Although reimbursement shapes medical practice, it is hard to get a handle on this issue because reimbursement requirements seem to change and evolve over time, and different insurers approach it in different ways for different technologies. This paper and the 2 that follow attempt to explain the reimbursement challenges facing new medical device technology. This first paper addresses the particular characteristics of medical device innovation and explains how they complicate the technology assessment process. It also notes the importance of codes as a means to identify new technologies and procedures, citing some issues that affect technology adoption. The subsequent papers delve into specific coverage and payment matters affecting medical devices. The perspective presented in these papers is that of a medical device manufacturer, and the focus tends to be on Medicare, given the size of this insurance program and its impact on the US health care system, but the issues that are raised affecting medical innovation can be extended to all payers.

Key Words: Ambulatory payment classification, Centers for Medicare and Medicaid Services, diagnosis-related group, Healthcare Common Procedural Coding System, US Food and Drug Administration

INTRODUCTION

Medical invention, particularly medical device innovation, springs from clinical practice and unmet medical needs. Recent decades have witnessed accelerated advances in medical technology, and these advances have raised complex medical, economic, and social issues concerning their use. The US Food and Drug Administration (FDA) plays an important role in determining how new technologies are used, given its regulatory responsibilities: conducting premarket reviews of new products to ensure their safety and effectiveness, administering good manufacturing process requirements, and performing postmarket surveillance. In recent years, insurers have also had a significant impact because of their coverage and payment determinations, often referred to as “reimbursement.”

As any medical practitioner today knows, the challenges posed by the current reimbursement climate can be formidable. Reimbursement shapes medical practice, it creates technology “winners” and “losers,” and it is complicated. It is hard to get a handle on this issue because reimbursement requirements evolve over time, and different insurers use reimbursement requirements in different ways for different technologies.

In this paper and the 2 that follow, we attempt to explain the reimbursement challenges facing the use of new medical device technology. In this first paper, we address the particular characteristics of medical device innovation and explain how they complicate the technology assessment process. We also note the importance of coding to identify new technologies and procedures for coverage and payment, and we cite some issues associated with coding that affect technology adoption.

The subsequent papers will delve into other aspects of reimbursement—coverage and payment—that affect the use of medical devices. The perspective we present will be that of a medical device manufacturer, and our focus will tend to be on Medicare, given the size of this
insurance program and its impact on the US health care system. However, the issues we raise concerning the impact of reimbursement on medical innovation can be extended to all payers.

THE IMPORTANCE OF REIMBURSEMENT

The past several decades have been marked by a steady stream of medical advances that have helped people live longer, healthier lives. New medical technology—new drugs, medical devices, biologics, and medical procedures—has been largely responsible for this, making possible earlier and more precise diagnoses, as well as more effective treatments. What was considered investigational or experimental only a few years ago has now become commonplace. In addition, advanced medical care has become available to an expanded number of patients at lower cost sites of care because of the advent of less invasive diagnostic and surgical techniques.

Medical imaging procedures in particular have played a central role in these advances, with improvements and refinements in computed tomography (CT), ultrasound, and magnetic resonance imaging to diagnose disease; the development of image-guided minimally invasive interventions; and the use of radiation therapy. As for the future, advances in molecular and cell biology have opened the door to diagnosing and treating patients on the basis of disease susceptibility, miniaturization, and telemetry now make it possible for physicians to monitor their patients remotely, and health information systems hold the promise of integrating care delivery.

New medical technology has helped transform medical practice over the years, making possible greater patient access to earlier and more precise diagnoses, as well as more effective treatments. But there is a cost associated with this progress, and increasingly, cost concerns are a fact of life in medical decision making.

Some analysts have raised cautionary flags concerning new medical technology’s role in escalating the costs of health care and have questioned whether the costs associated with these advances are too high [1,2]. These analyses typically measure health care outlays as a percentage of the gross domestic product and forecast problems for the economy if efforts to keep this percentage below some arbitrary level are not successful [3]. International comparisons are also frequently cited, in which countries with smaller health outlays than that of the United States have secured better health outcomes with lower investments than ours [4]. In a similar vein, other researchers have found significant geographic variations in what Medicare pays for medical care, with no apparent effect on quality or better outcomes [5].

