Getting Paid for All Your Hard Work: The Basics of Reimbursement for Healthcare Products and Services

Introduction

You may be wondering why the official publication of the Regulatory Affairs Professional Society (RAPS) has an article about reimbursement. After all, the job of most regulatory affairs professionals is to successfully navigate the maze of FDA regulations in order to obtain clearance to market products. They don’t need to be concerned about what happens next since that’s the job of the marketing and reimbursement people—right?? … Wrong! Marketing, reimbursement and regulatory functions can no longer operate independently and in fact, must work together closely to ensure product success.

Today’s healthcare market is increasingly more sophisticated and is relying more and more on clinical evidence to drive the reimbursement process. This will necessitate regulatory affairs professionals involving reimbursement people early on in the product planning process and adjusting clinical strategies to not only meet FDA’s needs, but also to ensure that products will be reimbursed adequately, allowing for success in the marketplace.

This article provides a basic overview of the key elements of medical product reimbursement: coverage, coding and payment. It also will help
you understand how the clinical and regulatory plan can affect product reimbursement. You will see that the process of obtaining product reimbursement differs greatly from FDA’s regulatory approval process and you will better understand why it is necessary to develop a well-planned and coordinated regulatory-reimbursement strategy.

Key Elements of Reimbursement

When thinking of new product reimbursement, most people immediately think about “codes.” Do I need a new code? Can I use an existing code? They don’t realize that there are other essential elements that must be in place for a product to secure adequate reimbursement. In fact, the other elements may be far more important than what code to use.

Reimbursement consists of the following key elements:
- Coverage;
- Coding; and
- Payment.

Coverage is the decision by a payer to pay or not to pay for an item or service. Coverage decisions are made by all types of payers—both Medicare and non-Medicare. They may be issued on a case-by-case basis or formalized in medical policy. Either way, the decisions are increasingly being based on clinical and scientific data that demonstrates the medical benefit to the patient. The decisions typically will be based on whether reviewers believe there is adequate evidence to determine whether a decision can be made about the “medical necessity” of the item or service. Without a favorable coverage policy, there will be no reason to have a code since you cannot bill for the product and be paid.

Coding is the language of billing. Codes tell a payer what items or services were provided and why. ICD-9 Diagnostic codes are used in all healthcare settings to describe “why” a patient was provided the services being billed. There are several other types of codes, specific to the site of service, that describe the “what” that was provided to the patient. These codes include CPT, HCPCS, and ICD-9 procedure codes to name a few. These codes also are specific to a given product or procedure and are necessary for a payer to properly administer claims.

Payment refers to the amount a provider is reimbursed for an item or service. When a claim is filed with the payer using the appropriate diagnosis and procedure codes and the item or service is a covered benefit, then the claim is paid. It is important to note, however, that methods for determining payment values vary by the site of service. For example, hospitals billing for Medicare services are paid using the Diagnosis Related Groups (DRG) system for inpatient hospital stays and the Outpatient Prospective Payment System (OPPS) using Ambulatory Payment Classifications (APC) to determine payment for hospital outpatient services. While many non-Medicare payers use DRGs to determine payment levels, many negotiate separate rates or are paid on a fee-for-service basis. Physician services, skilled nursing facilities, home health agencies and durable medical equipment all have their own unique systems for calculating payment rates as well. So depending on where the product is used or who the payer is, the device may or may not be paid for.

Each of these three elements independently has the ability to doom a product to market failure. Clearly, if payers are unwilling to cover a product or service, there will be no payment regardless of the existence of a code or an associated payment value. An absence of a proper code or the assignment to an inappropriate code can complicate the billing process to the degree that it prevents or limits payment, thereby impeding market penetration. Finally, the failure to achieve an adequate level of payment can and often does prevent adoption of new technology.

As you can see, the road to successful reimbursement and ultimately product success is not as simple as “getting a code” and market clearance from FDA. It takes all three elements—coverage, coding and payment—
The Parallel Path

Although coding and payment are both critical to reimbursement success, regulatory affairs professionals may have limited ability to affect their outcome. A substantial opportunity to affect a product's reimbursement success is in the area of coverage. Successful coverage is directly related to the relevance and quality of the clinical evidence that supports the product. Regulatory affairs professionals directly control the type and quality of the studies that are performed in support of FDA clearance. That, in turn, provides the base of evidence to support favorable coverage decisions. It is for this reason that it is imperative that regulatory affairs professionals work to develop a parallel regulatory and reimbursement path that addresses the needs of both FDA and the payers who control the destiny of the product in the marketplace through policy-making decisions.

