FDA INSIGHTS

CAS Approval and Reimbursement

Let's not forget about the individual patient.

BY DOROTHY B. ABEL, WITH ANGELA C. SMITH AND KENNETH J. CAVANAUGH

The views and opinions presented in this article are those of the authors and do not necessarily reflect those of the US FDA, the US Department of Health and Human Services, or the Public Health Service.

One of the topics you will be sure to see on the agenda at vascular meetings this year is reimbursement for carotid artery stenting (CAS). What makes reimbursement for CAS unique as compared to that of other new technology? Rarely does the "introduction" of a new technology encompass such a full range and magnitude, of issues such as off-label use, turf battles, patient selection and credentialing, as CAS. Because of these issues, opinions associated with reimbursement for CAS are diverse and extreme. Although this makes for interesting and sometimes entertaining debates, the impact on public health and individual patient care is the most important aspect to contemplate. This article provides answers to common questions regarding CAS approval and reimbursement.

HOW DOES THE CURRENT REIMBURSEMENT POLICY AFFECT THE DIFFERENT PATIENT POPULATIONS?

According to the Centers for Medicare & Medicaid Services (CMS), reimbursement for CAS is currently restricted to patients at high risk of morbidity and mortality for carotid endarterectomy (CEA) who have >70% symptomatic stenoses, treated with an FDA-approved system, as well as patients treated under an approved Investigational Device Exemptions (IDE) application or as part of a postapproval study. Reimbursement is therefore not available for patients who fall outside of the selection criteria for clinical studies.

The selection criteria for IDEs are generally tailored to include a patient population that will allow for the collection of more easily interpretable and complete data that can be used to support a marketing application. One concern is that many patients who may benefit from CAS are not included in clinical studies and reimbursement. As such, data are not currently being generated for a large portion of potential CAS candidates. For example, patients with a relatively low risk of complications associated with CAS as compared to CEA may or may not be eligible for participation in studies.

WHAT DOES THE FDA DO FOR THE PATIENT?

The mission of the Center for Devices and Radiological Health (CDRH) is to promote and protect the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products. Our work encompasses the total product life cycle (ie, research through postmarket), but does not include cost assessment or reimbursement determinations.

In determining whether to allow a device to be used in a clinical research study, we consider the potential risks and benefits for the proposed patient population to be included in the study. For marketing applications, we consider the risk/benefit profile of the specific device demonstrated in the study for the specific population. Our assessment is in the context of identifying treatment options for the patients. We do not require that these studies demonstrate that a new technology should be the treatment of choice for the population.

The amount and type of data necessary to approve a specific device for different patient populations is based on the acceptable level of risk given the potential benefit that the treatment offers the patient. For example, if patients are not at high risk of having a stroke associated with their carotid artery disease, the risks associated with the device must be shown to be lower than for patients at high risk of stroke. As such, large, randomized, controlled clinical studies are needed for low-surgical-risk, asymptomatic patients.

Although the FDA has different levels of evidence required for labeling a device for CAS for specific patients, the FDA does not regulate practice of medicine. Clinicians can and have used stents that are cleared for marketing by the FDA for other indications (eg, treatment of biliary strictures) for CAS. In such cases of off-label use, the individual clinician and the institution take on the responsibility of ensuring that the device is reasonably safe and effective for treating the patient.

WHAT DOES THE CMS DO FOR THE PATIENT?

CMS is a separate agency from the FDA, although both agencies lie within the US Department of Health and Human Services. The mission of CMS is to ensure health care security for patients who receive benefits through Medicare and Medicaid. As part of this mission, CMS decides which procedures will be reimbursed for patients covered by these two services.

Coverage decisions are typically made by analyzing the relevant clinical data to determine whether a specific procedure is reasonable and necessary. If CMS decides to cover a procedure (not a specific device), they also specify the patient population that will be covered and the amount that a given physician will be reimbursed for performing the procedure.

For additional information on the coverage decision-making process, and on the CAS decision in particular, please refer to the interviews with Steve Phurrough, MD, MPA, CMS Director of Coverage and Analysis, in the September 2003 and June 2005 issues of *Endovascular Today.*

WHAT ARE THE EFFECTS OF FDA AND CMS DECISIONS ON THE TYPE OF TREATMENTS THAT PATIENTS WILL RECEIVE?

The CDRH decides whether or not medical devices can be marketed, which can obviously affect the treatment options available for a given patient. However, the FDA does not recommend or require that physicians perform specific procedures or use specific devices when treating a patient. The FDA does not regulate the practice of medicine, and so the treatment decisions are left to the individual physicians who best know how to care for their patients.

