Advances in Breast MRI

Breast MRI gains momentum for screening high-risk women

Making the business case for dedicated breast MRI

Breast MRI develops role as surgical planning tool

The comprehensive breast center: Greater than the sum of its parts

Getting paid for breast MRI screening — It’s a jungle out there
Advocates of breast MRI screening won a major victory in 2007, when the American Cancer Society (ACS) published new guidelines recommending that women at high risk for breast cancer augment their annual mammogram with an annual breast MRI. But breast MRI proponents shouldn’t rest on their laurels, as more work remains to ensure that breast MRI screening is available to all women who would benefit from it.

The ACS guidelines are applicable to an estimated 1.4 million to 1.6 million women in the U.S., and in general state that MRI screenings should be provided in addition to annual mammography for women with certain risk factors, such as BRCA1 or BRCA2 genetic mutations or a lifetime risk of breast cancer of 20% to 25% (see sidebar for additional criteria).

ACS based its decision on a growing body of evidence pointing to the effectiveness of breast MRI in a screening environment for high-risk women. The first data published, in 2000, about multimodality screening at the University of Bonn in Germany of women at high genetic risk, demonstrated that the sensitivity of breast MRI was more than double that of mammography and ultrasound combined. This pioneering work by Dr. Christiane Kuhl, vice chairman and professor of radiology, stimulated other researchers to conduct similar studies that validated these findings.

One of the university’s most recent prospective studies revealed that breast MRI doubled the sensitivity of diagnosing ductal carcinoma in situ (DCIS) and high-grade DCIS in particular, as compared to digital mammography. MRI was positive in 92% of cases, while mammography was positive in only 56%, according to Kuhl, who presented the study in 2007.

“Breast MRI exams, used in conjunction with mammography and ultrasound on a case-by-case basis, make screening of young high-risk women much more effective.”

— Dr. Christiane Kuhl, University of Bonn, Germany
Research has yet to prove that breast MRI screening impacts the morbidity or mortality of a patient diagnosed with breast cancer. But from the perspective of a high-risk woman, breast MRI screening that detects a cancer at an earlier stage may allow the option of a lumpectomy instead of a mastectomy, and adjuvant treatment that is less debilitating.

Some 5% to 10% of all breast cancers are attributed to mutation in a breast cancer susceptibility gene. Women with BRCA1 and BRCA2 mutation genes have an average lifetime risk of between 60% and 85% for breast cancer, and have an estimated risk for a second primary breast cancer of up to 60%. This cohort represents up to 50% of all familial cancers, the others occurring in women with a strong family history of breast cancer who are suspected as having yet-to-be identified gene mutation. By comparison, the average woman has a 10% to 12% lifetime risk of acquiring breast cancer.

Because familial and hereditary breast cancer tends to occur when women are young and tends to be aggressive, frequent screening is recommended starting at age 30, or as early as 25 if a family member had breast cancer at age 30. For these women, mammograms may not be as diagnostically accurate, and the cumulative radiation dose may be more detrimental than with the average woman.

Clinical trials conducted between 2000 and 2007 in the U.S., the U.K., and other countries in Europe demonstrated that multimodality surveillance programs for these high-risk women substantially improve the early diagnosis of breast cancer.

Women at the age of 30 will have much denser fibroglandular tissue, and high parenchymal density is linked to a higher absorption rate of x-rays compared to involuted breasts, Kuhl said. Also, the BRCA1 mutation is believed to be associated with increased radiosensitivity. Because familial breast cancer tends to exhibit aggressive biologic behavior, short screening intervals are recommended.

In addition to the difficulty of interpreting mammograms of dense breasts, BRCA1-associated breast cancers tend to have benign morphologic features and only rarely exhibit calcifications.

Breast MRI can counteract most of these issues. “Breast MRI exams, used in conjunction with mammography and ultrasound on a case-by-case basis, make screening of young high-risk women much more effective,” Kuhl said.

### Building momentum

For some breast specialists, the ACS guidelines justified the recommendations they had been making all along to their high-risk patients. At Breast Imaging of Oklahoma in Edmond, breast MRI screening had been an integral component of a pioneering high-risk program from its inception in February 2003, according to Melissa Craft, R.N., Ph.D., program director and clinical oncology nurse.

But in some cases, word has been slow to get out about the availability of breast MRI as a screening tool. Breast imaging center administrators report that many high-risk women presenting for mammograms or other procedures say that the ACS breast MRI guidelines were never discussed with them by any other medical professional prior to their arrival. The majority of referrals that originate from the medical community are originating from genetic counselors, breast surgeons, and gynecologists.

The situation is different at facilities or radiology practices with renowned experts in breast MRI. These sites are experiencing a surge of interest from patients, a trend that first became evident several months after the release of the ACS guidelines.

Dr. Steven Harms, a breast imaging specialist who started using breast MRI in the early 1990s, reports that the number of independent inquiries from both regional patients and those from out of state have increased dramatically at his facility, Breast Center of Northwest Arkansas in Fayetteville.

In addition, easy Internet access to information and increased media coverage are educating women independent of their physicians. Celebrities such as actress Christina Applegate, who publicly attributed a breast MRI exam to the early detection of familial breast cancer, are also increasing public awareness.
Radiology practices are educating referring physicians by including the ACS guidelines within their mammography reports, but are not marketing breast MRI screening directly to patients. The procedure currently is not recommended for the majority of women with an average risk of 10% to 12%, or even women with a moderate risk of up to 20%.

Even among some high-risk women, breast MRI screening sometimes can be a tough sell. As part of a substudy of the American College of Radiology Imaging Network (ACRIN) digital mammography clinical trial, participants were invited to have a breast MRI at no cost -- and 40% declined, according to Dr. Wendie Berg, Ph.D., a breast imaging specialist at American Radiology Services in Baltimore.

Berg and colleagues will present their findings in detail at the 2008 RSNA meeting in Chicago, but she noted that claustrophobia and fear of potential side effects of contrast agents were among the primary reasons ACRIN participants declined the offer.

**Ramping up**

Demand for breast MRI screening is still projected to rise, however, and breast imaging facilities are ramping up to meet it, as well as significantly increased use of breast MRI for diagnosis and staging. Breast MRI training courses proliferating throughout the country are filled to capacity.

The clinical and administrative team of Mount Carmel Imaging Center in Columbus, OH, headed by medical director Dr. Dan White, developed an online computer-based program containing teaching files, a comparison of equipment and breast MRI computer-aided detection (CAD) software, an overview of scanning and hanging file protocols for diagnostic workstations, and comprehensive information about establishing a breast MRI program.

“When we started eight years ago, there was no place to go to learn how to set up a breast MRI program,” White said. “It requires lots of hours, particularly in private practice, to keep up with the workload, both with respect to performing and interpreting the studies and managing all the documentation and paperwork required to maintain patient records and to obtain reimbursement.”

