



By Judith Hickey

## Considering Reimbursement Issues During the Regulatory Planning Process for Product Success

As the regulatory expert, you successfully helped your company receive 510(k) clearance on its revolutionary new device. You participated in developing an appropriate and dynamic marketing campaign. The sales force is gaining favorable responses from the physicians. Then you learn that payers are not covering or paying for the device. Your management team meets with several payers, including CMS, who inform them that the product is interesting; however, they consider it “investigational” because there is insufficient clinical evidence to support coverage. Additionally, the products to which the new device is substantially equivalent are also considered “investigational” and are not covered. What went wrong?

In today’s environment, payers are increasingly sophisticated and rely more and more upon specific clinical evidence and health economic data to drive the reimbursement process. This makes it necessary for regulatory professionals to involve reimbursement professionals early in the product planning process and adjust clinical and regulatory strategies— not only to meet FDA’s needs, but to also ensure that the product will be reimbursed adequately, achieving marketplace success.

This article demonstrates how the clinical and regulatory plan can impact product reimbursement. It explains why obtaining product reimbursement differs greatly from FDA’s regulatory approval process, and why it is necessary to develop a well-planned and coordinated regulatory-reimbursement strategy.

### The Regulatory and Reimbursement Pathways

Regulatory professionals may feel their ability to affect the reimbursement outcome is limited. Where you have a substantial opportunity to impact a product’s reimbursement success is in coverage. Successful coverage is directly related to the relevance and quality of the clinical evidence available to support a product. The regulatory professional controls the type and quality of studies performed to support FDA clearance, which, in turn, provide the evidence to support favorable coverage decisions. For this reason, it is imperative that you develop parallel regulatory, clinical and reimbursement paths that address the needs of both FDA and the payers who control the product’s marketing destiny through their policy-making decisions.

While you are familiar with FDA and know how to navigate the regulatory maze to obtain market clearance, you probably have no idea who

the payers are that you have to factor into your regulatory and clinical strategy. Since all payers make coverage decisions, you could be dealing with any number of insurance companies, HMOs, 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 one another's lead—particularly Medicare's—in making coverage decisions. Thus, by exploring Medicare's coverage process, it is possible to gain a better understanding of payers' decision-making and, more importantly, what your regulatory and clinical plan needs to include to support reimbursement.

### The Medicare Coverage Process

The Medicare federal health insurance program was 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), and pays for items that are deemed “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 and lifestyle changes. However, some exceptions exist where Congress has passed legislation requiring coverage and payment for such specific services as mammography. To be covered by the program, all other products or services must fall into one of the statutorily defined benefit categories and be cleared for market by FDA.

While these requirements are fairly straightforward, 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 CMS has attempted to do so, medical device manufacturers, providers and the agency cannot reach agreement on acceptable criteria upon which to base coverage decisions. As a result, standards for determining what is reasonable and necessary are ever-evolving.

Despite the lack of defined Medicare coverage criteria and processes, decisions about what products are covered continue to be issued. These decisions may be made on a national, local or claim-by-claim basis. National policy is formulated by the Coverage and Analysis Group—a division within the CMS Office of Clinical Standards and Quality. Local policy is made by local Medicare contract medical directors who are responsible for a

given service area's claims and benefit administration. The Local Coverage Decisions (LCDs) these contractors issue are binding only on beneficiaries in their assigned service area, whereas national policy is binding on all 42 million Medicare beneficiaries.<sup>1</sup>

Regardless of whether the decisions are local or national, they are predicated upon the principles of evidence-based medicine. 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 Association have long-standing, formalized programs to assess how technology under review impacts health outcomes. The BCBS Technology Evaluation Center (TEC) utilizes the following criteria when reviewing evidence on new technologies:<sup>2</sup>

1. Technology must have received final approval from the appropriate governmental regulatory bodies.
2. Scientific evidence must permit conclusions concerning the technology's effect on health outcomes.
3. Technology must improve the net health outcome.
4. Technology must be as beneficial as any established alternatives.
5. Improvement must be attainable outside the investigational settings.

In conjunction with other data sources, these technology assessments provide the basis upon which reimbursement coverage policy is developed.

The shift toward an evidence-based process has substantially changed the quality and strength of evidence manufacturers are required to produce to satisfy CMS and the other organizations conducting technology assessments. Critics of the revised process have claimed that device manufacturers should not be held to a “pharmaceutical gold standard” to garner a favorable coverage policy. CMS responds that, although there is a hierarchy of evidence, preferring randomized, controlled trials, it does consider less-rigorous evidence when making decisions. While recent coverage decisions demonstrate the agency's willingness to consider the entire body of evidence, including input from key opinion leaders, it is clear that the more rigorous the supporting studies, the more likely the product is to gain program coverage.