Other researchers have considered the impact of medical technology on patient outcomes over time and found many of these advances to be worth far more than their costs [6,7]. Health care spending is viewed more favorably in this type of analysis and is seen as contributing to economic well-being. Still other analysts have noted that the increase in health spending is often attributable to increases in the prevalence of treating certain diseases rather than the rise in spending per treated case [8]. Although experts may disagree at a policy level on how best to measure the value of technologic innovations in the health arena, health insurers confront these issues every day at a practical level as they process health provider claims for new technologies and procedures.

Because few patients are able to pay for their health care directly, third-party payers play a central role in determining how new medical technologies are used. Technology manufacturers rely on insurance reimbursement to create a favorable climate for selling their products, while health providers depend on this reimbursement to offset the costs of incorporating new products into their medical practices [9]. The decisions that are made on how to identify these new technologies and procedures with codes, as well as insurer determinations on whether to integrate them into their insurance products through coverage and payment determinations, shape clinical practice and condition the environment for further medical innovation.

Insurer coverage policies and payment rates are tied to procedure codes. As we show later in this paper, securing codes takes time and evidence of both clinical effectiveness and practitioner use. Manufacturers of new medical technologies and physicians considering using them, need to consider the adequacy of current procedure codes not only from a clinical perspective but also for the impact they have on coverage and payment. If a new procedure involves more costly equipment, is more difficult to perform, or requires more skill than current procedures, new codes are a necessary precondition for the new procedure’s securing a higher payment rate. New codes also spur insurers to consider whether the new procedure should be covered and, if it is covered, to spell out whether the coverage is limited in terms of patient indications, sites of care, or qualified providers.

These are difficult decisions even when there is a rich body of evidence about the impact of new technologies on health outcomes. However, insurers often have incomplete information about new medical products when they are first marketed. For medical devices in particular, conclusive evidence is often not available until after it has been in use for some time [10].
PROBLEMS IN ASSESSING NEW MEDICAL DEVICES AND PROCEDURES

Medical devices include products that range widely, from surgical tools and in vitro diagnostic tests, to medical imaging equipment and interventional radiology devices, to life-supporting implants such as pacemakers, heart valves, and defibrillators. In addition to the wide variety of device types, medical devices also vary in their complexity and in the degree of risk—and benefit—they pose. Because of this heterogeneity, appropriate clinical evaluation methods vary for different devices and procedures. The task of assessing these medical device procedures for reimbursement purposes—determining how they should be coded, whether they should be covered, and how much they should be paid—is further complicated by the incremental way device innovation proceeds [11,12].

Some medical devices represent novel new directions in medical care and can be considered “breakthrough” technologies. Others are new iterations or refinements of existing technologies. In both situations, new medical devices do not come to market fully mature. Instead, they are typically the result of a succession of relatively modest changes and refinements in existing technologies, for example, because of new power sources, materials, components, or design. These changes, though quite small in themselves, accumulate over time, transforming a medical device and affecting its clinical effectiveness. Similarly, the medical procedures associated with these medical products also evolve and are perfected. In this way, over time, seemingly small changes can accumulate, bringing about a generational change in a device and a medical procedure. These changes can open up new uses and lead to improved outcomes for patients. The use of imaging procedures such as CT and positron emission tomography, and now positron emission tomography/CT, illustrate this development process.

This incremental process of innovation raises the question of when assessments should be conducted. Although assessing medical devices and the procedures in which they are used early in their development process is possible, and preferred by insurers, these sorts of analyses raise difficult methodologic questions because both the device and the procedure are undergoing change, users are not yet proficient, and it is not yet clear which patients would benefit most.

In short, device procedures are a “moving target” for technology assessors [13, p 13]. Assessment findings can become out of date as device modifications occur and as medical practitioners gain experience with new technologies. An assessment of a particular technology at any point could well understate its effectiveness, particularly early in its evolution, because improvements in medical devices continue once they reach the market, after FDA clearance. In addition, the use of devices by practitioners in clinical practice typically spurs additional refinements and improvements. Because many medical devices and the procedures in which they are used are not yet perfected when they are first adopted, clinical adoption serves as the beginning of an iterative process of feedback from medical practitioners, leading to device redesign, use, and more practitioner feedback.

It is also important to note that medical practitioners also may use medical devices beyond their original uses and seek applications in other fields [14, p 19]. This situation, in which devices are used “off label,” raises difficult questions for insurers but tends to characterize how devices evolve. Furthermore, the iterative improvements that mark device innovation tend to parallel an increase in the skill level of practitioners, so that outcomes are often dependent on both product performance and practitioner expertise [15].

