



Commercial Reimbursement and Utilization for Invenia ABUS (Automated Breast Ultrasound)

Background

More than one-half of women younger than 50 years old and approximately one-third of women 50 years and older have dense breasts in the US.¹ Higher breast density is associated with decreased mammographic sensitivity and specificity and increased breast cancer risk.² Due to the shortcomings of mammography in this population of women, an individualized multimodal screening approach is recommended to improve the early detection of breast cancer. No clinical guidelines explicitly recommend use of supplemental breast cancer screening on women with dense breasts,³ but as of March 2018, 33 states have enacted legislation requiring that breast density, in addition to mammography results, be reported to women undergoing such procedures; additional states have introduced or are currently working on legislation.⁴ Most states require specific density inform language distinguishing dense (i.e., BI-RADS[®] C and D) from non-dense breasts and four states require that insurers cover subsequent examinations and tests for women with dense breasts.⁴ On October 25, 2017, a federal bill was introduced addressing these same areas.⁵ If enacted, the federal legislation could help to standardize density inform reporting requirements. The potential impact of federal legislation could be far reaching – not only impacting states with existing legislation, but reaching all 50 states in the US. [Click here to view the latest breast density inform map.](#)

Enactment of density inform legislation is expected to increase demand for supplemental screening in women with dense breast tissue. These legislative efforts are supported and encouraged by advocacy organizations, such as *Are You Dense, Inc.* and *DenseBreast-info.org*. These organizations are also emphasizing the importance of educating the public and referring physicians about the risks and challenges involved in screening dense breast tissue. According to the Mammography Quality Standards Act (MQSA), this should be a shared responsibility among the

interpreting physician, referring physician/Health Care Provider (HCP), and patient.⁶ Specifically, the MQSA encourages education and outreach to patients from medical/scientific organizations, industry, and interpreting physicians. In addition, outreach to referring physicians is encouraged from professional organizations and Continuing Medical Education (CME) providers.⁶

Despite widely available options for additional screening and legislation mandating density inform, uptake and adoption of supplemental screening has lagged. In addition to knowledge gaps, one study identified reimbursement uncertainties (e.g. billing, coding and coverage) as a key factor for slow uptake. In 2015, the CPT[®] codebook was updated to include two new codes for breast ultrasound, CPT 76641 and 76642, for complete and limited exams, respectively.⁷ These codes replaced CPT 76645. The new and old codes alike do not differentiate the technology used to perform an exam (handheld vs. automated) or intended purpose of the exam (screening vs. diagnosis).

In 2014, the FDA approved GE Healthcare's Invenia™ Automated Breast Ultrasound (ABUS) as an adjunct to mammography for breast cancer screening in asymptomatic women who have dense breast tissue with normal or benign screening mammography findings and no previous clinical intervention. Invenia ABUS is a 3D ultrasound system with a wide field-of-view transducer that scans the entire breast. As such, ABUS exams are ideal for screening and can be billed using CPT 76641. Screening would be indicated using an accompanying diagnosis code of Z12.39 (i.e., encounter for other screening for malignant neoplasm of breast), along with any other appropriate diagnosis based on findings from the mammogram. The limited exam, billed CPT 76642, is typically performed using handheld ultrasound and is a targeted exam that does not include all four quadrants of the breast. [For additional information, click here to access the Invenia ABUS reimbursement and coding guide.](#)

To better understand the reimbursement potential of ABUS in a commercially-insured population, a retrospective study was conducted to evaluate the use of supplemental screening with breast ultrasound, as a proxy for Invenia ABUS.

Specifically, the following were examined:

1. Average reimbursement (including patient out-of-pocket, OOP) and utilization for complete breast ultrasound
2. Top five corresponding diagnoses for complete breast ultrasound
3. Impact of complete breast ultrasound on demand and utilization for limited breast ultrasound
4. Breast ultrasound utilization pre- and post-enactment of density inform legislation in select states

