The Future of CAS Reimbursement

Steve Phurrough, MD, MPA, CMS Director of Coverage and Analysis, explains the implications of the recent CMS Decision Memorandum regarding CAS.

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On March 17, 2005, the Centers for Medicare & Medicaid Services (CMS) issued its long-awaited Decision Memorandum providing reimbursement for carotid artery stenting (CAS). *Endovascular Today* recently spoke with Steve Phurrough, MD, MPA, Director of Coverage and Analysis at CMS, to explain the implications of that decision (highlights of the decision are summarized in Table 1).

Endovascular Today: The recent CMS decision for reimbursement for CAS was far more restrictive than the FDA approval of the Guidant carotid artery stent system last August. In particular, asymptomatic patients are not covered, and high-risk, symptomatic patients are only covered if the stenosis exceeds 70%. Why the dichotomy?

Steve Phurrough, MD, MPA: There were a couple of things in our review that led to this decision. First, there was really only one major trial, the SAPPHIRE trial. SAPPHIRE was a randomized trial; ARCHeR was three separate observational studies using derived cohort comparative numbers for the endpoints of death and stroke. We were concerned that it was not an RCT and that the derived comparator endpoints may not have represented actual practice. There was also some concern about the fact that the randomization in SAPPHIRE was a bit different than would typically be seen. There was some preselection of people who would be put into a registry rather than randomized. Those were a few trial design issues that concerned us.

In addition, there was a fairly large trial, the Asymptomatic Carotid Surgery Trial (ACST), published late last year out of Europe on carotid endarterectomy (CEA) in an asymptomatic patient population. We believed it showed marginal benefit to CEA compared to medical therapy. In fact, medical therapy was better over the first couple of years, and then CEA did show some marginal difference over a 6-year period of time. However, the difference in the outcomes, the mortality, was less than 1% per year. We thought that was relevant because the SAPPHIRE trial, the randomized trial, was a noninferiority trial, meaning they were just trying to prove that CAS is no worse than CEA (or is as good as, depending on your viewpoint). Typically, what we like to see are superiority trials, but in this case, it was noninferiority. So, if SAPPHIRE is demonstrating that CAS is as good as CEA, but ACST only demonstrates a marginal benefit of CAS over medical therapy in the asymptomatic population, then we were concerned that the benefits of CAS in the asymptomatic, high–surgical-risk population needed better evidence.

EVT: Would CMS contemplate changing its position with respect to asymptomatic patients if studies showed superiority over CEA or medical therapy?

SP: Sure. There are studies underway now, and there are some postapproval studies ongoing through the FDA that we think will provide more information that in fact may cause us to change our decision. I think the major information that needs to be present in good-quality trials is whether CAS is better than CEA. That is the basic information we need to have. If the trials are not "good trials," or the evidence is not as strong as we would like it to be, we will look at other kinds of evidence, such as CEA versus best medical therapy. The determination to modify our decision will depend on the kind of evidence that comes out of these trials. We think there is likelihood that, as the evidence matures in the field of CAS, it may well show benefit. We were just not comfortable that it had shown benefit currently.

EVT: Do you think the studies that are presently ongoing such as CREST, CARESS, ACT I, and the post-market surveillance studies will be sufficient to help you make that determination?

SP: Well, CREST is limited to the symptomatic population. CARESS is the major asymptomatic population, and as I understand it, there are some thoughts on the part of NIH and the FDA to merge CREST and CARESS, so that they have both the asymptomatic and symptomatic population. That will obviously provide supporting information for the non–high-risk surgical patients, but I think it will be sufficient for us to help answer the questions about the high–surgical-risk patients, too. So, yes, I think CREST and CARESS are trials that we are anxious to see. I understand the manufacturers have some other trials in progress; I just don't know what those are at the moment.