All of this makes technology assessment difficult. Although insurers would prefer to base coverage and payment determinations on a body of evidence generated before a technology’s availability in the marketplace, the realities of the device innovation process mean that reimbursement decisions are often made before technologies are fully mature, before the development of conclusive evidence.

WHERE FDA FITS IN

The FDA estimates that more than 8,000 new medical devices are marketed each year in the United States. As noted above, most of these technologies, including imaging procedures, are typically the result of a series of small and incremental refinements, not breakthrough discoveries.

The FDA regulates medical devices on the basis of the risks they pose. This approach toward evaluating device safety and effectiveness was authorized by Congress in 1976, and it differs significantly from the way the agency evaluates drug safety and effectiveness. Jennifer Henderson and John Smith [16] provided a full explanation of FDA regulation of medical devices in a recent article in this journal.

The FDA classifies about half of the new medical devices that are marketed each year as low-risk products, exempt from any premarket review requirements. Examples of these low-risk devices are bandages, splints, and surgical drapes. The other half of the new medical devices that are marketed each year consists mainly of new iter-

1 Ramsay et al [15, p 59] noted that both individual operators and institutions learn through experience. These “learning curves” complicate the evaluation of medical technology, and they are an impediment to rigorous assessment.
ations of previously marketed devices that pose only medium risk.

These devices must be found to be “substantially equivalent” to products already on the market, and they are subject to good manufacturing and other product-specific performance requirements (or “special controls”) by the FDA through its 510(k) premarket notification program. About 8% of these medium-risk products are subject to special controls that require clinical data. In most cases, however, clinical data are not required for FDA clearance. Most diagnostic imaging devices, like CT, magnetic resonance imaging, and ultrasound scanners, reach the US market through this 510(k) premarket notification program. Other examples of medium-risk products are endoscopes, patient monitoring equipment, and dialysis catheters.

Fewer than 100 of the 8,000 new medical devices that come to market in the United States in any given year undergo full “premarket approval” review to determine their safety and effectiveness. These devices, which tend to be high-risk devices, such as pacemakers, heart valves, and implantable pumps, typically undergo formal clinical trials as part of their premarket review [17]. Other devices subject to this more stringent review process are devices that have changed significantly from predicate devices that have been available in the market, or devices with new indications for use. Digital mammography equipment is an example of imaging technology reviewed by the FDA under this “premarket approval” review program.

In 2001, the FDA cleared 3,507 new products for marketing under its section 510(k) premarket notification program and approved 29 devices, representing breakthrough technologies, under its premarket review program. That same year, the FDA supervised 1,098 clinical trials involving new medical devices, and it approved 216 new clinical studies designed to test the safety and effectiveness of experimental devices in humans [18].

Insurers today view FDA clearance (under the 510[k] premarket notification program) or approval (under the FDA’s “premarket approval” program) as a necessary, but not necessarily sufficient, demonstration of clinical effectiveness. Problems tend to arise when insurers expect to base coverage and payment determinations on clinical trial data documenting the effectiveness of products the FDA regulates as being of medium risk. These products typically are cleared for market without clinical trial data, and in situations in which these data are required by the FDA, insurers may not be satisfied with the clinical endpoints of the studies.

The overwhelming majority of new medical devices that come to market each year do not raise billing-code, coverage, or payment questions. Most of these technologies fit within existing coding and payment categories or are similar to existing items for which coverage determinations have already been made. But when new devices, or the procedures associated with their use, do not fit into established insurance categories; when they attract attention because of their cost; or when they are used in new ways or for new indications, reimbursement plays an extremely important role [19].

REIMBURSEMENT CHALLENGES

Insurer coverage and payment processes not only determine whether current technologies will be made available to patients, but they also create a climate that can provide incentives or disincentives for manufacturers to innovate in the first place. A medical device industry study based on a survey of device manufacturers in the United States, an analysis of secondary research information, and confidential interviews with industry executives, security analysts, and other informed observers conducted by the Lewin Group [14, pp 52-62] in 2000 documented this. The Lewin survey identified Medicare coverage and payment processes as often being “inconsistent and confusing” and noted that although manufacturers express similar views about private health insurer coverage and payment processes, “concerns regarding Medicare are particularly acute, reflecting the program’s size and scope, as well as the program’s influence on payment policy in all sectors of the health care market” [20, p 1].