While you know who you are dealing with at FDA and know how to navigate through the regulatory maze to obtain market clearance, you probably have no idea who these “payers” are that you now have to factor into the regulatory and clinical strategy. Since all payers make coverage decisions, you could be dealing with any number of insurance companies, Health Maintenance Organizations, managed care organizations or government payers. Each has its own criteria and processes for making coverage decisions. Fortunately, they all have some common elements and in many cases follow each other’s lead—particularly Medicare’s—in making coverage decisions. By exploring the Medicare coverage process, you can gain a better understanding of the coverage decision-making process and, more importantly, better understand what your regulatory and clinical plan needs to include to support reimbursement.

Medicare Coverage

The Medicare program is a federal health insurance program established in 1965 to address the needs of the elderly and disabled. The program is administered by the Centers for Medicare and Medicaid Services (CMS) formerly the Health Care Financing Administration (HCFA). The program pays for items that are “reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.” The statute specifically excludes products or services for screening, lifestyle changes and most outpatient pharmaceuticals, to name a few. There are some exceptions where Congress has passed specific legislation to require coverage and payment for specific services such as mammography screening. All other products or services must fall into one of the statutorily defined benefit categories and be cleared for market by FDA to be covered by the program.

These requirements are fairly straightforward. Unfortunately, the rest of the process is not quite as clearly defined. In fact, the agency has never implemented any final rule governing how it makes determinations as to what products and services are “reasonable and necessary.” Although the agency has made attempts to do so, medical device manufacturers, providers and the agency cannot come to agreement as to what would be acceptable criteria for basing coverage decisions. As a result, standards for determining what is reasonable and necessary are ever-evolving and subject to continuous change.

Despite the lack of a defined Medicare coverage criteria and process, decisions about what products are covered and when continue to be made. These decisions may be made on a national, local or claim-by-claim basis. The Coverage and Analysis Group—a division within CMS’s Office of Clinical Standards and Quality—formulates national policy. Local policy is made by medical directors of the local Medicare contractors who are responsible for claims and benefit administration for a given service area. Local Medical Review Policies (LMRPs) issued by the contractors are binding only on beneficiaries in their assigned service area whereas national policy is binding on all 39 million Medicare beneficiaries.

Regardless of where the decision is made, either local or national, decisions are predicated on the principles of evidence-based medicine to guide the deliberations. While this is not a new approach for most non-Medicare payers, it represents a major change in how Medicare makes coverage policy. Organizations such as the Blue Cross Blue Shield (BCBS) Association have long-standing, formalized programs to assess how a technology under review affects health outcomes. The BCBS Technology Evaluation Center (TEC) uses the following criteria when reviewing the body of evidence for technologies under review:

1. The technology must have final approval from the appropriate governmental regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

These technology assessments in conjunction with other sources of data provide the basis upon which coverage policy is developed.

Like their private-sector counterparts, CMS is trying to formalize its review process. In April 1999, the agency published an outline of how it will conduct coverage reviews until a final rule can be adopted. This process combines elements of the technology assessment process used by groups such as the Blues and introduces elements typically seen in FDA’s approval process. While this process does not apply to local contractor decisions, contractor medical directors may use the evidence review standards that have evolved during the implementation of this process to guide their decisions.
Coverage reviews are triggered when any of the following, alone or in combination, exist:

- Request by a manufacturer and/or key opinion leaders;
- Request by a local contractor;
- Inconsistent local policy exists;
- The product represents a substantial advance in technology;
- Disagreement about the technology exists among experts; and
- Program integrity concerns (overutilization, high cost, etc.) are raised.

A formal written request for a coverage decision must be submitted along with information that describes the product or service to be covered and any evidence or data that supports the technology. Once received, the agency reviews the request and when they feel they have complete information, the review process can begin.

Usually, the staff of the Coverage and Analysis Group reviews the information to determine if there is adequate evidence upon which to base a coverage decision. In some cases, this can be done with an internal review and in other cases, the agency may choose to refer the product for a formal technology assessment by the Agency for Healthcare Research and Quality (AHRQ) or one of its designated Evidence Based Practice Centers, such as the BCBS TEC. A referral to an outside organization adds substantially to the time it takes to complete the review. Some reviews have taken up to two years before a decision is reached.

