Utilization Management of Cardiovascular Imaging: Pre-Certification and Appropriateness
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Utilization Management of Cardiovascular Imaging

Pre-Certification and Appropriateness

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Rapid technological advances with enhanced clinical application have promoted the utility as well the growth of cardiac imaging. However, this has also raised concerns about over-utilization and inappropriate use in imaging. The imaging community, which initially took pride in increasing imaging volume, now fears limited access and reduced reimbursement. Nonclinicians, i.e., payers, have become gatekeepers to cardiac imaging, with decisions often lacking firm foundation within medical literature. The near-ubiquitous presence of radiology benefits managers is clearly impacting on the use of cardiac imaging, often through an indiscriminant reduction in imaging volume. Medical societies and clinicians were slow to respond to spiraling costs of cardiac imaging, but now recognize the need to promote appropriate and cost-conscious use of imaging. Through the development of guidelines and appropriateness criteria, physician-directed efforts are focused on eliminating unnecessary testing and promoting increased awareness of health care costs. This paper attempts to review some of the current issues concerning the responsible use of cardiovascular imaging.

Cardiovascular imaging comprises echocardiography, nuclear cardiology (single-photon emission computed tomography [SPECT] and positron emission tomography), cardiac computed tomography (CCT), and cardiac magnetic resonance (CMR), and has experienced widespread popularity and growth. Cardiovascular imaging when integrated into clinical practice promotes prompt, efficient, and cost-effective patient care. The appropriate use of these methods often permits selective use of more expensive and hazardous procedures, such as angiography.

However, the benefits of cardiovascular imaging may be offset by either low quality or inappropriate testing. The reasons for poor test performance are often inexcusable but result from a lack of detailed knowledge regarding best-practice standards for image acquisition or the inaccurate or unclear interpretation of the images. These quality issues indicate a need for mandatory laboratory accreditation and physician certification. Inappropriate testing may be the result of many factors, including established practice habits, personal opinion, and self-referral, which may contribute to perceptions of inappropriately increased imaging volume. As cardiovascular specialists, we must be "good stewards of the gifts—and responsibilities—that have been entrusted to us" (1). Both low-quality testing and inappropriate testing can and should be easily rectified, and indeed, there are ongoing efforts within the cardiovascular community to address these issues at multiple levels. Much of this effort, however, is
being overshadowed by a debate aimed at primarily limiting the growth of cardiovascular imaging.

**Growth of Cardiovascular Imaging**

Medical imaging procedures are performed at an increasing rate, with double-digit growth for most modalities in each year throughout the past decade. Technologic advances in imaging, financial incentives to the imager, the practice of defensive medicine, and empowered patients requesting procedures have all contributed to increased imaging procedure volume and expenditures. Imaging services exceed $350 for every individual within the U.S., totaling more than $100 billion annually (2). Growth of cardiovascular imaging is a reality; however, it is viewed differently by frontline providers (who mostly see imaging as contributing to good decision making and better patient care) and third-party payers (who primarily feel concerned about its economic impact). This opinion piece will briefly look at some aspects of this debate, including the problems with current strategies by third-party payers, the need for additional research, and the increase in utilization of cardiovascular imaging services.

Procedural volume is a complex measurement. In its often quoted report (3) to Congress in 2005, which served as the catapult for the discussion of medical imaging overuse, Medicare Payment Advisory Commission (MedPAC) stated that the growth rate in imaging far exceeded that of other services, increasing annually by 10.1% between 1999 and 2002 (Fig. 1). However, these data do not account for the shift in location of imaging procedures, from hospitals (Part A Medicare) to physician offices (Part B Medicare). This alone accounts for up to 25% of the increases previously noted. The concern of uncontrolled growth based on financial incentives was not substantiated, and MedPAC concluded that no determination of inappropriateness was possible due to the lack of credible data. Thus, the true nature of test use remains uncertain, further mandating the need for additional research.

The MedPAC 2007 report (4) reveals that the growth rate for some medical imaging has leveled off and is now keeping pace with that seen with all Medicare services. In 2005, imaging procedures increased at a rate of 6.5%, compared with 5.7% noted for all services (Fig. 2). The highest growth rates for cardiovascular imaging are in CT and MR, which are predominantly performed by radiologists. Growth in nuclear medicine studies, of which myocardial perfusion imaging (MPI) represents over one-half of all examinations, substantively fell during this period (11.3% to 5.4% annual growth).