Methodology

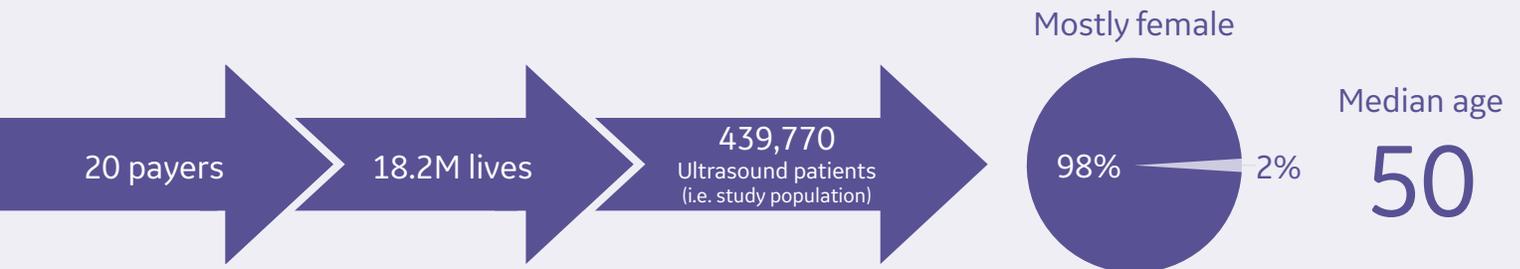
This was a retrospective study using administrative claims data (medical and pharmacy) from multiple payers that were adjudicated by Magellan or a Magellan partner. Breast ultrasound claims billed using CPT 76641 and CPT 76642 and incurred between January 1, 2015 and December 31, 2016 were included in the analysis. Patients aged at least 18 years were included in the analysis. Reimbursement rates were based on average allowed amount.

Sample Characteristics

Data from 20 regional payers, totaling 18.2M lives, were analyzed. Using this dataset, a total of 439,770 patients were identified as having a breast ultrasound claim during the study period (i.e., study population). The leading age group was 40 to 59 with an overall median age of 50 years. Majority (98%) of the population was female. There were more patients from the South Atlantic than any other region.

Commercial Payers

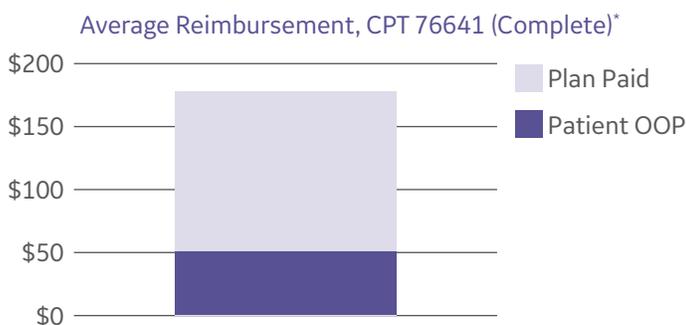
(BLINDED)	HealthNow
(BLINDED)	HMSA
BCBS FL	Horizon NJ Medicaid
BCBS NE	HPHC
Caresource	Independent Health
Capital Blue Cross	Sunshine State Health Plan
CHC of FL	Superior Health Plan
Connecticare	Tufts
Gateway Health	Tufts Health Plan - Network Health
HAPA	



Outcomes

1. Complete Breast Ultrasound Reimbursement

Among the 439,770 patients included in the study, breast ultrasound was positively reimbursed subject to patient copay and deductible. Average reimbursement for the complete procedure billed with CPT 76641 was \$177 (range, \$3-\$351) and OOP was \$52 (range, \$0-\$147).



*Reimbursement (allowed amount) = patient copay and/or deductible + plan paid amounts

In general, when a unilateral complete exam is performed it is billed with CPT 76641 without the presence of modifiers. If medical necessity requires bilateral imaging, the modifier 50 is appended to the claim. When this modifier is used, Medicare will allow 150 percent of the standard reimbursement. Some commercial carriers require modifier 50, while others prefer use of LT and RT to indicate bilateral procedures. Modifier codes were not available within the Magellan dataset. As such, the average reimbursement reflected was based on all claims, regardless of bilateral procedure status.

2. Top Diagnoses

Top diagnoses were analyzed for all complete breast ultrasound claims. The leading primary (diagnosis position 1) and secondary (diagnosis position 2) diagnoses were unspecified lump in breast (ICD-10 N63.0) and inconclusive mammogram (ICD-10 R92.2), respectively. Encounter for other screening for malignant neoplasm of breast (ICD-10 Z12.39) was not as common and did not appear in the top 5 diagnoses for the primary or secondary

diagnosis position, but it is the most likely diagnosis to accompany claims for a bilateral screening breast ultrasound. The top five primary and secondary diagnoses for complete breast ultrasound are listed below.