CMS seeks accurate, well-defined clinical trials published in peer-reviewed journals. They should

detail measures of statistical significance (p-values, power, etc.). Treatment-allocation procedures (e.g., 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 and the majority of CHF patients are over the age of 65, your sample should include a proportion of patients over 65 that reflects the actual disease prevalence in that age group. More importantly, if you are requesting Medicare beneficiary coverage, it is absolutely critical to study that age group in your trial to allow the trial's results to be generalized to the Medicare population as a whole. Studies also should be free of bias that could cause the treatment effect to be over- or understated.

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

Bear in mind that evidence is no longer just for FDA anymore, and that agency clearance is no guarantee of coverage. Failing to collect adequate evidence during the regulatory process can delay or ultimately doom the product to failure. Some products have languished in the marketplace for 10 years due to lack of coverage or adequate payment.

In 1991, several pelvic floor stimulators received 510(k) clearance. However, because Medicare had a national non-coverage decision in place, the technology languished. It was not until 2000, when CMS reconsidered its decision and approved coverage under certain circumstances, that the technology began to be adopted to treat female urinary incontinence.

### Coverage Considerations for the Regulatory Professional

To prevent potentially disastrous outcomes, consider the following:

- Include a product reimbursement assessment as early in the regulatory process as possible.

- Identify outcomes relevant to payers and include them in your clinical trials.
- Consider having a biostatistician work with the clinical team to design a trial that will collect the information needed for coverage.
- Conduct as rigorous a trial as possible, understanding that a trial that provides "all things to all people" may not be achievable. Simply make informed choices about the outcomes and methodologies you select.
- Partner with reimbursement and marketing personnel/consultants and ensure frequent communication about one another's strategies.
- Consider having select payers review and provide feedback on your clinical trial protocol, bearing in mind that coverage is not guaranteed even if it proves the hypothesis.

### Demonstrating Value

Although Medicare does not currently consider cost, per se, when making coverage decisions, private payers do. If your company plans on marketing to payers other than Medicare, you need to demonstrate the technology's benefits relative to its cost. This cost/benefit relationship is often referred to by payers and providers as "value."

Audiences other than payers require demonstrated value as well. This is especially true when the product purchaser will not be reimbursed by the insurer 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 at a fixed rate under the DRG payment structure. As a result, there is no means of covering your device's cost. How can you persuade a hospital to purchase the device?

This case has to look at value from the hospital's perspective. If the data show that patients utilizing the device during their hospital stays are discharged earlier, have fewer complications, and require fewer medications and other interventions, it may be possible to demonstrate that the hospital actually makes more money from the reimbursed amount by adopting the technology. An example is vascular closure devices used to seal femoral artery punctures after catheterization procedures. The device usually does not receive separate reimbursement but allows for earlier ambulation and hospital discharge.

Many manufacturers fear that collecting such data will be prohibitively expensive or time-consuming, but there are a couple of approaches to consider. One is to collect most of the data during the pivotal trials to support FDA approval or postmarketing surveillance. Regulatory affairs professionals who understand the reimbursement process can help design clinical trials that will collect the data necessary to support economic decisions.

Another approach is to use an economic model, which enables the use of 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 a high up-front cost, as most implantable devices do, but long payback periods. Models can be used to show the break-even point or cost savings accrued over time.

Ensuring that the model is credible to payers and purchasers is vital. Reliable economic models depend upon the validity of both the model's

structure and the data utilized. In structuring the model, it is critical to seek advice from experts such as physicians with knowledge about a disease's clinical course. Feedback from potential payers and purchasers is always beneficial.

## Conclusions

While it is not easy to navigate the labyrinth of reimbursement coding, coverage and payment, it is crucial to the market success of the new medical technology. The clinical study and regulatory route for FDA approval can help or hinder a company's efforts to receive coverage and adequate reimbursement. Therefore, it is important for the regulatory affairs professional involved in the clinical study design to consider these issues at the same time that the clinical and regulatory strategies are being planned.

## REFERENCES

1. 2005 CMS Statistics from the U.S. Department of Health & Human Services at: [www.cms.hhs.gov/MedicareMedicaidStatSupp/downloads/2005\\_CMS\\_Statistics.pdf](http://www.cms.hhs.gov/MedicareMedicaidStatSupp/downloads/2005_CMS_Statistics.pdf)
2. Blue Cross Blue Shield website, TEC criteria at: <http://www.bcbs.com/tec/teccriteria.html>

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