The technology assessments seek to evaluate the rigor of the scientific evidence and the effectiveness of the technology as demonstrated by published literature. The review is conducted based on a series of questions developed by agency staff usually in conjunction with the organization conducting the assessment. These questions are designed to not only assess issues of reliability and validity and ferret out problems of bias, but also to try to identify the benefits to the Medicare beneficiary as well as how the product or service compares to the existing standard of care.

The shift toward an evidence-based technology assessment process has resulted in a substantial change in the quality and rigor of evidence that manufacturers are required to produce in order to pass muster with CMS and the organizations conducting technology assessments. Critics of the revised process claim device manufacturers should not be held to a "pharmaceutical, gold-standard" in order to garner a favorable coverage policy. In response, the agency asserts that although there is a hierarchy of evidence with randomized, controlled trials being preferred, they do consider less rigorous evidence when making decisions. While recent coverage decisions demonstrate the agency's willingness to consider the entire body of evidence and include input from key opinion leaders, it is clear that the more rigorous the studies supporting a product are, the more likely they are to be covered by the program.

CMS is seeking evidence that includes rigorous, well-defined clinical trials that are published in peer-reviewed journals. The articles should report in detail measures of statistical significance (p-values, power, etc.). Treatment-allocation procedures (for example, randomization) should be clearly described with patient inclusion and exclusion criteria that reflect the population as a whole. For example, if you are studying a device that treats congestive heart failure (CHF) and the majority of patients with CHF are over the age of 65, you would expect the sample to include a proportion of patients over 65 that reflects the actual prevalence of the disease in that age group. More importantly, if you are requesting coverage for Medicare beneficiaries, it is absolutely necessary to study them in your trial in order to allow the results of the trial to be generalized to the Medicare population as a whole. The studies also should be free of bias that could cause the treatment effect to be over- or understated.

Raising the evidence bar can have a significant effect on clinical plans. If the product is an implantable device being cleared through the PMA process, chances are good that the studies conducted for FDA will be sufficiently rigorous for CMS as well.
If on the other hand, the device is going through the 510(k) process, the level of evidence required to gain market clearance may fall far short of the standards required for a favorable coverage decision. Hence, it is imperative to factor this into the clinical plan and either conduct a more rigorous trial than FDA requires or conduct additional studies to satisfy the needs of CMS.

Once the technology assessment is completed, the agency can choose to make their decision or they can refer it for further review by the Medicare Coverage Advisory Committee (MCAC). The MCAC was modeled after FDA review panels and is comprised of specialty panels that review different types of technologies. The panels are comprised of physicians, industry representatives and consumer representatives that review referred technologies and make determinations as to the adequacy of the evidence and the resultant health effect. It is important to note that not all technologies will be referred to MCAC. Usually, MCAC referrals are made:
- When a technology is subject to broad public controversy;
- Where there is a split in opinion between researchers and clinicians; or
- Where there is the potential for a major financial effect on the Medicare program.

Like a technology assessment, a referral to MCAC further delays the decision-making process.

Unlike FDA that typically accepts the recommendations of its panels, CMS has made it very clear that it might not follow MCAC recommendations. The MCAC does, however, play an important role in that it provides stakeholders with an open forum to discuss the merits of their technology and to discuss and/or dispute issues raised about the rigor of the evidence supporting it.

One of the more useful things to be developed as a result of MCAC was the “Interim Guidelines for Evaluating Effectiveness.” This document, which is available on the CMS Web site at www.hcfa.gov/coverage, was developed by the MCAC Executive Committee to provide guidance to the panels on how to assess the adequacy of the scientific evidence. It also provides a framework for measuring the size and direction of the health effect of a given technology. Although this document is intended for use by the panels only, it does seem to reflect the current mindset of agency decision makers. As a result, this can be an extremely useful tool for developing clinical trials.

Assuming the evidence reviewed by the panels is “adequate,” the panel will try to assess the size and direction of the health effect produced by the technology. The “Interim Guidelines for Evaluating Effectiveness” ask the panels to classify the technology into one of seven categories that describe the health effect in comparison to currently available alternatives:
- Breakthrough technology (no currently available alternative);
- More effective;
- As effective, but with advantages;
- Less effective, but with advantages;
- Less effective; and
- Not effective.

The advantages may include fewer complications, less invasive procedure, better tolerated by patients, etc. Again, CMS clearly states that cost is not a consideration; however, the most recent attempts at promulgating a coverage rule had a similar classification for determining “value.”

Given increasing financial pressures on the Medicare program, it is not unreasonable to assume that “value” won’t ultimately be defined to include cost savings.