CPT – 76641 (Complete Procedure)

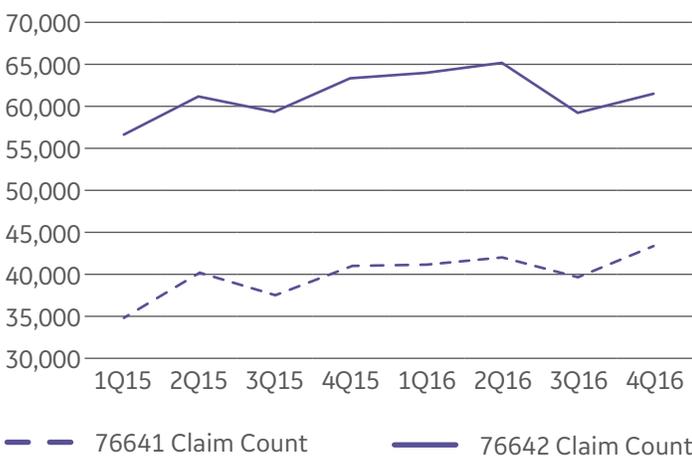
Diagnosis Position 1 (Total Diagnoses = 277,896)			Diagnosis Position 2 (Total Diagnoses = 103,929)		
ICD9/10	No. Members	Percentage	ICD9/10	No. Members	Percentage
N63	31,010	11%	R92.2	13,003	13%
R92.8	23,315	8%	793.82	7,545	7%
R92.2	22,287	8%	Z12.31	7,384	7%
Z12.31	22,253	8%	N63	6,007	6%
611.72	16,016	6%	R92.8	4,223	4%

611.72/N63 – lump or mass in breast; 793.82/R92.2 – inconclusive mammogram; R92.8 – other abnormal and inconclusive findings on diagnostic imaging of breast; Z12.31 – encounter for screening mammogram for malignant neoplasm of breast

3. Demand and Utilization for Limited Breast Ultrasound

Prior to 2015, breast ultrasound was billed with a single code, CPT 76645. This code was replaced in 2016 with the complete (CPT 76641) and limited (CPT 76642) codes that exist today. This action caused concern that utilization of the two codes would somehow result in lower overall utilization and/or impact total breast ultrasound revenue. Among the claims analyzed in our study, utilization of the complete procedure did not appear to cannibalize utilization of the limited procedure (i.e., targeted ultrasound); year-over-year (Y-O-Y) trend in volume was 7% and 4% for the complete and limited procedures, respectively. These results are consistent with common practice patterns. Following a screening mammogram, asymptomatic patients with dense breasts are often referred for a bilateral ultrasound exam, whereas limited exams are performed with pending suspicious findings on a bilateral complete exam and for patients presenting with symptoms (e.g., lumps, nipple discharge, etc.). As such, availability of these codes has complimented one another and may present an opportunity for increased revenue.

Claim Count by Quarter



4. Density Inform Impact

One aim of the study was to understand the impact that the density inform legislation had on breast ultrasound utilization. To explore this, claim count for utilization (CPT 76641 and 76442 combined) was compared Y-O-Y post-enactment of density inform legislation for nine states.

- Eight out of nine states had an increase in claims Year 1
- Three states had an increase in claims in Years 1 and 2
- Two states had an increase in claims in Years 1, 2, and 3
- Oregon had the largest trend in Year 1 with a 269% increase in claims over the Year prior to enactment of density inform legislation

Benefit eligibility and subsequent population changes can also play a large role in breast ultrasound utilization trends. For this reason, for the same states, population changes for women aged 18+ years were also analyzed to better understand impact of legislative efforts and other factors that may be driving the above utilization trends. Population trends for these states mirrored the directional trends for utilization. Noted exceptions were Missouri and Hawaii. In Year 1, Missouri’s utilization decreased 5% while the population increased 7%. The results here highlight opportunities for further patient and physician education. Conversely, in Year 3, Hawaii’s utilization increased 3% while the population decreased 4%. The directional difference in these trends suggest a positive impact that could be a result of density inform legislation. Utilization trends, both upward and downward, from this study highlight and reinforce the same opportunities.