White believes it is important for private practices to offer breast MRI as a women’s imaging service, but it needs to be done correctly. He does not recommend that a center initiate a high-risk screening program at start-up; instead,
American Cancer Society March 2007 recommendations for breast MRI screening as an adjunct to mammography

Breast MRI screening is recommended for women who have the following:

- A BRCA1 or BRCA2 mutation
- A first-degree relative who has a BRCA1 or BRCA2 mutation
- A lifetime risk of 20% to 25% or greater, as defined by BRCAPRO or other models that are largely dependent on family history
- A history of chest radiation between ages 10 and 30
- Li-Fraumeni syndrome and first-degree relatives
- Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives

It takes an experienced reader an average of five to 10 minutes to read a breast MRI screening study. If cancer is suspected or diagnosed, review and interpretation, even with the assistance of breast MRI CAD, increases to 20 to 60 minutes.

Breast MRI gains momentum for screening high-risk women

it should move into screening after first getting experience in diagnostic breast MRI.

That opinion is echoed by Dr. Constance Lehman, Ph.D., vice chair of radiology and head of breast imaging at the University of Washington School of Medicine in Seattle and director of radiology of the Seattle Cancer Care Alliance. “Only sites with significant experience in diagnostic breast MRI should accept patients for screening MRI,” she said.

She and other breast imaging experts recommend that the availability of MR-guided intervention should be a mandatory prerequisite for offering breast MR imaging. In 2001, lack of access to MR-guided biopsy was identified as the single major reason for the delayed adoption of breast MRI in clinical practice.

Technology and equipment innovations of the past seven years have minimized this roadblock. If a facility is not equipped to perform an MRI-guided biopsy, it should partner with a local facility that is.

**Workflow of breast MRI screening**

Breast MRI equipment is typically scheduled at capacity, and the “tag team” approach used at Memorial Hospital West in Pembroke Pines, FL, may be typical. While one technologist is preparing one patient, another technologist is performing the scan on another.

One MRI technologist interacts with the patient to complete the patient questionnaire, asks the patient if she has questions and answers them, reviews MRI safety protocol to verify that the patient doesn’t have a pacemaker or aneurism clips, and verifies that all prior mammograms, ultrasounds, and/or breast MRI films or DICOM CDs have been received.

“We want our patients to be comfortable, and if we sense that the patient is claustrophobic, we need to address that issue, too,” explained Aymet Guerrero, chief MRI technologist. “If a patient is claustrophobic, we would prefer to determine this in advance.”

A breast MRI scan takes 30 to 60 minutes, according to Guerrero. She and her colleagues perform up to 10 scans per day, a volume they say has nearly doubled in the past 12 months.

Reading workflow is a matter of preference, according to the radiologists interviewed. Exam worklists are configured as shown below:

- All breast imaging — mammography, ultrasound, and breast MRI
- Diagnostic mammograms and all breast MRI
- Breast MRI only — both screening and diagnostic intermingled
- Breast MRI diagnostic only and breast MRI screening only, segmented by category
Reducing recalls and false positives
Conventional wisdom is that high recall rates and a high level of false positives are the Achilles’ heels of breast MRI. But the prevalence of both can be reduced when studies are read by more experienced radiologists.

In one study, led by Dr. Ellen Warner at Toronto-Sunnybrook Regional Cancer Centre in Ontario, researchers documented a decline in the breast MRI recall rate from 26% in the first year of screening to 13% in the second year, and a leveling out of 10% in the third year. A recall rate ranging from 8% to 17% was reported in the results of clinical studies between 2000 and 2007. A 10% recall rate is comparable to the recall rate of mammograms.

Harms at Breast Center of Northwest Arkansas recalls approximately one patient out of every 100 who is screened on an annual basis. Recall rates of 10% are more common, especially with patients having their first breast MRI, which often reveals potentially suspicious findings that were not visible on mammograms.

Breast MRI success stories
In one week, we had two women, both of whom were BRCA-positive. One was in her early 40s and the other in her early 50s. Both were asymptomatic. Each had a negative mammogram and a negative ultrasound. But breast MRIs revealed a 1-cm lesion that was an invasive ductal carcinoma in one patient and a 3- to 4-cm invasive lobular cancer in the other patient. Without breast MRI, both invasive cancers would have gone undetected for another 12 months.

— Dr. Daisy Frau-Reyna, Memorial Health System, Hollywood, FL

A patient with a nipple retraction was referred by a breast surgeon for breast MRI screening. The patient had had a mammogram in another facility six months previously with negative results, and at her insistence, an ultrasound was performed, also with negative results. When the retraction didn’t change, she consulted with a surgeon. If she had come to our center for her mammogram, we would have recommended a breast MRI because this was a physical change that merited investigation. The breast MRI revealed a large spiculated mass. A directed ultrasound and a biopsy were subsequently performed.

— Dr. Stephen Feig, Aurora Breast MRI of Orange County, Orange, CA

I still vividly remember the first time that I identified a 4-mm cancer that was otherwise occult. One patient, whose daughter was diagnosed with breast cancer when she was in her 30s, came to me for a consultation about the breast pain that she had and wanted to confirm that her breast tissue was dense. Ultimately, the MRI showed that her painful left breast was normal but her right breast had a 5-mm invasive ductal carcinoma. Her recent mammogram had been negative. She was able to have a lumpectomy, and there was no nodal involvement.

Another patient was referred to me whose mammogram had revealed multiple calcifications. An ultrasound was performed which was very complex with cystic nodules. An ultrasound-directed biopsy was performed, and she was advised that she had nothing to worry about. Because of discordant findings and the difficulties of her exams, she was referred to our center for a breast MRI. We saw an abnormality in this exam, and with an MRI-guided biopsy, discovered a lobular cancer. All the patient’s nodes were negative. This patient was so appreciative that after her recovery from surgery and adjuvant treatment, she drove over two hours from her home to personally thank us.

— Dr. Dan White, Mount Carmel Imaging Center, Columbus, OH
Breast MRIs should be read by experts in breast imaging. Radiologists who do not have this experience will be making their interpretations in a vacuum,” said Dr. Stephen Feig, director of breast imaging at Aurora Breast MRI of Orange County in California. “It is important to compare prior mammograms, prior breast ultrasounds, and prior breast MRI. This helps keep the callback rate lower.”

As compared to textbooks and image databases of mammograms, reference material for consultation is much more limited for breast MRI, Feig noted. “Interpreting a breast MRI, even with the use of breast MRI CAD which helps with the diagnosis, is an art as well as a science, based on clinical knowledge, practical experience, and intuition,” he said.

Mount Carmel Imaging Center maintains an average sensitivity of 95%, a specificity of 97.8%, a positive predictive value (PPV) of 89.2%, and a negative predictive value (NPV) of 99% for all the breast MRIs it performs. That compares to statistics in the literature pointing to an overall a sensitivity range of 85% to 95%, a specificity range of 88% to 98%, a PPV of 24% to 71%, and an NPV of 95% to 99%.
At Memorial Healthcare System of Hollywood, FL, all new mammographers are asked to read five to six breast MRIs a week, according to Dr. Daisy Frau-Reyna, a radiologist specializing in breast imaging. Frau-Reyna reviews their findings before reports are submitted.