In examining Medicare’s coding, coverage, and payment processes, the Lewin Group’s [14] study found that the systems for making these decisions are “separate and largely uncoordinated”; manufacturers are required to negotiate “multiple, distinct, and complex processes.” As a result, Lewin found that it can take the Centers for Medicare and Medicaid Services (CMS) officials from 15 months to 5 years (and, in some cases, longer) to add new medical technologies to the Medicare program [20, pp 1-2]. The time it takes manufacturers to manage these reimbursement hurdles are particularly troublesome because most medical devices have life spans of only 12 to 18 months [21, pp 21-3]. Most device manufacturers surveyed by Lewin felt that the Medicare coverage and payment processes were not clear, transparent, consistently and fairly applied, or predictable [14, p 54].

The medical device industry has favored increased transparency in these reimbursement processes, as well as coordination among them, so that requirements can be understood, review times reduced, and patient access speeded. Although efforts are under way at CMS to do this [22-24], spurred by congressional interest, the current situation tends to dampen medical device innovation, involve high compliance costs, and result in delayed patient access to technologies that have already been cleared by the FDA.
Before discussing issues surrounding coverage and payment for medical devices, the subjects of our next 2 papers, we address the importance of procedure codes that identify medical procedures. We also point out issues associated with securing these codes that affect reimbursement and, consequently, technology use.

**USING PROCEDURE CODES TO IDENTIFY NEW DEVICE PROCEDURES AND TECHNOLOGY**

Codes identify medical technologies and procedures and, as such, serve as the basis for insurer coverage and payment determinations. The American Medical Association (AMA) plays an important role here, maintaining, through its CPT® Editorial Panel, the coding system used to identify physician procedures. Current Procedural Terminology (CPT®) codes are widely accepted in the United States for identifying medical procedures performed by physicians and other health care practitioners. These codes are updated each year through a process that involves the advice of medical specialty groups.

Health care insurers process more than 5 billion claims for payment annually. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential [25]. In addition to CPT®, 2 other coding systems play a role in reimbursement, identifying medical technologies and procedures: the International Classification of Diseases, 9th rev (ICD-9), coding system and the Healthcare Common Procedural Coding System (HCPCS), maintained by CMS. Through an agreement between Medicare and the AMA, CPT® serves as the foundation (Level I) of the HCPCS coding system. These 3 coding systems and their uses are identified in Table 1.

The ICD-9 codes, maintained by federal health officials, serve as the basis for hospital inpatient payment. The ICD-9 codes identify patient diagnoses and hospital procedures, and they determine the diagnosis-related group (DRG) to which a hospital discharge is assigned and, ultimately, the Medicare payment that is made. The ICD-9 diagnosis codes are also used in tandem with CPT® codes that identify physician procedures; they serve to document medical necessity of the procedure for insurers. The ICD-9 codes are updated on an annual basis through a process managed by federal staff members.

Although Medicare hospital inpatient payment rates are based on ICD-9 codes, Medicare’s hospital outpatient payment system uses CPT® codes to identify medical services. These outpatient services are grouped into ambulatory payment classifications, and CMS sets payment rates for each of these ambulatory patient classifications. The CPT® codes also serve as the basis for other Medicare payment systems, including the Medicare physician fee schedule, the clinical laboratory fee schedule, and ambulatory surgical center payments. Payment rates are assigned to individual CPT® codes under the physician and clinical laboratory fee schedules. For care provided in ambulatory surgery centers, CMS groups’ CPT® codes that are covered in this care setting are placed into 9 payment groupings, each of which has its own payment rate.

Where CPT® codes are not sufficient to describe medical procedures and technologies fully, CMS makes use of another code set to supplement CPT® codes. The HCPCS codes serve that purpose. The HCPCS codes are used regularly in the Medicare physician fee schedule and the hospital outpatient prospective payment system. These HCPCS codes are frequently used to identify new imaging procedures, until CPT® codes are assigned by the AMA. These temporary imaging codes are often referred to as G codes, because their alphanumeric identifier begins with the letter G. The HCPCS codes are also used to identify items of durable medical equipment reimbursed under Medicare’s Durable Medical Equipment Prosthetics, Orthotics, and Supplies fee schedule. Medicare staff members manage the HCPCS coding system, updating it yearly.