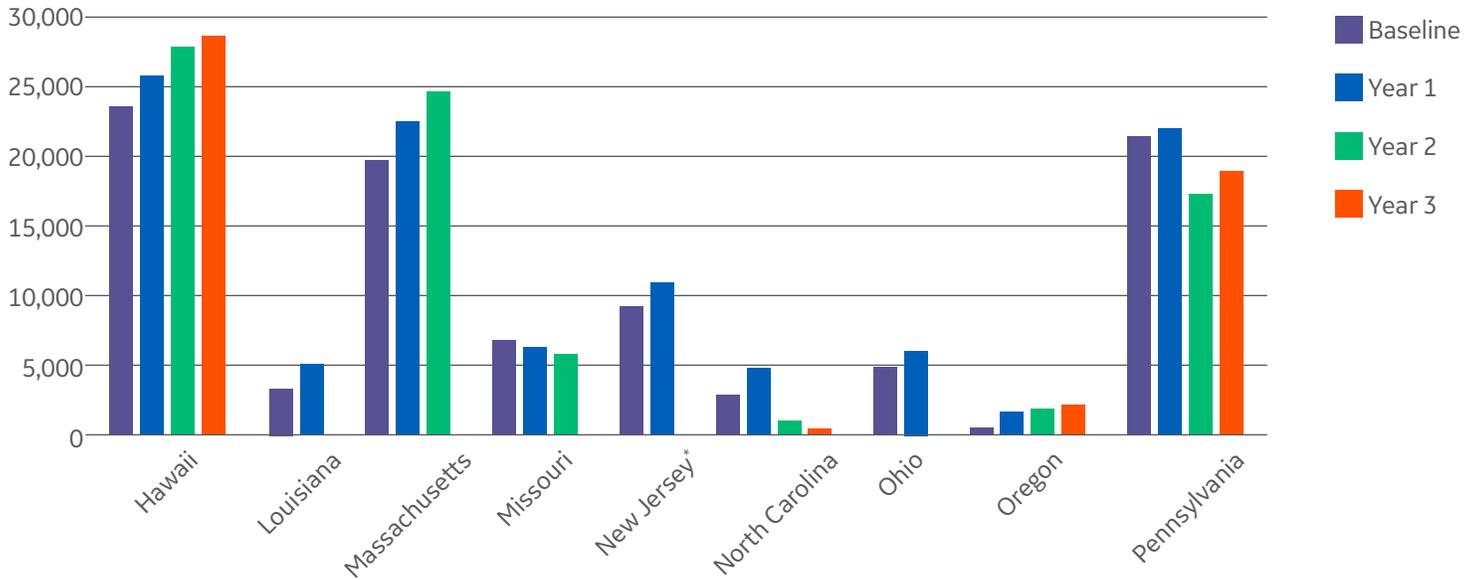
In general, increased utilization trends from this analysis signal a positive impact due to awareness of density information. In addition, these upward trends signal an increase in demand for breast ultrasound and present opportunities for market expansion. While at first glance negative utilization trends can be viewed as concerning, they enforce the need for a comprehensive implementation plan that includes patient and referring physician education to create supplemental screening demand.

While we could look at population trends to examine their impact on utilization, other potential factors (e.g., benefit eligibility, breast density status for the eligible population) were not available in our dataset and could not be measured or controlled for within this analysis.

State	Claims, Y-O-Y Trend		
	Year 1	Year 2	Year 3
Louisiana	54%		
New Jersey*	19%		
Ohio	29%		
Massachusetts	14%	11%	
Missouri	-5%	-9%	
Oregon	269%	37%	11%
Hawaii	14%	7%	3%
North Carolina	69%	-77%	-59%
Pennsylvania	2%	-23%	12%

*State with insurance coverage beyond mammogram.

Breast Ultrasound Claims Count



*State with insurance coverage beyond mammogram.

Conclusions

Due to the limitations of mammography in detecting cancer in dense breast tissue and the increased risk factor of dense breast tissue, an individualized multimodality approach is recommended to improve screening outcomes. Various studies support the use of ABUS as an adjunctive tool to increase the sensitivity of screening for women with dense breast tissue.^{8,9}

Amongst 20 commercial payers, breast ultrasound was reimbursed, subject to patient copay and deductible. Average reimbursement for complete breast ultrasound was \$177. In states with a density inform law and/or insurance coverage mandate, breast ultrasound utilization and target population (i.e., women aged 18+) increased Y-O-Y, highlighting opportunities for market expansion, and emphasizing the need for continued education on cancer risk with high breast density and the screening limitations of mammography within this population. As additional states pass similar legislation and/or a federal bill is passed, demand for supplemental screening in women with dense breasts is expected to grow.