“As with mammography, the volume you read increases your proficiency and efficiency,” she said. “It’s important that mammographers become experienced with this procedure. It’s becoming an intrinsic component of breast imaging.”

What about lower-risk women?
Given breast MRI’s utility in high-risk women, to what extent should it be used for women of average and moderately high risk? On this issue, opinions diverge.

“In view of the greatly superior diagnostic power of virtually all possible clinical scenarios, it is not justifiable to discourage the use of breast MR as an adjunct to mammography for individualized screening of women at average risk,” Kuhl said.

But this application is not considered feasible, for numerous reasons:

There are not enough qualified radiologists to interpret breast MRIs, nor the facilities to perform them to meet the needs of even women at high risk.

The procedure averages at least $1,000, and the cost would be borne by the patient.

Positive predictive value will be lower, with higher risk of unnecessary biopsies.

Another proponent of greater access to breast MRI screening is Dr. Ferris Hall of Beth Israel Deaconess Medical Center and Harvard Medical School, both in Boston. “I believe that mammography is going to be replaced by MRI as the standard for breast screening,” he wrote in the June 2008 issue of Radiology.

In an interview with AuntMinnie.com, he noted that the use of a 20% lifetime risk of cancer for referring women to breast MRI screening was arbitrary, and that a woman with a lifetime risk of just 12% should deserve the same treatment.

Hall predicts that new technology will make breast MRI easier to interpret and reduce the cost of the equipment. “Clinical trials may prove that screening is needed only in 24- versus 12-month intervals,” he said. “We just don’t know.”

What is known is that breast MRI screening guidelines are sound, and while new technologies may supersede this, if the U.S. is serious about early breast cancer detection for high-risk women, breast MRI is a vital tool.

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While evidence grows in support of the clinical efficacy of breast MRI, making a business case for installing a dedicated system can still be a challenge. Any facility considering the plunge must analyze various factors, from procedure volume to staffing needs to reimbursement.

Fortunately, if you’re thinking about buying a system, you can use the knowledge and experience gained from those who have gone before you. While breast MRI is a relatively new technology, many imaging facilities are finding that it can be implemented wisely, to the benefit of both patient care and a facility’s bottom line.

**Decision-making keys to success**
The decision to install a dedicated breast MR system requires careful thought and planning to develop a sustainable business model.

Facilities debating whether to add a breast MRI service should start by analyzing the number of mammograms they perform each year, according to Dr. Robin Shermis, director of breast imaging at Toledo Hospital in Ohio. He believes that any facility that provides between 15,000 and 20,000 mammograms each year should consider installing a breast MRI magnet.

“We installed a dedicated breast MR system because this equipment is specifically tailored to these studies, and therefore you get better images.”

— Dr. Robin Shermis, Toledo Hospital, Ohio

If a healthcare system doesn’t have a single center that achieves that level of procedure volume, then several facilities within the network could install one breast MRI unit to serve all the facilities. Without those numbers, the economic viability of the enterprise could be questioned.

“We installed a dedicated breast MR system because this equipment is specifically tailored to these studies, and therefore you get better images,” Shermis explained. “It has a spectacular biopsy system that is easy to use.”

Installing a breast MRI system also has competitive advantages. To be considered a complete breast imaging center, a multimodality approach to screening and diagnostic workup is required, according to Dr. Robert Lapidus, medical director of the Women’s Imaging Centre in Lafayette, LA.

At the center, breast MRI is used both for screening high-risk women and imaging women who are newly diagnosed with breast cancer to complete local staging of disease, assess for multifocal or multicentric disease, or detect contralateral lesions. The site initially projected that it would image two to three patients a day on the system, but it exceeded that expectation as it came out of the gates performing three to five breast MRI studies per day.
Women’s Imaging Centre has also received referrals from physicians and requests for exams from a category of patients outside the recently released American Cancer Society guidelines for breast screening: patients with a personal history of breast cancer, those with diagnoses of atypical ductal hyperplasia, and those diagnosed with ductal carcinoma in situ and lobular carcinoma in situ in the past, according to Lapidus.

Bay Radiology started its cost-benefit analysis of breast MRI by measuring its mammography procedure volume.

— Charles Allan, Bay Radiology Associates, Panama City, FL

Toledo Hospital looked at the number of cancer diagnoses, biopsies, ultrasound studies, and surgical interventions it was performing.

— Clark Corey, Toledo Hospital, Ohio

Cost-benefit analysis
In performing a cost-benefit analysis, Charles Allan, business manager of Bay Radiology Associates in Panama City, FL, started his assessment with the knowledge that his facility had a very high volume of mammography studies. He then recognized that there was limited breast MRI service offered locally, and general surgeons were sending their patients out of town for breast MR scans.

Taking the costs involved in acquiring and using dedicated breast MRI, Bay Radiology calculated that it would need 3.7 patients per day to break even. With an installation in March of this year, Allan reports that the center is not quite to that level, but anticipates that it will reach that number soon. The group is initiating a robust marketing campaign aimed at physicians and their clients.

Breast MRI developer Aurora Imaging Technology of Andover, MA, has created business models to assist in the decision-making process, said Clark Corey, administrative director of radiology at the Toledo Hospital in Ohio. In deciding whether to add breast MRI, the hospital looked at the number of cancer diagnoses, biopsies, ultrasound studies, and surgical interventions it was performing.

Another consideration concerning economic viability involves staff utilization. Bay Radiology’s mammography technologists have been trained by Aurora to perform breast MRI studies, so the facility did not have to provide training, according to Allan.

Toledo Hospital had a learning curve in getting the breast MRI service up and running that impacted productivity somewhat after installing the system in November 2007, Corey said. But the facility is now scanning between six and seven patients per day, with projections that it could manage up to eight patients per day.

Lapidus of Women’s Imaging Centre concurs that a center does not need a dedicated MRI technologist to perform breast MRI exams. “All of our technologists can be cross-trained to do not only mammography, but MRI as well,” he explained. This approach provides important efficiency and benefits in regard to staffing. Additionally, mammography technologists are the personnel most accustomed to dealing with breast patients and are expert at positioning and comforting anxious patients, he noted. With everything under one roof, the center is able to provide patients and their referring physicians with results in a streamlined fashion.

Considering throughput
With breast MR that is performed on a standard MRI system, using breast coils, usually images are acquired on one breast at a time. A dedicated breast MRI system offers higher throughput by performing bilateral imaging that includes axillary and chest wall regions in approximately 20 to 25 minutes, according to Allan.
Both Shermis and Lapidus recommend the use of computer-aided detection (CAD) software to analyze images. CAD is integral to the operation of the system because it provides the hanging protocols to organize image datasets to facilitate interpretation, Lapidus explained.