Many new technologies do not raise coding issues. If a new technology is adequately identified by established codes, there is some probability that insurers have already made coverage and payment determinations that will apply to the new technology as well as the technologies that preceded it. In these situations, manufacturers know

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1. In 1983, the US Department of Health and Human Services entered into an agreement with the AMA specifying that Current Procedural Terminology (CPT®) would be the means to report physician services under Medicare. In 1987, Congress required hospitals to use CPT® for reporting outpatient surgical procedures.

2. The CPT Editorial Panel has 16 members. Although it is composed primarily of physicians nominated by the AMA, it also has representatives from CMS; the Blue Cross Blue Shield Association; America’s Health Insurance Plans, a national trade association representing health plans and commercial health insurance companies; and the American Hospital Association. The CPT Advisory Committee advises the CPT® Editorial Panel on each proposed CPT® change. This advisory committee is composed of more than 90 physicians and a small group of allied health professionals. Each member of the advisory committee represents a medical specialty society.

3. Updates and modifications to ICD-9 codes are the responsibility of the ICD-9-CM Coordination and Maintenance Committee, a federal interdepartmental committee cochaired by representatives of CMS and the National Center for Health Statistics.

4. Decisions about additions, revisions, and deletions to the permanent codes in HCPCS Level II are made by government staff members at CMS, the HCPCS Workgroup. Coding decisions for HCPCS are coordinated with both public and private insurers.
the reimbursement environment for the new technologies they develop. However, if a new technology, and the procedures associated with its use, represents an innovative approach not adequately captured by established codes, or if it confers additional benefits while costing more than the technology or procedures being replaced, new codes may be needed to distinguish it from previous technology, and the process of securing new codes can be both lengthy and complex.6

The Lewin Group [14, p 53], in its first report for the Advanced Medical Technology Association on the outlook for medical technology innovation, made the point that “new technologies that represent incremental advances over existing ones often have coverage and reimbursement precedents that will be followed by payers. If there is pre-existing coverage for a similar device and the assigned payment level is adequate, payment problems generally do not arise. An example might be a new version of a pacemaker or improvement to an artificial joint. Other times, however, a new version of a device offers new features at a higher cost, creating problems with reimbursement. For example, the recent introduction of new technologies used in cervical cancer screening that were more accurate but more expensive than conventional Pap tests was met with considerable resistance by payers.”

Table 1. Key Coding Systems Affecting Reimbursement

<table>
<thead>
<tr>
<th>Coding System</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-9-CM</td>
<td>Diagnosis Codes</td>
</tr>
<tr>
<td>International Classification of Diseases, Clinical Modification, 9th Rev</td>
<td>• Maintained by NCHS*</td>
</tr>
<tr>
<td></td>
<td>• Required by Medicare to document medical necessity in outpatient settings</td>
</tr>
<tr>
<td></td>
<td>• Used with ICD-9 procedure codes to determine Medicare DRG** assignment</td>
</tr>
<tr>
<td>CPT® (HCPCS Level 1)</td>
<td>Procedure Codes</td>
</tr>
<tr>
<td>Current Procedural Terminology</td>
<td>• Maintained by CMS</td>
</tr>
<tr>
<td></td>
<td>• Identify hospital Inpatient procedures for Medicare DRG system</td>
</tr>
<tr>
<td></td>
<td>• Used with ICD-9 diagnosis codes to determine Medicare DRG assignment</td>
</tr>
<tr>
<td>HCPCS Level 2</td>
<td>Procedure Codes, Technology Identifiers</td>
</tr>
<tr>
<td>Healthcare Common Procedure Coding System</td>
<td>• Maintained by CMS</td>
</tr>
<tr>
<td></td>
<td>• Identify Procedures not in CPT®, as well as Items of medical technology (drugs, biological products, medical devices) for Medicare fee schedules, and other Medicare payment systems</td>
</tr>
</tbody>
</table>

*National Center for Health Statistics, a component of the Centers for Disease Control, located in the US Department of Health and Human Services

**Diagnosis Related Group, the unit of payment in the Medicare hospital inpatient prospective payment system

***Ambulatory Payment Classification, the unit of payment in the Medicare hospital outpatient payment system

Time Frames and Coding Requirements

As mentioned above, coding decisions for ICD-9 codes, CPT® codes, and HCPCS codes are generally made on an annual basis. The Lewin Group found that it takes a minimum of 15 months to secure a new code because of filing requirements. However, depending on the timing of the product launch, requirements associated with requesting a code, and the time it takes for new codes to become effective once decisions have been made, it may take as long as 27 months after a new technology has been cleared by the FDA for a new code to become effective [20, p 2].