Much of the health policy rhetoric regarding cardiac imaging has been focused within the office-based practice, as the majority of the imaging growth has been noted in this environment. The increase is presented in the context of self-referral and that a cardiologist has strong financial incentives to increase the volume of cardiac imaging procedures performed in his/her office. Preliminary data suggest the converse to be true, as appropriate use of imaging procedures, such as SPECT, is actually higher among cardiologists (5), suggesting that cardiologists have begun to use guidelines and appropriateness criteria in their practices. Advantages of office-based cardiovascular imaging include performing the right test at the right time by a physician skilled in cardiovascular physiology and anatomy who is usually knowledgeable about the patient’s history and thus can integrate the clinical and imaging data, as well as increased patient comfort, convenience, and choice.

To further add to the complexity of understanding imaging procedure

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**Figure 1. MedPAC Evaluation of Growth in Physician Services From 1999 to 2000**

The average growth of physician services during this period was 22%. Adapted from MedPAC Analysis of Medicare Claims Data, March 17, 2005, Executive Director, Medicare Payment Advisory Commission, Mark Miller.

**Figure 2. MedPAC Data for Annual Growth From 2000 to 2004 and from 2004 to 2005**

The rate of growth for imaging appears to be leveling off compared with all physician services. A prominent decline in growth of nuclear medicine procedures is noted. Adapted from reference 4. CT = computed tomography; E & M = evaluation and management.
growth is the documented regional variation in use of individual tests (3,6). The Dartmouth Atlas has demonstrated marked volume differences (Fig. 3) unlikely accounted for solely by demographics or comorbidities, thereby suggesting alternative reasons such as reimbursement/financial gain and/or density of catheterization laboratories and subspecialized cardiac imagers. Whether there is under- or overuse of selected tests within a region is not known.

Cardiovascular specialists must now accept responsibility for the appropriate and cost-efficient use of the cardiac imaging procedures they order. This requires a substantial investment of time and money from medical specialty societies and individual health care providers for education, the creation of decision analysis tools, and data collection instruments. This is being actively encouraged by multiple imaging societies. Some of the best tools, in their opinion, have been providing timely, evidence-based guidelines and the establishment of appropriateness criteria (AC). However, the growth of imaging has an impact on health care providers, especially in the setting of a budget neutral payment system, where agreed upon increases in reimbursement for evaluation and management services were blunted to pay for new/evolving imaging technology. Health plans, therefore, have mainly seen this growth in terms of increased economic exposure; not surprisingly, they have partnered with procedural governors, the radiology benefits management (RBM) companies to primarily contain growth of imaging and limit their economic liability. That the benefits of this approach are unsubstantiated has not prevented health plans from enthusiastically embracing this strategy.

RBM Companies

Radiology benefits management programs were established to rein in the exponential growth and associated cost of medical imaging. The most commonly used tools are provider exclusion from the imaging network, prior notification and pre-certification. The RBM model is perceived by insurers to be effective and have a 70% market penetration. The financial model for a RBM program is usually based on incentives that potentially reduce a health plan’s costs. Thus, these groups are motivated to cut procedural volume, even if it means this being done in an apparently indiscriminate fashion. The RBM companies are profitable organizations and are now being integrated within health plans, as evidenced by the recent purchase of a RBM for $300 million (7).

The RBM program functions as a filter, deciding which indications for a specific procedure are deemed acceptable (reimbursable), and frequently require supplemental information for a study to be approved for reimbursement. The process by which these decisions are made is most often a “black box” with proprietary algorithms. These decision trees are the intellectual property of each RBM company and are neither “transparent” nor consistent from plan to plan. Many RBM companies claim that their processes are based on guidelines and AC, but none completely adopt a specific published set of American College of Cardiology (ACC) or American College of Radiology standards.

Pre-Certification (Authorization) and Prior Notification

The use of utilization management is not new and has been used in the past in an attempt to contain spiraling costs, usually for expensive procedures presumed to be overused, as evidenced by a rapid increase in volume. Over 20 years ago, in Massachusetts, the insertion of a permanent pacemaker required review and formal approval prior to implantation, or risk nonpayment by the state’s Medicare agency. However, this resource-intensive and time-
consuming approach lasted only a short time, as data analysis subsequently revealed that the expense saved by the reduction of unnecessary procedures was more than offset by the costs of this approach.