“The other thing that CAD does with MR is to give you the functionality to place regions of interest on different points on the images so you can gather kinetic data,” Lapidus said. “It also allows you to do color mapping in order to evaluate lesions in terms of their morphology, as well as their dynamics in contrast uptake and washout.”

Reimbursement reality
Whether a center will be reimbursed for these relatively costly procedures must be factored into making the decision about economic viability of offering this approach to breast imaging.

“We were encouraged by the fact that breast MRI was not subject to the Deficit Reduction Act cuts,” Lapidus said. “In fact, if those procedures were subject to the DRA cuts, we would have thought twice about implementing the program due to financial constraints.”

One of the challenges Allan has faced in Florida is the restrictive preauthorization guidelines imposed by the largest private insurance carrier in the area that were put into place in January 2008. Allan believes that insurance coverage will improve once the general medical community considers breast MRI to be the standard of care for specific patient groups.
The vital importance of marketing

After a cost-benefit analysis is completed and the scanner is either on the way or installed, the importance of marketing the system cannot be overlooked.

The Toledo Hospital Breast Care Center and Toledo Radiological Associates' joint venture is also allied with the ProMedica Health System, so marketing has been robust in this collaborative effort, according to Corey. They targeted a number of specialty physician groups, including ob/gyn physicians, surgeons, primary care physicians, general surgeons, and radiation oncologists, with visits to their offices, grand rounds, and brochures.

Because Toledo Hospital's scanner is located in the breast center, the patient can remain in the same area throughout all diagnostic activities, which provides a level of comfort for most women. The same is true for the Women's Imaging Centre, whose marketing strategy has followed a similar path to the Toledo Hospital, including placement of several items in the lay press.

However, Lapidus credits one of the most effective marketing strategies to be a weekly breast conference held at 6:30 a.m. on Thursdays, where positive biopsies from the trailing week are reviewed through the lens of pathology and radiology. Results are projected on a large LCD monitor for a multidisciplinary audience that includes radiologists, pathologists, breast surgeons, and radiation oncologists. While the patient's primary care physician is invited, their turnout is limited.

“The surgeons learn a lot about [breast MRI],” Lapidus explained. “At first, they were reluctant to integrate it into their practice patterns, but after they've seen the capabilities of it, they really started utilizing the modality.”

He reports that surgical interventions have changed as a result. In some cases, surgeons have steered clear of lumpectomies for patients with multifocal or multicentric disease. They also use lesion maps to perform tailored lumpectomy for patients with complex tumors.

Accreditation coming down the pike

While the American College of Radiology (ACR) does not specifically accredit breast MRI or other niche MR studies, Corey believes the society is in the early stages of exploring accreditation for this imaging technique, in order to continue its “center of excellence” goal.

In addition, the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories (ICAMRL) reports that the new Medicare Improvements for Patients and Providers Act of 2008, passed in July, requires that by 2012 providers of advanced diagnostic imaging services must obtain accreditation to receive reimbursement. Currently, the ICAMRL is the only accrediting agency that offers such certification for breast MRI.
Breast MRI develops role as surgical planning tool

By Lin Muschlitz
AuntMinnie.com contributing writer

As breast MRI solidifies its role in the screening of certain high-risk patients, increasing numbers of breast surgeons and radiologists are examining its use as a surgical planning tool as well. They’re finding that using breast MRI prior to surgery catches areas of occult disease, enables the development of better surgical plans, and decreases resection rates for breast cancer patients.

The use of breast MRI prior to surgery is still relatively novel, with clinical guidelines yet to be established and research studies still under way to validate its clinical efficacy. But as sites develop their own approaches to patient selection and usage, anecdotal evidence indicates that breast MRI is making a difference.

The University of Florida in Gainesville began using breast MRI three years ago to plan breast surgery, coinciding with the capability to do MRI biopsies at the medical center. MRI has value in better estimating tumor size, according to a study published in the Journal of the American College of Surgeons in May 2008 by a research team including Dr. Stephen Grobmyer, a surgeon in the division of oncology and endocrine surgery at the university.

“It helps us find spots of multicentric disease and ... to identify a small subset of patients in whom there is occult cancer in their contralateral side,” Grobmyer said. “That combination of findings ... alters our treatment plan about one in five times. We think it’s helpful in making decisions.”

Grobmyer emphasizes that research is still ongoing, and there are no firm national recommendations for using breast MRI in a surgical planning role, but an evolution is under way. He sees MRI reducing the rate of margin-positive excision because it allows surgeons to plan operations better. It also allows specialists to better select patients for breast conservation and those patients who should receive preoperative chemotherapy for larger lesions to get tumor shrinkage and allow clear resection. “We are strong advocates for having the ability to do MR-directed biopsies if you’re going to have a program in MR,” Grobmyer said. “With ... the ability to do breast MR-guided biopsies, you can work up a lot of these lesions that you don’t know about.”

One case at the center involved a woman in her 40s who presented with a lesion in the right breast. The patient had stereotactic biopsy that showed invasive lobular cancer. She was contemplating breast conservation, so a breast MRI was performed on her bilateral breast. The MRI study showed the index lesion on the right side and also a previously undetected 1-cm invasive ductal cancer on the left side. Breast conservation was achieved in that case.

“There’s just case after case of this,” Grobmyer said. “It’s not every case; it’s only one in five that we find it, but we think that the patients we find it in are most appreciative of that early detection.”
Patient presented with palpable left breast lump. Mammogram showed area of clustered microcalcifications at 6 o’clock in left breast. Left breast biopsy confirmed primary ductal carcinoma in situ (DCIS). Breast MRI was recommended to evaluate extent of disease prior to treatment. Breast MRI findings were consistent with DCIS and measured to a larger extent at 54 x 10 x 12 mm.
If a woman is going to choose mastectomy for a localized, small lesion, Grobmyer said the benefit of MRI is reduced, although there is a 3% to 4% chance of finding a contralateral occult lesion. In a younger person who is considering breast conservation, an MRI is more likely ordered because the information acquired by MRI produces more value in this population. Generally, for older patients with small, well-differentiated breast cancers, the prognosis is excellent so there is less rationale for ordering the study.

“The younger patients with more time at risk and more time to live are more likely to develop recurrence of problems, so they might receive most benefit from this procedure,” Grobmyer said.

But Grobmyer noted that there are still no national guidelines regarding using breast MRI as a preoperative surgical tool.

“The use of breast MRI as a broad recommendation in the preoperative setting is not well-established by any professional group on any side that I am aware of,” he said. “If it is going to be used, it needs to be done in the proper setting.”

**Mastectomy versus breast conservation**

Although a Mayo Clinic study published in May 2008 of 5,464 women with early-stage breast cancer between 1997 and 2006 found that women who get MRI studies are more likely to choose mastectomies, Mercy Women’s Center in Oklahoma City is seeing the opposite occur.