Additional studies are needed to further document the impact of breast density inform legislation on supplemental ultrasound screening demand. In the meantime, physician and patient education remain of high importance. While advocacy organizations lead the charge to educate the general community, medical/scientific organizations, industry, CME providers and interpreting physicians are all encouraged to help with ongoing education initiatives for patients and referring physicians.

Invenia ABUS is a 3D automated breast ultrasound system marketed by GE Healthcare. Based on an Invenia ABUS equipment purchase price of \$300K with a 15-month payment term and Medicare reimbursement rate of \$168 for a free-standing facility, it's estimated that providers would have recouped equipment purchase costs (breakeven) in Year 1. Based on the results of the study, typical breakeven would be 2-3 patients per day based on an ROI calculator. It is feasible for providers to implement this technology and have a positive return on their investment in the first two years of implementation.

Real World Experience: Imaging for Women

Imaging for Women (IFW), located in Kansas City, Missouri, conducted a retrospective study analyzing 30 months of data, starting after initial installation of their ABUS, to document the impact of ABUS on several clinical and operational outcomes. Average reimbursement (sum of plan paid plus patient OOP divided by total count of exams) for a bilateral ABUS examination was highest for Blue Cross Blue Shield (\$208.69), followed by Medicare (\$206.21) and Cigna (\$191.33). Average ABUS reimbursement across all payers was \$202.84 for a bilateral exam and \$98.96 for a unilateral exam. Average patient OOP ranged from 5% to 54% of total.

Payer	Average Reimbursement [†]	
	Bilateral	Unilateral
Blue Cross Blue Shield	\$208.69	\$202.84
Cigna	\$206.21	
Medicare	\$191.33	
United Healthcare	\$183.47	
Aetna	\$181.52	

[†]Reported reimbursement rates are based on contact terms negotiated between Imaging for Women and individual insurance carriers. Reported reimbursement rates from this study are not guaranteed for other practices and settings.

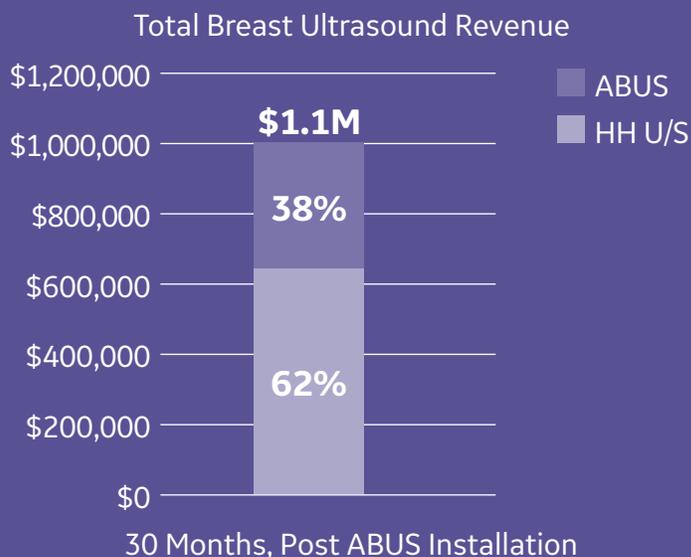
Source: Data on file. GE Healthcare. 2017.

Notable success of the IFW supplemental screening program was driven by a three-prong strategic plan to drive demand and eliminate patient compliance barriers.

1. Education (e.g., in service education on role of ABUS in screening and monthly newsletters targeting referring physicians; patient density inform letters that explain breast density status and the risk that density poses).

2. Care coordination and operation efficiencies (e.g., referring physician surveys to document communication preferences and process for obtaining orders for supplemental testing; EMR expansion to document breast density status within scheduling tool; same day option for scheduling mammogram and ABUS, and insurance eligibility checks at time of scheduling to estimate patient OOP costs).
3. Payer advocacy (e.g. payer engagement to share clinical outcomes data for supplemental screening with ABUS).

During the first 30 months, addition of ABUS increased IFW's breast ultrasound revenue by 61% and totaled \$1.1M (38% from ABUS; 62% from handheld ultrasound). As a free-standing facility offering same day supplemental screening, they averaged 5 to 10 ABUS procedures per day (median 6.995). This resulted in a breakeven on equipment cost within the first 12 months.



ABUS – automated breast ultrasound;
HH U/S – handheld diagnostic breast ultrasound.

Source: Data on file. GE Healthcare. 2017.

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Imagination at work

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