It is worth noting that the criteria for Category I CPT® code7 assignment include the existence of supporting US peer-reviewed literature as well as the use of the new technology or procedure by a large number of physicians at sites around the country [26]. Developing

7 Category I CPT® codes describe medical procedures or services with 5-digit CPT® codes and descriptor nomenclature. New and revised Category I CPT® codes are released annually and become effective on January 1 each year.
this evidence and securing the widespread use of a new procedure by physicians adds to the time it takes from FDA approval or clearance of the device to a successful request for a new code. The evidence standard raises particular uncertainties for manufacturers (and physician users) of new technologies, such as imaging technologies, that clear the FDA under the 510(k) premarket notification process, with little or no clinical evidence of effectiveness. The AMA’s CPT Editorial Panel has made available no specific explanations of the level or strength of evidence needed to secure a Category I CPT code.

Furthermore, CMS, in its management of the HCPCS coding system, specifies that coding applications can be made only for medical device technologies with 3 months of market experience [25]. There is no basis in the Medicare law for this HCPCS requirement. In effect, it requires that the product be marketed and sold without a proper way to identify it for billing purposes and, therefore, without good prospects for coverage and payment.

These sorts of coding requirements create a “chicken-and-egg” situation whereby new codes are assigned if there is widespread use of a new technology and clinical proof of its impact, but health care practitioners are discouraged from using the new technology in the first place because it does not have a unique code or a fair and appropriate payment amount assigned to it.

**Insurer Reluctance to Reimburse for New-Technology CPT Codes**

Category III CPT codes are tracking codes that are used to identify new and emerging technologies and to facilitate data collection or to substantiate widespread use. These codes are a relatively new addition to CPT, and they were designed to accommodate new technologies and procedures that do not meet the criteria for Category I CPT codes but nevertheless are needed to identify new procedures. Unfortunately, some payers view these alphanumeric codes as identifying experimental procedures, and they tend not to cover or provide payment for them, despite the fact that CPT clearly states that their Category III status does not indicate that they are experimental or of limited utility [26].

The AMA’s CPT Editorial Panel assigned 8 new Category III codes to identify cardiac CT procedures, effective in 2006. It will be interesting to see how insurers make coverage and payment determinations for these important new imaging procedures. Before 2006, no specific code existed to identify these new procedures adequately. During 2005, a Category I miscellaneous code was recommended for billing purposes. Despite the absence of specific codes, some local Medicare contractors chose to cover these procedures. On the other hand, the Blue Cross Blue Shield Association’s Technology Evaluation Center [27] reviewed the clinical data available and found that “The evidence is insufficient to determine whether the use of computed tomographic angiography improves net health outcome or whether it is as beneficial as any established alternatives.”

With the assignment of Category III codes to identify these new technology procedures in 2006, Medicare’s local contractors will need to develop coverage and payment policies referencing the new codes. If local Medicare contractors choose to cover these procedures, they will set payment rates locally, because payment weights are not assigned to Category III codes. Private payers will also develop policies in response to these codes. For example, Aetna [28] issued a clinical policy bulletin on January 27, 2006, referencing the new codes and the 2005 Blue Cross Blue Shield Association Technology Evaluation Center report, finding cardiac CT angiography “experimental and investigational” and noncovered.

Recently, one of Medicare’s local contractors went so far as to propose a local coverage determination that would have automatically denied coverage and payment for all Category III CPT codes, finding them to be investigational, because these codes were created to track the utilization of emerging technologies, services, and procedures. The AMA’s CEO, Michael D. Maves, MD, objected to this proposed action in a letter to the carrier, stating that “it is not reasonable to categorically deny payment for all CPT Category III codes.” The letter went on to say, “It is the intention of the CPT Editorial Panel and AMA policy that CPT Category III codes should be eligible for payment and, as such, each Category III code should be considered for payment based upon its individual merit.” [29]

Because Category III codes tend to flag new technologies, with the possibility of leading insurers to deny coverage and payment, product sponsors and practitioners need to consider carefully the possible reimbursement consequences of a Category III code assignment.8 There might be times where new technologies fare better if applications for new Category I CPT codes are deferred, and unlisted CPT codes are used to identify the new procedures, even if reimbursement is lower than appropriate, until Category I CPT criteria, requiring clinical evidence of effectiveness and practitioner use, can be clearly met. Because insurers require clinical evidence of effectiveness for coverage, the assignment of a Category I code can increase the prospects for coverage and an appropriate payment level.