Breast MRI studies at Mercy are resulting in decisions to choose breast conservation as well, resulting in a net gain in lumpectomy patients. Mercy’s overall conservation rate is higher now than before it started the MRI program. Their research findings have been accepted by the *American Journal of Surgery* and will be appearing soon.

“We are converting some to mastectomy, but it’s an appropriate conversion,” said Dr. Alan Hollingsworth, medical director at Mercy. “When there’s tumor beyond the ability of neoadjuvant chemotherapy, sometimes mastectomy is more appropriate. We think we have more people who were contemplating mastectomy, that, once they see they have just a solitary focus, they’re going with breast conservation.”

Mercy Women’s Center also has a breast radiation program that requires preoperative breast MRI. Patients who have the assurance of no other area of cancer in the same breast are candidates for the partial-breast radiation program.

Using a blanket approach for breast MRI, the center found opposite cancers in 3.7% of patients — disease that was missed by mammography. Of 597 patients in which MRI alone found 22 additional patients with cancer, 15 were invasive, significant cancer and seven were in situ. That equates to large numbers of patients who would go untreated without breast MRI.

MRI studies are most useful in younger patients with dense breast tissue and those with invasive lobular cancer, which tends to permeate breast tissue and not form a well-defined mass. However, other findings showed older patients with low-density mammograms who had abnormal areas on their MRI study.
Of the patients who had preoperative MRI and were initially thought to be good lumpectomy candidates, Hollingsworth said almost 8% had more tumor than was anticipated — so much more it looked as though mastectomy might be necessary. Half of those were completely separate tumors than the primary.

Breast MRI showed more tumor at the site of the index lesion than was sometimes realized with mammography or ultrasound. The larger extent of disease at the tumor site allows the surgeon to plan a wider excision.

“One of the ways we quantified it was how often people had to go back to the operating room for an unsuccessful lumpectomy,” Hollingsworth said. “Our reincision rate was 8.8%. This [was] out of [approximately] 600 patients. People are surprised to know that the average reincision rate is about 25%.”

By creating a road map for preoperative staging and doing a better job up front, MRI creates a cost savings.

A comprehensive approach

In performing oncoplastic surgery, Dr. Gail Lebovic of the Cooper Clinic in McKinney, TX, uses breast MRI on all newly diagnosed patients and for annual follow-up of cancer patients. Lebovic attempts to preserve as much of the breast tissue or skin as possible, and breast MRI helps evaluate fully the woman’s clinical situation.

“Had we not had the MRI, [the patient] would have had the biopsy in the right breast, then a year later [she] would have gone for her mammogram, and the left side might have had invasive [cancer] at that time,” Lebovic said. “But we caught it before she had any invasion.”

By creating a road map for preoperative staging and doing a better job up front, MRI creates a cost savings.

In one case, a 64-year-old woman was referred to the clinic for a wire-localized biopsy following an abnormal mammogram in the right breast and a stereotactic biopsy that was nondiagnostic but showed atypical cells.

Many surgeons might have prepared the patient for surgery, performed the wire-localized biopsy, found a small area of ductal carcinoma in situ (DCIS), and would have been done. Instead, Lebovic and her colleagues viewed all the woman’s films and were concerned about her left breast calcifications. With breast MRI, they were able to see DCIS throughout her entire left breast.

“Had we not had the MRI, she would have had the biopsy in the right breast, then a year later [she] would have gone for her mammogram, and the left side might have had invasive [cancer] at that time,” Lebovic said. “But we caught it before she had any invasion.”

Looking at the breast in three dimensions with MRI helps surgeons evaluate patients in the same 3D environment they work in. As a result, planning is much more thorough and the surgery more complete. The ability to rotate images helps surgeons get a feel for tumors and surrounding tissue.

Breast MRI is also used for women who are found to have a positive lymph node without any indication by mammogram or ultrasound. In addition to locating a lesion, if a tumor is invading the chest wall or skin, MRI can help provide a more thorough evaluation of the tumor before surgery goes into the chest wall, which helps avoid additional surgeries for positive margins.

By incorporating preoperative breast MRI into the surgical plan, treatment options become complete, which is better for patients.
Moving forward

Breast MRI adds value not only in ensuring the best surgical procedure the first time, but also in postoperative follow-up.

“As time goes on, if a woman has partial mastectomy and radiation, if there are questions over areas of thickening or some concern over scar tissue, and it becomes evident that an MRI might be helpful in working that up, an MRI is done,” said Dr. Margaret Lawler, a breast surgeon at the Faulkner Breast Centre in Boston.

And as the technology improves, it will be more broadly used.

“It would be terrific if we could use MRI to assess margins and to accurately assess extensive disease,” Lawler said. “I think that broader indication will come if technology improves so that we can more accurately, more specifically diagnose cancers with MRI.”

Despite resistance by some experts to use breast MRI as a standard test prior to surgery, the technology’s growth is evident.

“Medical literature studies have shown that [breast MRI] can change the surgical technique in ways that one would feel, at least intuitively, may be beneficial,” Lawler said.

Top 10 indications for breast MRI

1. All newly diagnosed breast cancer patients; to define the extent of disease multifocality and/or presence of contralateral abnormalities, and to assist with planning or surgical treatment

2. Adjunct to mammography and ultrasound in women with clinically difficult exam and dense breasts on these examinations (women younger than 40)

3. Preoperative assessment in patients with mammographic abnormalities or dense breast tissue (i.e., preop breast reduction or revision reconstruction)

4. Yearly follow-up for breast cancer patients

5. Screening patients at high risk for breast cancer, especially those with suspected or proven mutations of BRCA1 and BRCA2

6. Further evaluation of suspicious clinical findings or imaging results that remain indeterminate after mammographic and ultrasound evaluation

7. Evaluation of silicone gel implant integrity (supported by recent U.S. Food and Drug Administration recommendations)

8. Breast cancer screening in women with breast implants as adjunct to mammography

9. Monitor response to neoadjuvant hormonal therapy and/or chemotherapy

10. To determine primary site in patients with axillary nodal disease and unknown primary disease

— Dr. Margaret Lawler, Faulkner Breast Centre, Boston

“I think that broader indication will come if technology improves so that we can more accurately, more specifically diagnose cancers with MRI.”

— Dr. Gail Lebovic, Cooper Clinic, McKinney, TX
As the concept of comprehensive breast centers reaches from well-funded academic institutions to the private center and community hospital setting, the one-stop-shop approach is not only increasing the quality of life for women with breast cancer, it is saving lives. The multidisciplinary approach creates coordinated care that benefits patients on multiple levels.

By eliminating a segmented approach to diagnosis, treatment, and follow-up, patients receive comprehensive care that removes the anxiety of protracted test results, the uncertainty of who is in charge of their care, and the need to travel to multiple sites. In addition to state-of-the-art imaging services, including mammography, ultrasound, and breast MRI, some centers offer patients psychological services and diet and fitness programs as part of a total wellness approach.