It is appropriate to use this paradigm to frame a discussion of RBM companies and the utilization strategies they employ. Pre-authorization or pre-certification requires formal approval by the health plan or its utilization manager (i.e., a RBM). This process must be completed before an imaging procedure is performed or else the laboratory risks nonpayment for the test. In many instances, this approval must be obtained by the referring physician, often a primary care doctor with no incentive to go through this sometimes complex and time-consuming process other than to ensure that his/her patient receives the test that was intended. After information is submitted by telephone or through Internet-based applications, a decision is reached and the imaging procedure is authorized or a denial is issued.

“Soft” denials are more focused on the process of prior “notification” and “educational” information about why the test is not recommended or supported for payment. In this setting, the testing procedure may usually be performed and reimbursed even if denied, but the notification procedure must still be completed. A substantial amount of time may be needed to navigate through the process, which then results in a series of telephone conversations to support staff, nurses, and often physicians. The burden is most often placed upon the referring physician and not on the laboratory, which prompts the ordering physician to question whether it is worth the hassle and expense of the prior notification process to obtain the test. This therefore leads to questions of access and availability for testing.

**Impact of Pre-Authorization:**

Potential Benefits

Utilization management, through RBM companies, has often been described as a method to promote improved quality in imaging. In fact, some of these programs have been labeled as quality initiatives, although there are no data to substantiate this claim. What does follow implementation of a RBM program is a transient volume reduction by the removal of “unnecessary” procedures with a resultant favorable impact on health care costs. Financial savings may then be realized by health care plans.

Education of the referring physician is also possible via the pre-certification process. Once familiar with the restrictions of test ordering, the health care provider may better understand which indications for testing may not be evidence-based. Feedback is virtually immediate, adding to the potential instructional value by applying this while the patient is in the office. However, the obvious limitation is that the process would be optimal if done with the ordering professional, rather than the office staff, who have limited access or understanding of the key medical information. Furthermore, as the process becomes persistently tedious, loopholes may be found and the entire process may be “gamed” by a more complete understanding of the decision tree.

Many pre-authorization or prior notification plans have developed rather sophisticated Internet-based portals, which permit a rapid evaluation of test candidacy compared with “widely accepted guidelines.” Although RBM companies often have on-line and telephone approval that may require up to 30 min, some vendors have streamlined this process with the use of fax or on-line forms, which may be completed in certain circumstances within 8 min.

The use of a RBM program is felt to be applicable and beneficial in all clinical settings. As stated by Curt Thorne of Medsolutions Inc, “it’s not just that you have a few guys that are bad all the time. It’s that everybody has problems sometimes” (8). Putting this in a better light, it would appear that all test-ordering physicians have room for continually improving their performance and practice patterns. Pre-certification and prior notification has professional societies and individual physicians rethinking our practice habits and renewing our need to consider the economics of health care. It is possible that in the future, plans could consider “gold carding” those practitioners who demonstrate substantial compliance with RBM rules. Physicians who achieve positive quality and efficiency metrics should be permitted to move to a less onerous review process that would improve operating efficiencies and reinforce the “educational message” that was being conveyed.

**Impact of Pre-Authorization:**

**Potential Problems (Table 1)**

<table>
<thead>
<tr>
<th>Concerns Regarding Pre-Certification and Prior Notification</th>
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<tbody>
<tr>
<td>- No evidence for improved quality of care</td>
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<td>- Favors indiscriminant volume reduction</td>
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<tr>
<td>- Lack of transparency</td>
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<td>- Not firmly based on appropriateness criteria</td>
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<td>- Inconsistent processes, with confusion and inefficiency</td>
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<td>- Reduced timeliness</td>
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<td>- Labor intensive</td>
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<td>- Negative economic impact</td>
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<td>- Steerage to the test of least resistance</td>
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<td>- Scant data available for feedback/education</td>
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<td>- No opportunity to refine process</td>
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<tr>
<td>- No correlation with imaging results or outcome</td>
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<td>- No mechanism to understand practice variation or local expertise</td>
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Lack of quality improvement. There are no data that prior notification/pre-certification or the use of a RBM program improves quality of care. The use of the term “quality” in the context of these cost-containing programs is misleading. Whether the procedure is needed or useful in many cases is not the critical factor, as many programs result in imaging volume reduction due to the hassle factor associated with pre-certification and prior notification, causing the provider to choose an alter-
Inconsistent processes. Among the wide variety of health plans, several different approaches regarding prior notification and pre-certification have been employed. Additionally, different RBM programs are used for various plans within the same geographic area, adding to the confusion of accreditation and certification due to different criteria and decision algorithms. Staff who deal with these differing methods must understand and work with nonuniform processes, leading to confusion, time inefficiency, and errors.