TABLE 1. PATIENT INCLUSION

Patient Inclusion

CMS has provided for reimbursement for CAS for patients that are high risk for CEA and meet the following criteria:

- Using FDA-approved CAS systems and embolic protection devices with symptomatic carotid artery stenosis >70%
- In Category B IDE clinical trials or in CAS postapproval studies with
  a) Symptomatic carotid artery stenosis between 50% and 70%, or
  b) Asymptomatic carotid artery stenosis between >80%

High Risk for CEA

- Significant comorbidities and/or
- Anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection), and
- Surgeon determines that the patient would be a poor candidate for CEA
- High-risk determination should be documented in the patient's medical records prior to performing any procedure

Significant Comorbidities (include but not limited to)

- Congestive heart failure class III/IV
- Left ventricular ejection fraction <30%
- Unstable angina
- Contralateral carotid occlusion
- Recent myocardial infarction
- Previous CEA with recurrent stenosis
- Prior radiation treatment to the neck
- Other conditions that were used to determine patients at high risk for CEA in the prior CAS trials and studies, such as ARCHeR, CABERNET, SAPPHIRE, BEACH, and MAVERIC II

Symptoms of Carotid Artery Stenosis

- Carotid transient ischemic attack (distinct focal neurologic dysfunction persisting <24 hours)
- Focal cerebral ischemia producing a nondisabling stroke (modified Rankin scale <3 with symptoms for 24 hours or more)
- Transient monocular blindness (amaurosis fugax)
- Patients who have had a disabling stroke (modified Rankin scale >3) are excluded from coverage

Measurement of Carotid Artery Stenosis

- Should be measured by duplex Doppler ultrasound or carotid artery angiography
- Must be recorded in the patient's medical records
- If measured by ultrasound prior to the procedure, the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be <70% by angiography, then CAS should not proceed

TABLE 2. FACILITY REQUIREMENTS

Required Infrastructure

Necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program, specifically:

- High-quality x-ray imaging equipment, such as high-resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation
- Advanced physiologic monitoring, including real-time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately
- Emergency management equipment and systems (resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support)

Credentialing

- Each institution should have an oversight committee empowered to:
  - a) Identify the minimum case volume for an operator to maintain privileges
  - b) Set (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation
- The committee should apply published standards from national specialty societies (including those published in the *American Journal of Neuroradiology* and *Journal of the American College of Cardiology*)

Data Collection

- Facility must collect data on all CAS procedures performed at that particular facility
- Data must be analyzed routinely (at least every 6 months) to ensure patient safety
- Data will also be used in the process of re-credentialing the facility
- Data must be made available to CMS upon request

Facility Evaluation

- Facilities must provide written documentation to CMS that the facility meets one of the following:
  - a) The facility was an FDA-approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE and ARCHeR
  - b) The facility is an FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST
  - c) The facility is an FDA-approved site for one or more FDA postapproval studies, or
  - d) The facility has provided a written affidavit to CMS attesting that the facility has met the minimum facility standards

EVT: Does the difference between FDA and CMS decision making come down to legislative mandates? The FDA is required to determine what is "safe and effective" and CMS is to determine what is "reasonable and necessary." Is that a key distinction here?

SP: That is the actual law that we have to follow. The real question is: What is the difference between "safe and effective" and "reasonable and necessary"? In most cases, you come up with the same answer. I think the cases in which you may not come up with the same answer are those in which the populations are different, when there is evidence that becomes available that one of the two entities may not have reviewed, or if there is an ongoing safety issue that may not be completely resolved. If the risk-benefit ratio is narrow, then we may be a bit more concerned about giving it to our population versus the FDA's approval for the general population.

I think that those are the kinds of instances in which we may do something different than the FDA. It's going to be uncommon. I think we have done something different from the FDA only twice, so it's going to be uncommon, and we'll have to be careful to make sure we attempt to be consistent in how we discuss why we would or would not do that.

EVT: What was the other instance in which CMS varied from the FDA?

SP: The MADIT II decision on implantable defibrillators.

EVT: Prior to conducting the studies, did the sponsors receive any input from CMS?

SP: We did not meet with the companies prior to any of the trials. They did present us the trial results prior to FDA approval, but the trials were already underway. We have been involved in discussions setting up both CREST and CARESS, but not in SAPPHIRE or the ARCHeR trials.

EVT: Did the sponsors of CREST and CARESS follow your recommendations?

SP: Our recommendations were joint discussions with the FDA and NIH; they were not separate and independent recommendations. I think that CREST currently has a good design and we are comfortable with that particular design. I am not sure what's happening with CARESS right now. If CARESS is rolled into CREST, and CREST is expanded, we would expect that there would be a change in power calculations that would change enrollment numbers. I think we were comfortable conceptually with how CARESS was going to be done.