Whether the comprehensive breast center is housed within the same walls or not, certain pivotal aspects are present, according to Barbara Rabinowitz, Ph.D., founder and trustee emeritus of the National Consortium of Breast Centers.

“They provide prospective consensus, treatment, planning [and] meetings,” Rabinowitz said. “There's this whole interdisciplinary group of professionals who come together to discuss circumstance[s] ... along the trajectory when the woman's breast is believed to have cancer all the way through her treatments and adjuvant therapies.”

Regular conferences with breast radiologists, breast surgeons, medical oncologists, and pathologists map out a patient's total treatment plan as part of the multidisciplinary approach.
In addition, a “breast navigator,” a professional who could be a nurse, clinical social worker, or someone else, ensures patients move through the process in efficient fashion, in a way that makes them feel emotionally supported and with the education needed to make necessary decisions about their course of action.

“There’s this whole interdisciplinary group of professionals who come together [at comprehensive breast centers].”
— Barbara Rabinowitz, Ph.D., founder, National Consortium of Breast Centers

In 1979, arguably the first comprehensive breast facility was the Breast Center, started in Van Nuys, CA, by Dr. Melvin Silverstein.

“It was a freestanding site,” Rabinowitz said. “It ran on an interdisciplinary format, and so we always think of that center as the first identifiable, recognizable comprehensive breast center.”

From those humble beginnings, the growth of comprehensive breast centers expands, with imaging playing a major role as healthcare becomes more disease-focused and specialists stress the need for coordinated care.

The evolution of treatment
M. D. Anderson Cancer Center in Houston has the advantage of possessing the resources needed to have state-of-the-art equipment in multiple modalities with respect to breast imaging, including peripheral support of a nuclear medicine center with a PET/CT scanner for women with metastatic disease.

M. D. Anderson’s comprehensive breast center is housed on the fifth floor. The facility includes medical oncology clinics, breast surgical oncology clinics, breast radiation therapy clinics, a plastic surgery area, and a cancer prevention area. The center tries to complete a woman’s imaging in the morning, followed immediately by a doctor visit, often with biopsy results available.

Breast MRI is housed one story down and is part of the entire MR imaging group. The breast center has dedicated slots for performing breast MRI. Because of housing issues and the equipment’s specific needs, the breast MRI scanner is currently directly next door to the clinics.

The breast center also has onsite breast cytologists, allowing for immediate readings of biopsied cells. Within 10 minutes, the patient gets a preliminary result of positive or negative cells, which she hand-carries to her doctor. The outline for the treatment plan begins and is followed by the final report after 48 hours.

“That’s the meaning of a comprehensive breast care center, where we’re trying to do this very smooth transition from imaging, diagnosis, and a firm preliminary report that allows the patient to discuss possibilities with the clinician in one day,” said Dr. Wei Tse Yang, chief of breast imaging.

Having an onsite cytologist is a rare and expensive luxury for the facility. Usually in a general practice, even if it’s a comprehensive breast center, the cytologist would have to service multiple different organ sites to be cost-effective.
Quality of life
For any woman, a breast cancer diagnosis is life-altering. From the time of diagnosis, comprehensive breast centers work to coordinate care for every patient through information and support. Same-day results and in-person time impact the patient’s quality of life. In addition, having one facility in charge from start to finish minimizes the chance of losing information in a shuffle.

Dr. Jennifer Engels, a diagnostic radiologist and breast specialist at Cooper Clinic in McKinney, TX, gives results of all screening mammograms in person the same day. The center also does extra views at the same time if they’re needed. A written report follows in the mail, but each patient has the benefit of a discussion of the results prior to leaving the office.

“I think when people are worried about breast cancer, any day that they have to wait is very significant in the quality of life,” Engels said.

A second radiologist does second reads on all mammograms. If the second radiologist is not in agreement or sees something additional, the two radiologists review the findings together and decide whether additional tests are needed. If the woman is still available, the center performs more tests immediately.

In addition to the second reads, radiologists at Cooper Clinic also use computer-aided detection (CAD) on their digitally acquired mammograms. With CAD, some imaging centers drop the second reads, but the center plans to maintain its approach as volume grows, Engels said. The center’s practice is building and has between 50 and 60 patients per month.

For biopsies, the local pathology lab provides results within 24 hours. Following the report, Engels and the oncoplastic surgeon work closely and discuss the kind of surgery needed. The approach speeds up the entire process, allowing women to know what is happening sooner.

Cooper Clinic’s breast MRI scanner came on board in August, and the system has a built-in MRI biopsy component. So if a lesion can be detected by ultrasound and a biopsy is needed, an ultrasound biopsy would be used. If the area can’t be detected on ultrasound but is suspicious due to its appearance on MRI, the surgeon will do an MRI-guided biopsy.

Changing patient care
Unfortunately, timely diagnosis often escapes some imaging sites. In one case, a woman had a mammogram with abnormal findings. Another imaging center told her she would have to wait three weeks for a follow-up appointment, but she was leaving for vacation, and her anxiety over the mammogram’s results was building.

In the long run, it’s better to be as thorough as possible up-front, even though it can take a couple of extra days,” Engels said. “If you can save that patient one more surgery, that is huge.”

The Cooper Clinic breast center was able to see her the same day she called. Engels took new views and was able to assure the woman that there was no evidence of cancer. An immediate answer eliminated three weeks of unnecessary anxiety.

“She literally broke down in tears and was the most thankful person you’d ever seen ... I was able to resolve this problem before she went on vacation,” Engels said. “That’s just one example of how it can really make a difference in someone’s quality of life if we can take care of it right then and answer the question.”

The amount of healthcare savings from comprehensive breast care centers, and the
difference they make in a patient’s recovery time and mental and physical states, can’t be calculated. But the growth of such centers is testament to their effectiveness.

“The [number] of comprehensive breast centers has been progressively increasing during the last 10 years in recognition that it’s a good model for women to have coordinated care between all the physicians ... on a single site,” said Dr. Kamilia Kozlowski, clinical director and CEO of Knoxville Comprehensive Breast Center in Tennessee.

“Otherwise, with separate appointments between physicians’ offices with specialists in different locations, it’s so easy for information to fall between the cracks and not be conveyed from one physician to the other.”

Absence of the comprehensive approach also makes patients wonder who is in charge of their care. But patients should be careful of what’s in a name. Not all facilities that call themselves comprehensive breast centers actually are. Coordinated care is key to the concept.

“It’s not coordinated care [if] the diagnostic imaging is done separately,” Kozlowski said. “Any questions, then the patient goes to a surgeon’s office, which may be in a different location, and not all cases are discussed pre- and postsurgery.”

Variation exists among comprehensive breast centers. The common characteristic among them all should be the ability to diagnose, treat, and follow patients. Multidisciplinary conferences also are a major component in this approach, discussing in detail what specialists find, ensuring that nothing is missed on pathology. Everything is covered regarding treatment, including neoadjuvant chemotherapy and radiation therapy if needed.