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8 The Lewin Group [20, p 56], in its second report for Advanced Medical Technology Association on the outlook for medical technology innovation, stated that Category III “tracking codes, though available more quickly, are likely to be considered a ‘red flag’ to payers that the technology represented by the tracking code should not be covered.”
For example, a Bard endoscopic suturing device was assigned a Category III code after its clearance by the FDA under the 510(k) premarket notification program in 2000. Although the outpatient procedure associated with its use was assigned a reasonable hospital outpatient payment category by Medicare, insurers, both Medicare local contractors and private payers, were reluctant to cover it without a Category I CPT® code. Given its lack of widespread use in the medical community and the absence of conclusive clinical evidence documenting patient outcomes, the procedure has had difficulty in meeting the requirements for a Category I designation.

**System Complexity Due to Multiple Coding Requirements**

Because codes are needed for payment, and because Medicare’s payment systems vary in the codes they use, a single item of medical technology may require the development and use of several codes. This means that medical device manufacturers developing new medical products must navigate multiple coding regimes, each with separate rules and protocols concurrently, and that they must understand fully the “architecture” of Medicare’s various payment systems, each of which has differing rules for payment.

For example, a special type of catheter used in a particular interventional radiology procedure, when performed in an inpatient setting, may not need a separate code to identify it because Medicare does not make payment for the particular items associated with inpatient care. Instead, hospitals receive bundled payment amounts—DRG payments—for the various inpatient procedures that take place in this setting. Because the DRG payment system is based on ICD-9 codes, ICD-9 codes are used to identify the surgical procedures performed. Device manufacturers need to review existing ICD-9 codes to ensure that they are sufficient to describe the procedures involving the new technology and seek new ICD-9 codes (and appropriate DRG assignments for these new codes) when needed.

If the same interventional radiology procedure is performed in the hospital outpatient setting, Medicare rules require the hospital to use CPT® codes, not ICD-9 codes, to identify it in this setting. Medicare groups these CPT® codes into various payment bundles, termed ambulatory payment classifications, for which it pays hospitals a prospective payment amount for the costs facilities incur. The Medicare payment to hospitals equates to the technical component fee for the procedure.

As for the physician who performs the medical procedure in the hospital, they need to use CPT® codes to identify the procedure that is performed (in this case, the use of the new catheter), because the Medicare physician fee schedule is based on CPT® codes, and physicians are paid separately from hospitals. Therefore, in reimbursement planning, product sponsors must be sensitive to whether current CPT® codes sufficiently identify the new procedure and the physician skill associated with it. William Thorwarth, MD [30], in a previous issue of this journal, provided an excellent description of how CPT® codes are used to identify physician procedures, the process by which these codes are assigned by the AMA’s CPT® Editorial Panel, and the way these codes are given relative weights for payment purposes.

It is also possible that the hospital may be eligible for special “pass-through” payments for using the new catheter technology in hospital outpatient settings. These items of new technology are identified by another type of code: a HCPCS temporary national code, known as a “C code.” C codes identify new items of medical technology used in the hospital outpatient setting. They serve the same purpose as Category III CPT® codes in that they identify new device procedures. The CMS has used these temporary HCPCS codes to facilitate complete hospital reporting of their charges for medical devices [31].

**SUMMARY AND CONCLUSION**

This introductory paper has emphasized the importance of reimbursement processes for medical device technology development and use. It has explained the way new medical devices come to market and how device technologies and procedures are perfected over time. This paper has also touched on the difficulties associated with assessing fast evolving new device technologies and procedures. Although insurers tend to expect conclusive evidence on patient outcomes before coverage and payment decisions are made, this sort of evidence may not be readily available for many new device technologies, especially those that the FDA clears for marketing without significant clinical trials, such as many imaging technologies.

Evidence of effectiveness is also a criterion for Category I CPT® code assignment, a matter that complicates the use of emerging medical technologies. Category III CPT® codes are assigned to identify these new technology procedures. Insurers, however, often deny coverage for procedures identified by these codes. Although coverage and payment are considered important reimbursement hurdles for new device technologies, securing Category I CPT® codes poses challenges as well, in terms of both the time it takes and the evidence required. Our next papers will focus on specific coverage and payment issues that affect new product development.
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