Timeliness. Pre-authorization and prior notification require that these procedures be completed before the performance of the imaging procedure. Even when obtaining pre-authorization requires <10 min to perform, it is an added chore to the medical office and is unlikely to be completed while the patient is present. This mandates callbacks to the patient, requiring additional time and potentially delaying the testing procedure. However, a far worse situation results when the initial screening mandates further dialog, including peer-to-peer discussion of the need for the testing procedure. The frequently overburdened physician must then take time to contact the RBM company and plead his/her case on the need for the procedure, causing additional delays in testing. Finally, a patient may have been scheduled for an imaging procedure far in advance but arrives at the laboratory without the requisite approval. This necessitates rescheduling the study and creates additional delays in diagnosis and evaluation.

Expense. One RBM company, which claims to have the most user-friendly, Internet-based process, estimates that prior notification will require about 5 min for each patient. This assumes, however, that all required data will be readily at hand when the process is initiated, which is often not the case, such as when charts are not available. Furthermore, some medical knowledge is required on the part of the individual trying to obtain the required approval for the test. It has been estimated that this “rapid” process, performed by highly skilled personnel, will result in costs for pre-authorization of more than $80,000 per year for a large, single-specialty cardiology practice. Assuming that 5 plans mandate prior notification, this amount could be extrapolated to total more than $7,500 per cardiologist per year just for prior notification of diagnostic imaging procedures. The impact of these costs would be even more dramatic for a primary care physician, who may lack the experience and expertise in office personnel to order cardiovascular imaging procedures and who gains no benefit from going through the process other than permitting access to the testing procedure for his/her patient. This is a very unacceptable situation for most primary care physicians who would then rather forego ordering the procedure that requires pre-certification.

Steerage. The idea that a certain imaging procedure might not be ordered due to an onerous process for prior approval raises a concern about “steerage,” whereby an alternative procedure that does not require pre-certification or prior notification might be selected. A noninvasive imaging method that would not require these pre-certification processes may be preferentially selected, even if it does not provide equivalent information or if local expertise with that modality may not be as high as with the procedure originally selected. Potentially more concerning is the elimination of a noninvasive cardiac evaluation in lieu of proceeding directly to cardiac catheterization, which arguably exposes the patient to greater risk and society to a greater cost. Therefore, test selection, because of aggressive utilization management methods and the concept of steerage, would favor test selection based on the ordering path of least resistance and following corporate philosophy, rather than clinical acumen.

Education and research. Lastly, the utilization management tools employed by a RMB program often collect limited information, which may not be able to be mined for data analysis regarding practice habits and used for physician education and potential revision of AC and guidelines. As previously noted, the educational value that might be offered by pre-certification is often lost in that the health care pro-

There are no data that prior notification/pre-certification or the use of a RBM program improves quality of care.
Appropriateness Criteria: Alternative to RBM Usage

Volume estimates of imaging procedures and claims of excessive and inappropriate testing stimulated the ACC and a variety of other medical imaging specialties to search for ways to evaluate practice patterns and potentially change them.

The ultimate goal is for physicians to be guardians of responsible health care, specifically by providing high quality and appropriate cardiovascular testing.

imaging procedure use. Following this discussion at the Medical Directors’ Institute in 2004, the ACC formed a task force to examine the use of AC for cardiovascular imaging. The goal was to provide patients, practitioners, and payers with guidance regarding the appropriate use of these procedures. The basic concept is to provide assistance in the decisions to select which test, for which patient, under what circumstances, and at what time. After developing an approach based on the UCLA/Rand methodology (10), the ACC partnered with other specialty groups and payers to develop single modality evaluations, based on published literature and expert opinion, of the level of appropriateness of a specific imaging method. After the development and review of the applications and indications for SPECT MPI, the first set of AC was published in 2005 (11). Since then, a similar approach has yielded criteria for CCT, CMR, and echocardiography (12,13).

The indications rated within each set of criteria are patient-focused, clinically relevant, and based on probability of disease and level of risk to be useful in a wide variety of scenarios. The use of the AC enables an institution, a group of physicians, and even an individual provider to assess practice patterns and identify areas for possible improvement. The criteria may also be invaluable as a training tool, developing awareness of test ordering and appropriate practice patterns. The ultimate goal is for physicians to be guardians of responsible health care, specifically by providing high-quality and appropriate cardiovascular testing, preserving accessibility but with fiscal responsibility. Appropriateness criteria, such as guidelines, should serve to minimize variation in image procedure use and guide the most valuable use of testing and its frequency.

