Molecular Breast Imaging

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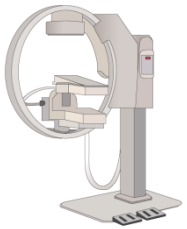


Technology In Brief

What Is It:
- Molecular breast imaging (MBI) represents a class of novel nuclear medicine imaging modalities designed to provide high-resolution functional imaging of breast tissue.

How Does it Work:
- Molecular breast imaging captures the increased metabolism present in cancerous cells through the use of targeted radiotracers. Following the conventions of standard nuclear imaging studies, molecular breast imaging utilizes technetium-99 to target breast lesions.

Adoption Status:
- Leading breast imaging facilities, centers seeking to differentiate from competition

FDA Status:
- Approved

Major Vendors:
- Dilon, Gamma Medica, GE Health care

Competing Products:
- Breast ultrasound, contrast-enhanced spectral mammography, MRI, tomosynthesis

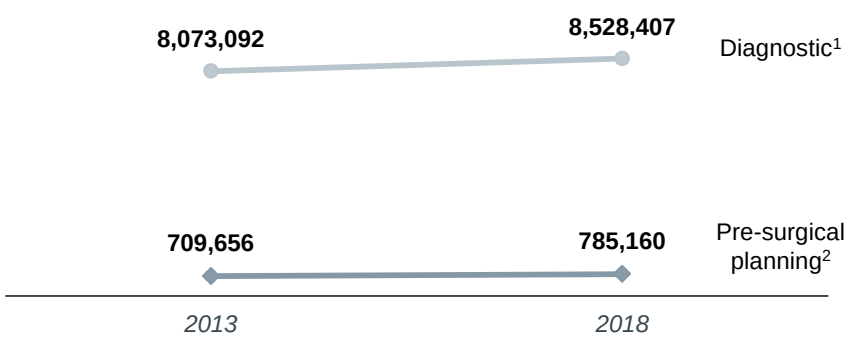
Consideration	Service Line Strategy Advisor's Take
Clinical	• Improved specificity over breast MRI, MBI helps physicians to better understand lesion malignancy • Similar results to breast MRI for pre-surgical planning and to mammography for high-risk or dense-breasted screening
Reimbursement	• MBI is currently paid using non-specific tumor codes for molecular imaging • There are not breast-specific reimbursement codes
Cost	• MBI systems range from $250K to $500K depending on the vendor and whether the system is a single- or dual-head system
Payer Coverage	• MBI is covered by Medicare and select private payers though others still consider this to be experimental
Market Potential	• MBI is best suited for dense-breasted and high-risk women as a screening tool • MBI also has potential to replace MRI in pre-surgical planning for women with contraindications to MRI
Operational Needs	• Hot lab needed to house radiotracer or courier used to transport doses to breast center each day • Close work with nuclear medicine specialists suggested to integrate use of molecular imaging
Impact in Accountable Care	• Improvements in patient care and possibly fewer exams to benefit in an accountable care setting
Competitive Take	• For AMCs: Possibly differentiating technology to provide another option for select patient groups • For community hospitals: Not yet seen as must-have for majority of breast centers due to limited volume and numerous other competing technologies
Position on the Adoption Curve	• Progressive

Source: Service Line Strategy Advisor research and analysis.

Improved Specificity, Sensitivity Seen Though Some Physicians Remain Skeptical

Market & Financial Overview

National Market Estimates



6%

Overall Market Growth

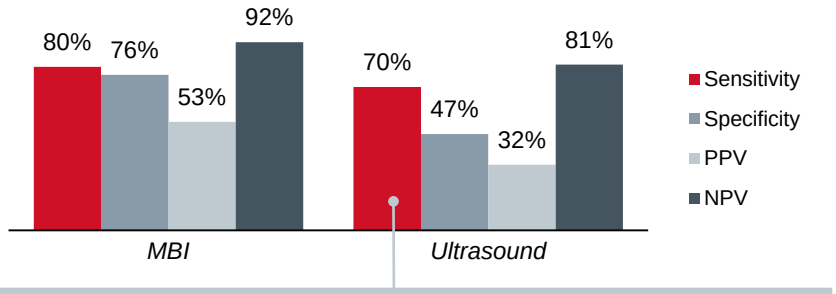
Reimbursement Rates

CPT	Description	2013 Final Rate	2014 Final Rate	Percent Change
78800	Tumor imaging, limited	$300	$383	28%
78801	Tumor imaging, multiple	$502	$383	-24%

Clinical Considerations

BMI vs. Ultrasound as Adjunct to Mammography

n=329



Mammography is the primary screening and diagnostic modality for breast cancer detection, whereas US and MBI are used when the results are inconclusive. Data shown above compares the effectiveness of MBI and US in their role as adjunct modalities to mammography in patient management. For patients with negative (or positive) mammograms and remaining concern, only a positive (or negative) finding from adjunct procedures can change management. MBI significantly contributes to the detection of high risk lesions in patients with negative or intermediate initial findings when compared to US, but still cannot replace the role of a biopsy.

Keys for Investment Success

- Proactively working with breast radiologists and surgeons to determine appetite for adding molecular breast imaging to pre-surgical planning pathway
- Forming a plan for handling radioisotope depending on proposed location for gamma camera
- Training nuclear medicine and mammography technicians on new technology to ensure proper positioning and interpretation for new technology
- Educating primary care physicians on challenges of imaging dense-breasted women to increase utilization of novel technology

Source: Weigert, et al. Results of a Multicenter Patient Registry to Determine the Clinical Impact of Breast-Specific Gamma Imaging, a Molecular Breast Imaging Technique, *American Journal of Roentgenology* , 2012.

1) Displaying volumes for diagnostic mammography
2) Displaying volumes for breast MRI