EVT: Another notable aspect of the recent decision has been the facility requirements (Table 2), particularly the credentialing process. Is that a first for the CMS?

SP: Well, we have conditions of participation for all Medicare hospitals that say you have to mandate physician credentialing. I think what's different in this Decision is that we re-emphasize that we expect hospitals to credential physicians, but we expect them to use national standards. I'm not aware that we have done that before. Our concern was that there are some cases in which there is a dominant physician in a facility, possibly resulting in standards being established for credentialing that match his particular talents and skill level, and we wanted to make sure that was not the case in this particular procedure because there are significant questions about the diffusion in this technology to other facilities. We wanted to make sure that national standards were being applied in the credentialing process.

EVT: Under the CMS Decision, are vascular surgeons required to be involved in the decision to submit any patient for CAS?

SP: Yes. Our expectation is that a surgeon will opine that the patient is high risk for CEA.

EVT: Is it accurate to say that the hospitals must come up with one policy that governs this procedure for the entire hospital? Can the cardiology and radiology departments have different credentialing policies?

SP: No, hospitals can decide to do that however they wish. If the hospital decides that radiologists need to have larger numbers of procedures than cardiologists do, that is acceptable as long as both of those standards meet a national standard. I believe that is what the credential committees are supposed to do. They take into account the basic knowledge and skill level of a certain specialty, and if members of that specialty want to perform a certain procedure, they establish the increased amount of knowledge you need to do that procedure. And that could vary among specialists. I think that is an appropriate role for a credentials committee.

In most hospitals, a department recommends to the hospital what their department standards should be, but it is up to the hospital to approve that department's recommendations. Under this decision, if a particular department were to make a recommendation that was less than a national standard for their particular specialty, we are saying that the hospital cannot accept that.

EVT: The collection of data that are required under this decision will be a very interesting resource. Will that information be made available to the public?

SP: Our goal is to make as much data public as possible, but we want to make sure that the data we are making public are good data, data that can be used to make appropriate decisions. Because we are not defining how those data need to be collected, until we see some of it in the future, it is hard to know whether we will make it public or not. It might not be data that you could aggregate. We were strongly encouraged to require a national registry, but that did not suit our purpose. We were not looking for a level of evidence that would cause us to change our coverage decision.

This was unlike some of our other decisions in which we required registries. In those cases, we did so because we thought there was already a sufficient basic evidentiary base, and we just wanted additional data. In this case, we do not think that CAS has the strong evidentiary base that it needs, so we want more trials to be done. So our requirement for registry data here is for facility standards purposes, which may not result in the collection of data that can be aggregated and examined as well. We hope that requiring data to be collected and compared to national norms will stimulate hospitals to take part in some of the national registries that are being developed. In these cases, the data may be good enough that we can use it to look at outcomes. You always have to wait and see how that falls into place.

EVT: Some have argued that the facility requirements are akin to turning carotid stenting into a destination therapy procedure. Is that an interest of CMS, or may that be a collateral effect?

SP: There was no intent to link these two in any manner. The only similarity is that we are establishing facility standards; we are doing it in a somewhat different manner, but we are establishing facility standards. In that regard it is like left ventricular assist devices (destination therapy), but it is not an outgrowth of those devices.

EVT: Will the future of reimbursement change? Is there an ongoing shift within CMS with respect to reimbursement decisions on predicate therapy?

SP: Our level of evidence for doing national coverage determination isn't changing. What is changing is that we are addressing more technologies, and there is no possible way of addressing all of them. First of all, those that we are asked to address we will address, because we are required to do so. However, there will also be instances in which we believe, based on review of the medical literature or a review of our claims data, that will result in our opening a coverage decision. Does that mean will we look at all stenting issues? No, we do not have any particular schedule that says, "Here are the issues that we are going to be addressing." We take them as they come up.

EVT: Private healthcare insurers are not bound by the CMS decisions, and approximately half of the covered lives under private insurance have a reimbursement policy for CAS that is consistent with the FDA's inclusion criteria (asymptomatic patients, etc). Does private insurance reimbursement create pressure on the CMS to offer similar coverage?

SP: It hasn't yet. ■

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