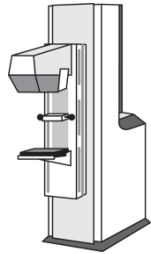


Digital Breast Tomosynthesis

Digital Breast Tomosynthesis (DBT)



Technology In Brief

What Is It:

- Digital breast tomosynthesis (DBT) is a non-invasive, 3D imaging technique for the detection and diagnosis of breast cancer

How Does it Work:

- Digital breast tomosynthesis generates three-dimensional images of the breast by analyzing multiple imaging planes and reconstructing images as a cine loop or a series of thin, high resolution slices, with rapid reconstruction of the whole breast

Adoption Status:

- There are currently over 750 tomosynthesis units installed in the U.S.

FDA Status:

- Hologic's Selenia Dimensions system approved February 2011
- GE's SenoClaire system approved September 2014

Major Vendors:

- Hologic and GE, although Siemens likely submitting for FDA approval in the near-term

Competing Products:

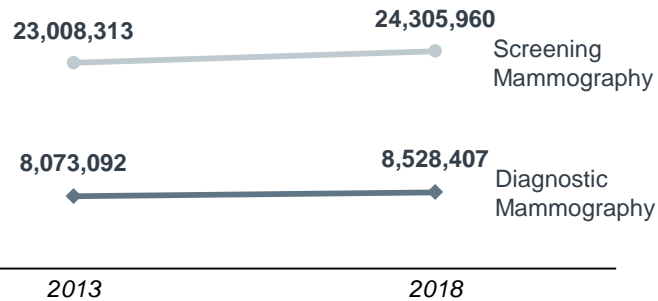
- Breast ultrasound, contrast-enhanced spectral mammography, molecular breast imaging, 2D digital mammography

Consideration	Service Line Strategy Advisor's Take
Clinical	<ul style="list-style-type: none"> • Improved visualization increases radiologist confidence in reading • Reductions in recall rate possibly leading to fewer unnecessary biopsy procedures
Reimbursement	<ul style="list-style-type: none"> • CPT codes are 77061, 77062 and 77063, and they provide additional incremental reimbursement from the digital-only codes • Patients will not be responsible for any co-pays associated with the new screening DBT CPT codes; the new screening add-on code, 77063, would be subject to the same co-insurance or deductible policies as other screening mammography services.
Cost	<ul style="list-style-type: none"> • DBT systems cost between \$425K-\$475K , a 20% increase over 2D-only systems • Upgrade available for select 2D systems for \$100K-\$150K per unit
Payer Coverage	<ul style="list-style-type: none"> • CMS recommends in the 2015 MPFS that only 77063 be used at this time in conjunction with the digital screening mammography code G0202 . In lieu of using the new diagnostic DBT CPT codes (77061, 77062), CMS created a new add-on G code (G0279) to be used with the existing digital diagnostic mammography codes (G0204, G0206) to reflect the work of tomosynthesis when provided with diagnostic digital mammography. Therefore, the stand-alone diagnostic DBT codes have been replaced by add-on codes, leaving no means to report diagnostic DBT when it is reported separately from a FFDM • Imaging centers have seen varying levels of success in securing additional reimbursement from private payers
Market Potential	<ul style="list-style-type: none"> • Tomosynthesis is thought to most benefit women with dense-breasts (i.e. younger women) • Potential for volumes similar to that of 2D mammography
Operational Needs	<ul style="list-style-type: none"> • Larger file sizes for DBT may pose a problem for some storage systems and is a significant variable cost associated with use • Eight hours of training required for technologists, radiologists, and medical physicists
Impact in Accountable Care	<ul style="list-style-type: none"> • Possible reduction in unnecessary imaging and biopsy procedures a benefit in shared savings model
Competitive Take	<ul style="list-style-type: none"> • For AMCs: Seen as the future of breast imaging by many, AMCs have been the early adopters of the technology • For community hospitals: Due to their greater expense, many community hospitals holding off on purchasing; those that invest do so for competitive purposes
Position on the Adoption Curve	<ul style="list-style-type: none"> • Early Majority

Operational Challenges Preclude Many from Investing

Market & Financial Overview

National Estimate



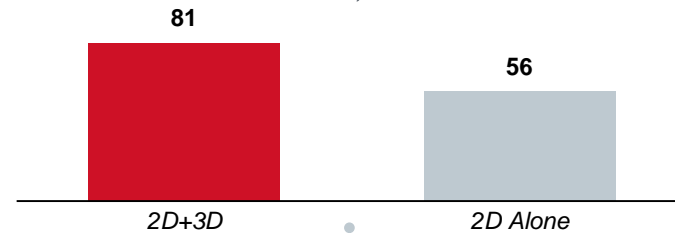
Reimbursement Rates

CPT	Description	2015 Final Rate
G0206 + G0279	Diagnostic digital breast tomosynthesis, unilateral	\$129.60 + \$56.57
G0204 + G0279	Diagnostic digital breast tomosynthesis, bilateral	\$164.69 + \$56.57
G0202+ 77063	Screening digital breast tomosynthesis, bilateral (list separately in addition to code for primary procedure)	\$134.97 + \$56.57

Clinical Considerations

Invasive Cancers Detected in Screening Population

n=12,631



Funded by Hologic, a 2013 study is the first large scale (n=12,631) observational study focusing on DBT's performance in a population-based screening setting. Research compares digital mammography alone (2D) to digital mammography in combination with DBT (2D + 3D). Statistically significant findings of this study show that using DBT in combination with 2D mammography during screening: increases detection of both invasive and in situ cancers by 27%, reduces false-positive rates by 15%, detects 40% more (25 additional) invasive cancers.



Keys for Investment Success

- Determining how tomosynthesis will be used (either as a screening or diagnostic tool) and how this will impact center operations
- Forming a plan for handling both a greater volume of data for storage and longer radiologist interpretation times will help to manage workflow, particularly in the screening setting
- Creating a clear plan for which patients will receive tomosynthesis will help to reduce the appearance that there are two sets of care
- Working proactively with payers to secure incremental payment and provide needed documentation for additional charges

Source: Skaane, Per "Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program" Radiology, 2013; American College of Radiology, "2015 Medicare Physician Fee Schedule Final Rule Summary of Payment Policy Rules", available at http://www.acr.org/~media/ACR/Documents/PDF/News/Detailed_Summary_of_MPFS_FINAL.pdf, accessed March 2015.