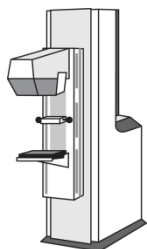


Full-Field Digital Mammography

Full-Field Digital Mammography (FFDM)



Technology In Brief

What Is It:

- Full-field digital mammography (FFDM) is an alternative to film-screen mammography for breast cancer screening and diagnosis. While only clinically superior to film systems for select patient demographics, operational and marketing advantages of digital mammography now render it the modality-of-choice for breast cancer screening and diagnosis.

How Does it Work:

- FFDM uses x-rays to produce images of the breast. An electronic detector plate converts X-rays into digital images that can be reviewed and archived on a computer. The radiologist can manipulate the brightness, contrast, and other features of the digital mammogram with post-processing tools.

Adoption Status:

- 84% of certified facilities utilize FFDM or CR

FDA Status:

- Approved in 2000; reclassified to Class II device in 2008

Major Vendors:

- GE, Hologic, Siemens, Philips

Competing Products:

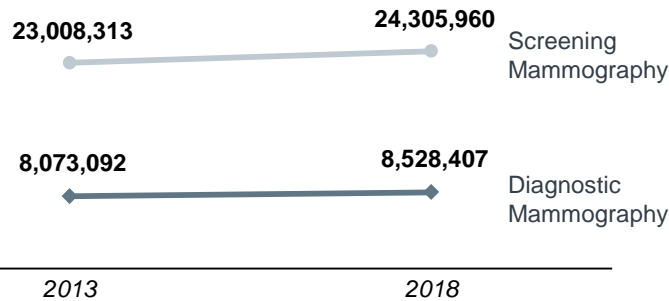
- CR Mammography, Tomosynthesis

| Consideration | Service Line Strategy Advisor's Take |
|---------------------------------------|---|
| Clinical | <ul style="list-style-type: none"> • Due to higher sensitivity in select patient populations, digital mammography is currently considered the clinical standard of care |
| Reimbursement | <ul style="list-style-type: none"> • Reaching break-even requires high annual volumes (~3,500 to 4,000 mammograms) • Approximately \$50 incremental reimbursement over film mammography (50-60% incremental reimbursement) |
| Cost | <ul style="list-style-type: none"> • \$225K for screening only system • \$300K-\$450K for multi-purpose systems • \$450K-\$500 K for tomosynthesis-capable FFDM systems |
| Payer Coverage | <ul style="list-style-type: none"> • Nearly 100 percent reimbursement from all private payers and Medicare • Incremental reimbursement for FFDM studies over film procedures from Medicare and private payers |
| Market Potential | <ul style="list-style-type: none"> • The aging population will likely increase the number of patients seeking mammograms. • This increase may be offset by recent changes in recommendations, which suggest biennial breast mammography screening in women between 50 and 74, but not necessarily in women under 50 |
| Operational Needs | <ul style="list-style-type: none"> • Space allocation much the same as film mammography, though the technology infrastructure to handle storage and retrieval of digital images may pose a problem for some institutions and is a significant variable cost associated with use • Increased patient throughput and diagnosis by decreasing image development time |
| Impact in Accountable Care | <ul style="list-style-type: none"> • The increased focus on preventive care as part of health reform will likely increase the number of patients receiving mammograms by eliminating co-pays for the test |
| Competitive Take | <ul style="list-style-type: none"> • Digital mammography considered the clinical standard of care • Organizations without digital mammography poised to lose market share • Digital breast tomosynthesis rapidly becoming a substitute for additional FFDM units in progressive institutions |
| Position on the Adoption Curve | <ul style="list-style-type: none"> • Late Majority |

Continued Debate Over Benefit of Mammogram May Dampen Volumes

Market & Financial Overview

Market Estimates

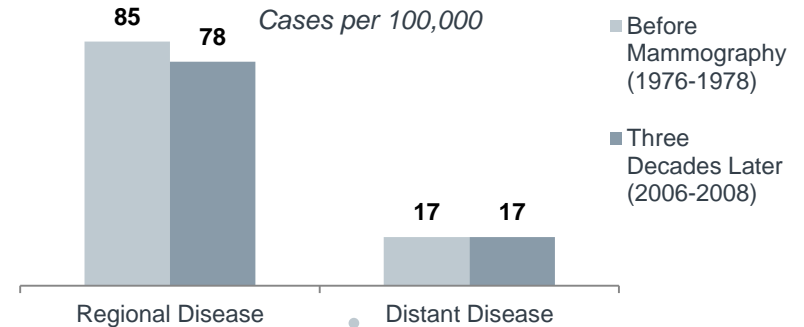


Reimbursement Rates

| HCPCS | 2013 Final Rate | 2014 Final Rate | Percent Change |
|--------------------|-----------------|-----------------|----------------|
| G0202 – Screening | \$104.11 | \$126.32 | 21% |
| G0204 – Diagnostic | \$125.89 | \$154.17 | 22% |
| G0206 - Diagnostic | \$98.67 | \$121.39 | 23% |

Clinical Considerations

Cases of Late Stage Breast Cancer Detected Before and After Mammography



A controversial study published in 2012 in the New England Journal of Medicine suggests that despite increased breast cancer detection rates due to increased screening mammography rates, mammography has “only marginally reduced the rate at which women present with advanced cancer.” Ultimately, the authors of the article suggest that screening mammography has not had a substantial effect on the number of breast cancer deaths and, on the contrary, represents a poignant example of medical over diagnosis.



Keys for Investment Success

- Hospitals must have the necessary exam volume to take advantage of increased capacity to achieve profitability with FFDM. Small mammography programs may have trouble achieving profitability with FFDM given its high costs – CR mammo may be useful in this case
- Operational benefit of digital mammography alone can justify the investment, as FFDM can increase productivity by up to 30%.
- As FFDM has become the standard-of-care in many markets, FFDM may be necessary simply to retain market share and stave off the competition.