Upon receipt of the MCAC’s report, the agency will finally issue a coverage decision (if it hasn’t earlier) in the form of a Decision Memorandum. These memoranda are published on the CMS Web site (www.hcfa.gov/8b3.htm), and they detail the findings of the various technology assessments MCAC reviews, and ultimately the rationale for either full or limited coverage or non-coverage. Like the MCAC guidance document, these Decision Memoranda can be useful in understanding current standards and trends in agency coverage policy.

As you can see from reviewing the Medicare coverage process, evidence is not just for FDA anymore and FDA clearance is no guarantee of coverage. Failing to collect adequate evidence during the regulatory process can delay or ultimately doom a product to failure. There have been products that have languished in the marketplace for 10 years due to lack of coverage or adequate payment.

To prevent that potentially disastrous outcome, consider:
- Including a reimbursement assessment of the product as early in the regulatory process as possible;
- Identifying outcomes that are relevant to payers and including them in the clinical trials;
- Conducting as rigorous a trial as possible understanding that you may not be able to run a trial that provides “all things to all people.”
- You simply need to make informed choices regarding what outcomes and methodologies are selected;
- Partnering with reimbursement and marketing personnel/consultants and ensuring frequent communication about each other’s strategies; and
- Having select payers review the clinical trial protocol to obtain feedback, keeping in mind that there are no guarantees of coverage even if the hypotheses are proven.

Value Demonstration

As stated earlier, Medicare does not currently consider cost per se when making coverage decisions. That is not to say that they won’t in the future. Private payers already consider cost arguments when making their policies, so if you plan on marketing to payers other than Medicare, you already have a need to be able to demonstrate the benefits of technology relative to its cost, which is referred to as “value.”

There may be other situations where you...
have a need to demonstrate value to audiences other than payers. This is especially true when the purchaser (the entity buying the technology) will not be reimbursed by the insurer (the entity paying for the patient’s healthcare) for your product. For example, you develop a device that is being used as an adjunct to some other major cardiac procedure. The primary procedure is covered by the payer and is paid a fixed rate under the DRG payment. Because of this, there is no other means of covering the cost of your new device. How do you convince the hospital administration to purchase the device?

In this case, you’ll need to look at value from the hospital’s perspective. What does the hospital gain by using the product? If the data show that patients who use the device during the hospital stay are discharged earlier, have fewer complications, and require fewer medications and other interventions, for example, you may be able to demonstrate that the hospital actually makes more money from the reimbursed amount by adopting the technology.

Many companies fear that collecting such data will be prohibitively expensive or time consuming. But there are a couple of approaches that can save both time and money. One is to collect as much data as possible during the pivotal trial for FDA clearance or post-marketing surveillance. Regulatory affairs professionals who understand the reimbursement process when designing clinical trials can identify data to collect that support economic decisions.

Another approach is to use an economic model. Economic models have the advantage of being able to use data from many sources, including literature, administrative claims databases, clinical trials and others, to demonstrate value. The cost and time required to make a value statement can be quite reasonable if efficacy data from a clinical trial can be combined with cost data from a claims database.

In addition, economic models can be used to project costs and benefits into the future. This is especially important for technologies that have high up-front cost, as most implantable devices do, but long payback periods. Models can be used to show the break-even follow-up time, or the cost savings accrued over time.

Ensuring that the model is credible to payers and purchasers is key. Credible models depend upon the validity of both the structure of the model and the data in it. Using expert advice for the structure of the model, such as physicians’ knowledge of the clinical course of a disease, and reliable sources for the data is critical. Feedback from potential payers and purchasers is always helpful as well.

Conclusion

While it is not easy to navigate the reimbursement labyrinth of coding, coverage and payment, they are crucial to the market success of new medical technology. The clinical study and regulatory route for FDA approval can help or hinder company efforts to receive coverage and adequate reimbursement. So it is important that you, as the regulatory affairs professional responsible for clinical study design, consider these issues at the same time that the clinical and regulatory strategies are being planned. Your company’s future growth may depend on it.

Martha Christian, MS, senior policy analyst with Princeton Reimbursement Group, assists clients by conducting reimbursement assessments and developing strategic plans for gaining reimbursement with a variety of payers. Melissa Martinson, PhD, principal advisor in health economics and statistics with the Regulatory and Clinical Research Institute, helps companies gain FDA approval and demonstrate the value of their products to payers, physicians, purchasers and patients. Both Princeton Reimbursement Group and Regulatory and Clinical Research Institute are in Minneapolis.

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