Knoxville Comprehensive Breast Center began operations 10 years ago. Its coordinated care approach includes multidisciplinary conferences that are attended by 100% of the specialists. As treatment of breast cancer has evolved over the years, the multidisciplinary approach has taken on new importance in covering various treatment options.

“With the recognition of the different tumor types, there are all kinds of different regimens,” Kozlowski said. “All aspects of their treatment are covered by the specialists, and we’re all communicating with each other. There’s a consensus of opinion as far as each individual woman’s treatment because it is so varied from one woman to the next.”

One specialist that Kozlowski sees as absolutely necessary in a comprehensive breast center is a dedicated breast radiologist. And a necessary part of diagnosis is breast MRI in conjunction with mammography and ultrasound.

“The real foundation of a comprehensive breast care center is the diagnostics,” Kozlowski said. “You really can’t practice complete diagnostic breast care unless you have an MRI.”
**Personal experience**

As a breast cancer survivor, Dr. Lillian Chou, a radiation oncologist at Radiation Oncology of the South Plains in Lubbock, TX, has a personal passion and commitment to offering the best comprehensive services to fight breast cancer. She is the first radiation oncologist to purchase a dedicated breast MRI scanner, and she has found that its contrast and resolution are superior to whole-body machines used for breast imaging.

Chou’s center does 150 to 180 mammograms per month, and offers walk-in mammograms. And with low volume, it can also perform breast MRI with a patient’s appropriate diagnosis and insurance agreement.

In addition to digital mammography, ultrasound, breast biopsy, and breast MRI, the center has PET and CT scans for patients with invasive cancer. Chou’s center is a private practice and uses community physicians.

“We participate in conferences at the hospital, so if there was any question about management, we can take our cases there to the conference, and there we have community doctors and the academic doctors,” Chou said. “You can do consensus on difficult cases.”

Chou started her breast center seven years ago with the idea of combining the comprehensive breast center with the cancer center and including other imaging like PET/CT.

“I think ... this model that I have with the community cancer center, the community breast center, and community imaging all in one is the future,” Chou said. “It’s just a matter of a mindset of getting the financial resources and the human resources to team up together, and it can be done in a community setting.”

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Breast MRI screening is a relatively painless exam for patients in clinically indicated populations. But getting paid for breast MRI screening can be a headache for providers, especially those who aren’t familiar with negotiating a jungle of rules and requirements.

Breast MRI has become an accepted screening tool for high-risk women, especially since the American Cancer Society (ACS) gave the technology a vote of confidence in 2007 by adding it to its breast cancer screening guidelines. But many payors appear to be dragging their feet when it comes to paying for breast MRI exams.

Reimbursement for breast MRI screening varies by insurance provider, individual insurance policy, geographic location, and not infrequently, the lack of understanding of the diagnostic value of the procedure by an employee of a third-party radiology benefits management company.

“Medicare reimburses very favorably for breast MRI procedures. However, only about 9% to 10% of the revenue for all women’s imaging-related procedures is received from Medicare and Medicaid,” according to Barbara Ossias, a reimbursement consultant and principal of Reimbursement Revenue Solutions of Middletown, MD. For breast MRI screening, government revenue is estimated at less than 1%.

For this reason, it’s anyone’s guess as to the number of breast MRI screenings performed in the U.S. Private insurance companies do not disclose their statistics, either for the procedures they approve or the ones they deny. This makes reporting of reimbursement for breast MRI screenings anecdotal at best.

“Based on my own analysis, reimbursement for a breast MRI screening of an asymptomatic but high-risk patient has improved markedly in the past several years,” Ossias said. “The American Cancer Society’s guidelines have had a very positive impact with an increasing number of national and regional health insurance companies.”

In March 2007, the ACS issued new guidelines recommending that women with more than a 20% lifetime risk of breast cancer have an annual breast MRI as well as an annual mammogram. In the U.S., an estimated 1.4 million to 1.6 million women meet the criteria. Because no statistics are published, neither the ACS nor any other professional or government organization that tracks diagnostic imaging utilization knows how many of these women request the exams, and from these, how many requests are accepted or denied.
The first hurdle: Negotiating payment
How much do private payors pay for breast MRI screening exams? Ossias said that the range she has heard for reimbursement from her company’s clients ranges from $600 to $1,600.

Ossias recommends that when negotiating with a private payor, a healthcare center should determine in advance what its total costs are for both the technical and professional components. The technical fee should include all the costs related to performing the exam, including contrast and administrative expenses.

To calculate the professional fee, a center must estimate the percentage of breast MRI procedures that it expects to perform that are for screening, compared to those that are diagnostic. Radiologists experienced in reading breast MRIs say that they can review a screening exam in five to 10 minutes, whereas a diagnostic exam will require 20 to 60 minutes. Since interpreting a breast MRI exam can have only a single fee associated with it, it is important that the fee proposed accurately represent this mix.

Reimbursement Revenue Solutions provides detailed information about payment rates and variables to providers in their geographic region. Providers also are informed of the specific policies and reimbursement procedures of private payors.

Health insurance companies and managed care providers start negotiations low, according to Ossias, and providers should not automatically accept the first reimbursement offer they receive. Private payors will start negotiations at or below the usual and customary charge (UCC) fee schedule published by Practice Management Information, a Los Angeles-based publisher that compiles payment data.

“UCC payments are the rate a provider will receive if the procedure billed is not covered under a contract between the facility and the payor. Contrast agents are usually reimbursed at cost,” Ossias explained.

“If a center enters negotiations with an insurance company or managed care company knowing the costs that it will incur, it may be in a stronger position,” she said.

While most centers interviewed by AuntMinnie.com stated that the payment they receive is fair or profitable, insurance companies that dominate the private health insurance market in some areas may strike a very hard bargain. Several centers said that they weren’t able to meet demand for breast MRI screening that they know exists in their communities due to reimbursement issues.

Documentation is key
If a woman meets the ACS guidelines for being classified as a high-risk patient, her insurance policy must then be reviewed to determine if the published policy covers her situation. In addition to the published policy of an insurance company, such as Aetna, Cigna, or UnitedHealthcare, it is imperative to check the specific policy issued by the insurance company, as coverage may differ.

The next step is to obtain precertification, even if it is not specified as a requirement for reimbursement, Ossias recommends. “Don’t assume anything, and do document everything,” she said.

She recommends that providers communicating with insurance companies and radiology benefits management companies document the telephone number they called, the date and time of the call, and the people they talked with and their title, and keep notes of the conversation. Providers should request that a copy of the precertification approval be sent by fax or e-mail. They also should verify at the time of precertification exactly what documents or information about the patient they will need to submit.