The development of AC is a useful step to allow health care providers to maximize the additive value of cardiovascular imaging to patient care. However, it is the evaluation of appropriateness and subsequent educational efforts that will have true impact. Several studies from a variety of locations have demonstrated that is possible to track test ordering patterns and overall compliance with AC (14–16). It is estimated that 80% to 97% of SPECT studies may be classified for the level of appropriateness by the use of these criteria.

The majority of data to date has been collected examining the appropriateness of SPECT MPI, as these criteria have now been available for more than 2 years. Thus far, available data indicate that the majority of SPECT studies are not performed in an inappropriate fashion. This “double negative” evaluation is clinically more valid than simply describing the number of appropriate studies, as the criteria clearly state that indications scored as “uncertain” should not be considered reasons for not performing the test or grounds for nonpayment, a category reserved for the inappropriate designation. Inappropriate SPECT studies are noted in 11% to 19% (14–16). This value appears surprisingly consistent and may help to establish a benchmark for test use.

Analysis of appropriateness, using the AC as a guide, provides information regarding which indications are most commonly found to be inappropriate. This group of applications for cardiac imaging appears to be a worthwhile target to reduce procedural volume, not in an indiscriminant manner, but in a focused attempt to eliminate unnecessary testing. For example, low-risk, asymptomatic individuals and many patients undergoing preoperative evaluation have commonly been found to have “inappropriate” tests performed on them (14,16); elimination of testing in these groups alone would likely drop the inappropriateness rate to <6% of all examinations. The AC evaluation studies have also shown substantial variation in test ordering based on the specialty of the physician, thereby identifying an audience for future educational initiatives. It is important to emphasize, however, that achieving a 0% inappropriateness rate is not anticipated or even desirable, as intangible factors, local practice, and clinical judgment must also be carefully considered.

Finally, the evaluation of the AC is an integral part of the process (10) and must permit the thoughtful and frequent revision of the criteria. Feedback from organizations may provide direction for developing new indications or providing literature to be considered in a revised designation for existing ones. The recently published review of the AC for SPECT MPI by the American
Society of Nuclear Cardiology (17) carefully examined 20 indications where significant variability was found within the technical panel ranking 52 indications. This review concluded that only 6 indications warranted additional review and possible revision and provided key references in support of those recommendations. Additionally, this review suggested 6 new indications for the ACC to consider for future criteria. A pilot project is currently underway examining the potential for an evaluation tool to track appropriateness. This project represents a unique collaboration of a professional society and major payer, which may produce a viable alternative to pre-certification and the use of a RBM program. It is anticipated that key areas for improvement concerning appropriate test use will be identified and the level of designated appropriateness may be correlated with test results and patient outcome.

The efforts within the cardiology community toward AC are to help drive testing based on clinical indications. The criteria are envisioned to facilitate reimbursement decisions and support the need for additional documentation when an inappropriate designation is determined. These coverage decisions would then be based on a well-founded and transparent standard. It is also hoped that superlative practice performance, as demonstrated by AC adherence, should negate the need for more onerous methods and identify “gold star” performers who would be exempt from pre-certification. Lastly, the AC are already being used as educational tools for physicians and laboratories, and efforts are now underway to spread this information to non-cardiologist referrals.

There are a number of concerns about the AC. These documents are both challenging to read and difficult to clinically implement. Inconsistencies are present across different modalities and occasionally supportive clinical data are lacking. Also, not all indications are addressed within any set of criteria. Finally, a number of methodologic issues remain, such as the composition of the technical panels that write the criteria and the methods used to address “consensus” formation.

Conclusions
Cardiovascular imaging is a mainstay of contemporary practice and plays a valuable role in patient management decisions. However, the growth of imaging and efforts to restrain volume now threaten quality, performance, and access. Although RBM companies will reduce health care expenditures and have focused additional attention of the medical imaging issue, problems abound with the use of pre-certification and prior notification. Alternative approaches, especially those using AC offer many advantages and still place renewed responsibility squarely on the back of the health care provider. The education, implementation, evaluation, and enforcement, which follow the development of the AC, will set the stage for the next strata in the continuum of quality and serve as metrics and a platform for “pay for quality” (not performance) initiatives (18). Neither RBM programs nor AC should serve as substitutes for experience and sound clinical judgment. However, practitioners must lead the efforts to provide rationale and thoughtful care in a cost-conscious environment, or decisions directly affecting medical care will lack an experienced and knowledgeable voice.

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