Like the FDA, CMS does not directly control the practice of medicine. However, by limiting the types of procedures that they will reimburse, CMS can indirectly affect the standard of care for more than 50 million Americans who rely on Medicare and Medicaid to cover their medical bills. In addition, they affect the care of millions more who are covered by private insurers that follow the recommendations of CMS. It is important to note that CMS is not actively seeking to mandate a standard of care in these situations; they are merely providing reimbursement guidelines based on their "reasonable and necessary" determination.

WHAT INVOLVEMENT DO THE FDA AND CMS HAVE IN CREDENTIALING AND TRAINING?

Approval orders for carotid stents include the following language: "…the labeling [must] specify the requirements that apply to the training of practitioners who may use the device as approved in this order." In addition, the approval orders include a requirement for the premarket approval application sponsor to implement a training program and to evaluate the adequacy of the program. Similarly, CMS has included a requirement for centers to be credentialed in CAS, either through previous or current participation in FDA-approved CAS studies or by meeting a set of requirements that they have developed.

HOW DO INDUSTRY, THE FDA, CMS, AND CLINICIANS INTERACT?

Development of CAS reimbursement policies has involved interactions between industry, the FDA, CMS, and clinicians. Individual companies and representatives from various clinical specialties have had conversations with the FDA and CMS, separately and together, about CAS studies (both pre- and postapproval) and pathways to expanded reimbursement. The goal of these meetings is to develop a plan that would minimize the number of studies required to meet the needs of both agencies. Of note is that the individual agencies cannot participate in meetings unless specifically invited by the company or the clinical group; that is, the agencies cannot invite each other to such meetings. As such, there is no guarantee that the FDA and CMS know what has been communicated to the other agency. Also, the FDA cannot influence the decisions made by CMS, but rather, can work with them to help identify the data needed to address their requirements.

WHAT ARE THE POTENTIAL PROBLEMS WITH THE CURRENT POLICIES?

There is a perception that there is too much government control.

Although neither CMS nor the FDA are charged with regulating medicine, their policies strongly influence treatment options for patients. CAS is unique in that off-label use of stents has led to general acceptance of this treatment option for a broad range of patient populations before robust data were available or issuance of a national coverage decision. Despite the fact that CAS is viewed by many as a viable treatment option, physicians are limited to the treatment of specific patients, using specific devices, in order for these procedures to be reimbursed. Although

this is the perceived problem, the real problem is that data are not available to identify all of the patient populations most likely to benefit from CAS.

Clinicians are receiving and giving inconsistent information/messages.

Given the skill set needed to perform CAS, there is a turf battle among the clinical specialties interested in taking care of patients with carotid artery disease. Each of these specialties brings its own expertise and biases to the clinic, partially due to a lack of comprehensive data to support a more uniform approach to patient care. Although this problem is not affected by the current reimbursement policies, it has led to the inclusion of credentialing requirements in these policies.

The industry may not easily recoup costs.

There are significant costs involved in conducting the clinical studies needed to demonstrate safety and effectiveness for FDA approval of a carotid stent. These costs are generally recouped in the marketing of the product postapproval. Further development and study of devices for specific patient populations may be hindered if reimbursement policies limit the ability of manufacturers to recover their costs. As such, it is critically important for all clinical studies to be optimally designed to ensure the collection of adequate data to support both CMS and FDA decisions.

WHAT DOES ALL OF THIS MEAN TO THE INDIVIDUAL PATIENT?

Given that industry, clinicians, CMS, and the FDA all recognize the importance of adequate training for CAS, there have been extensive efforts toward developing appropriate credentialing programs. Patients can be reassured that credentialed physicians should be reasonably proficient in CAS. The treatment of a patient with carotid artery disease, however, may still be strongly influenced by economic factors as well as medical opinions, in addition to available scientific evidence. This may limit the ability of an individual patient to receive his or her best treatment option.

As additional data are collected and presented to both the FDA and CMS, it is likely that CAS technology will be approved and reimbursed for broader applications. To obtain these critical data, industry and clinicians must be fully committed to conducting additional clinical studies. ■

Dorothy B. Abel, Angela C. Smith, and Kenneth J. Cavanaugh are Regulatory Review Scientists with the US FDA Center for Devices and Radiological Health in Rockville, Maryland. Ms. Abel is also a regular columnist for Endovascular Today. *Ms. Abel may be reached at (301) 443-8262, ext. 165; dba@cdrh.fda.gov.*

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