When talking with an insurance company, providers also need to ask if “gatekeeper” approval is also needed, and if so, document the call and request a copy of that precertification. “An insurance company representative may not advise that their gatekeeper approval is also needed, and claims are denied for this reason,” Ossias said.
Even if precertification is received, the process is comprehensively documented, and all necessary information is submitted, it doesn’t mean that payment will be made in a timely manner, or even at all. The insurance program of one large retail chain automatically sends all breast MRI screening claims it has precertified for additional medical review. Payments average at least six months from the submission date of the claim, according to one center claims manager, who noted that there is no logical reason for 100% of preapproved breast MRI screenings to require clinical review.

Some center operators stated that as long as they adhered to health insurance companies’ criteria, they were paid without hassle. Others reported the need to spend many hours on the phone and provide additional documentation that had not originally been requested to obtain reimbursement.

A number of insurance companies do not pay for a breast MRI screening procedure that has been precertified if a cancer is not found. One radiologist commented with frustration that “you can’t bill the patient because you have told them that their insurance company has approved the exam. So you absorb the cost, and then try to determine if the next patient with the same insurance policy should be told that they are ultimately responsible for paying, or if you take another chance.”

A particularly frustrating point is that sometimes payment is not made for one patient but is for another in which the policy, the patient’s risk level, and the process of precertification and documentation are identical, the radiologist said.

At this point, reimbursement administrators say, it is time to get on the phone and start calling. This can represent an escalating administrative expense that is not factored into the negotiated fee. With enough persistence and documentation, the provider gets paid.

The positive news is that with many insurance companies, once a medical director gets to know that a particular provider will screen only high-risk women, the hurdles may be eliminated.

Why the hassle? Reimbursement managers state that some insurance companies haven’t adequately trained their staff. But denial after approval is regularly occurring with specific insurance companies representing specific regions of the U.S., although no one knows the true magnitude of the problem.

The role of BRCA1 and BRCA2 testing
There is one exception to the uncertainty of reimbursement for breast MRI screening. Exams for patients who have tested positive for the BRCA1 and BRCA2 gene mutations — who have a 60% to 80% risk of developing breast cancer in their lifetime — receive unquestioned and generally hassle-free reimbursement.

The catch for the patient is whether that individual is willing to pay the approximately $2,800 cost for the genetic testing if it’s not covered by their current health insurance provider, and whether they want to publicly reveal this fact if they do test positive for fear of future health insurance company policy exclusions.

The good news about the DRA
The Deficit Reduction Act (DRA) of 2005 has devastated large segments of the outpatient imaging market, with its drastic reimbursement cuts. Miraculously, however, the DRA has largely left unscathed reimbursement for current procedural terminology (CPT) codes for unilateral (CPT 77058) and bilateral (CPT 77059) breast MRI exams. Mammograms are also similarly exempt. The contrast agents used in breast MRI exams (HCPCS A9579) tend to be paid at actual cost.
The bad news about breast MRI CAD
For many radiologists, breast MRI computer-aided detection (CAD) is an essential component used to review and accurately make diagnoses of breast MRI procedures. Until June 30, 2006, reimbursement could be claimed using category I CPT codes 76377 (3D reconstruction) and 76350 (image subtraction).

These have been replaced by CPT code 0159T, described as computer-aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation breast MRI.

Few health insurance companies are believed to reimburse for this code, citing it as experimental, according to Dr. Bruce Porter, medical director of First Hill Diagnostic Imaging in Seattle. The American College of Radiology (ACR) strongly recommends that providers claim the code with every payment submission when it is utilized, as this now is the only method of documenting the use of breast MRI CAD.

Accreditation requirements
Meanwhile, accreditation of dedicated breast MRI centers and/or women’s imaging centers is rapidly becoming a requirement for reimbursement. Hospitals and imaging centers with MRI equipment that is used for many different procedures, including MRI, are typically accredited by either the ACR or the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories (ICAMRL), a division of the Intersocietal Accreditation Commission (IAC) in Columbia, MD.

The commission is the only national organization that offers accreditation for breast MRI, and the cost for three-year accreditation is $2,700. In August 2008, Breast MRI of Oklahoma in Oklahoma City became the first dedicated breast MRI imaging center to receive ICAMRL accreditation.

Private payors who require accreditation include Highmark Blue Cross Blue Shield of Pennsylvania, and UnitedHealthcare will require accreditation of freestanding imaging centers and/or provider clinics in its network beginning in the fourth quarter of 2009. The concept of MRI accreditation got a further boost from the Medicare Improvements for Patients and Providers Act of 2008, which requires that providers of advanced diagnostic imaging services be accredited by 2012 as a condition to receive Medicare and Medicaid reimbursement.

Fortunately, accreditation is a straightforward process. If a healthcare facility is already accredited for MRI, it is unnecessary to apply for breast MRI. Women’s health clinics that only perform breast MRI procedures will be accredited only for breast MRI. They do not need to become accredited for other types of MRI procedures they do not perform.

Components for accreditation include medical and technical staff requirements, physical facility requirements focusing on safety and privacy, exam interpretation, reports and recordkeeping requirements, and quality assurance and preventive maintenance requirements. The ICAMRL’s accreditation protocol is to ensure that freestanding outpatient facilities meet nationally recognized quality and safety standards for performing breast MRI examinations.

“The IAC recognizes that medical staff acquire their expertise by more than one means, and our requirements offer several pathways to meet the requirements."

— Sandy Katanick,
Intersocietal Accreditation Commission, Columbia, MD
“The IAC recognizes that medical staff acquire their expertise by more than one means, and our requirements offer several pathways to meet the requirements,” explained Sandy Katanick, IAC’s chief executive officer.

A medical director is required to have interpreted a minimum of 1,000 breast MRIs, working in this specialty for a minimum of five years and completing 150 hours of category 1 CME relevant to breast MRI over the course of a career. Or, the physician must complete a residency or fellowship with MRI experience as an integral component, and have interpreted a minimum of 150 cases specific to breast MRI.

Medical staff must have interpreted a minimum of 500 exams, worked in the specialty for a minimum of three years, and completed the same CME requirements. The interpretation capabilities of each radiologist are evaluated based on the accuracy, clarity, comprehensiveness, and content elements required by the ICAMRL in reports. Three exams must be submitted on a CD with a DICOM viewer, and include all the acquired images in the exam, plus any 3D or subtractions used. One exam must have normal findings; the others need to demonstrate two different pathologies.

Technical staff also are offered a selection of criteria, including being credentialed in MRI, having one year of full-time MRI experience, or having an imaging credential in another specialty with one year of full-time MRI experience.

Applications are reviewed independently by two breast MRI specialists. Applicants are advised of any deficiencies and how to correct them, according to Mary Lally, ICAMRL’s technical manager who oversees breast MRI applications. “Approximately 35% to 55% are delayed on the first review, but for the vast majority, the requirements that still need to be met are minimal,” she said.

Breast MRI centers can speed up the accreditation process by detailing their written policies and procedures, especially those pertaining to safety, quality control, and routine maintenance. They should also include written protocols, including scanner settings and parameters.

“If facilities do not have written standards, it may take them time and staff resources to prepare them, and what is initially submitted may need modification or additional information,” Lally said.