
<tr>
<td>Breast cancer deaths averted</td>
<td>11.9</td>
<td>9.2</td>
<td>6.9</td>
</tr>
<tr>
<td>Life-years gained (LYG)</td>
<td>189</td>
<td>149</td>
<td>110</td>
</tr>
<tr>
<td>Number needed to screen (NNS) per death averted</td>
<td>84</td>
<td>108</td>
<td>144</td>
</tr>
<tr>
<td>NNS per LYG</td>
<td>5.3</td>
<td>6.7</td>
<td>9.1</td>
</tr>
</tbody>
</table>

Source: Cancer, August 21, 2017
Does My Insurance Plan Cover 3D Mammography?

Too often, the decision to take advantage of the best available healthcare procedure depends on how it will be paid for. Understanding your insurance coverage, deductible, and out-of-pocket expense is critical in making the right decision.

When scheduling your annual screening mammogram, it is critical to know whether 3D Breast Tomosynthesis is “paid for” by your insurance plan, versus merely “covered,” or not covered at all.

**Paid for:** Health insurance plans with preventative benefits may treat 3D Breast Tomosynthesis as they would any screening mammogram, and pay for the procedure in full, with no out-of-pocket expense and without the charge being applied to your deductible.

**Covered:** Plans that “cover” 3D Breast Tomosynthesis but do not consider it a preventative screening mammogram will apply the cost to your deductible. If your deductible has not yet been met, you may be responsible for all or part of the cost of the procedure.

**Not covered:** If your plan does not include preventative benefits, or if your plan does not specifically cover 3D Breast Tomosynthesis, you will be responsible for the entire cost of the procedure.

Insurance plans are unique to each individual. Before scheduling an appointment for any procedure, we encourage you to check with your insurance carrier for specific details about your plan and its benefits.

The Centers for Medicare and Medicaid Services (CMS) approved Medicare reimbursement for women undergoing tomosynthesis in 2014. On the state level, Connecticut passed legislation effective January 1, 2017 requiring health plans with preventative benefits to insure 3D breast tomosynthesis for baseline scans (for women age 35 through 39) and annual screening mammograms (for women age 40 and older).
### Advanced Radiology Carriers and Coverage (reported as of September 1, 2017)

<table>
<thead>
<tr>
<th>Insurance Carrier</th>
<th>Tomosynthesis Included in Preventative Benefits</th>
<th>Charges Applied to Deductible</th>
</tr>
</thead>
<tbody>
<tr>
<td>AARP - Medicare Complete UHC</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td><strong>Aetna</strong></td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Aetna Medicare</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Anthem</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Anthem Federal</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Cigna (MedSolutions / eviCore)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td><strong>GEHA</strong></td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>GWH - Cigna PPO - OPN Access</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td><strong>ConnectiCare (Individual / Small Group)</strong></td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>ConnectiCare (Large Group)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>ConnectiCare Medicare</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Harvard Pilgrim</td>
<td>YES</td>
<td>NO</td>
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<tr>
<td>Innovative Health Care</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicare</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicaid</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>UHC / Oxford</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>UHC / Oxford Medicare</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>UMR</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>WellCare</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>
Advanced Radiology imaging centers are located throughout Southwestern Connecticut, with easy access to major transportation routes.

To schedule an appointment, call 203.337.XRAY (9729)

Request an appointment online at AdRad.com/appointment
REFERENCES


5. FDA PMA submission P080003/S001 physician labeling.


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