CMS and Carotid Artery Stenting

 CMS's history with carotid and vertebral intervention, including the current status.

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Carotid artery stenting (CAS) with embolic protection has become one of the most widely studied medical procedures of all time. Specifically, the subgroup of patients who are being considered for revascularization to prevent stroke but are also at increased risk for carotid surgery either due to medical comorbidities or anatomic factors are the most in need of this less-invasive option. Randomized trial evidence from SAPPHIRE supports equipoise for CAS and carotid endarterectomy (CEA) in this high-risk group of patients. This year, publications in peer-reviewed journals of more than 8,000 CAS high-surgical-risk registry patients demonstrated that the American Heart Association’s (AHA) 30-day stroke and death rate benchmark of < 3% for asymptomatic patients and ≤ 6% for symptomatic patients can be met in NASCET and ACAS comparable populations.

Why, then, does the debate continue? The house of medicine cannot seem to solve its turf battles, and the Centers for Medicare & Medicaid Services (CMS) uses that dissonance to continue to withhold payment for this less-invasive therapy. The disconnect between this and the US Food and Drug Administration’s (FDA) approval of five carotid stent device systems as safe and effective continues to be a source of confusion and embarrassment as CMS tries to explain why CAS does not meet their criteria for what is reasonable and necessary. The final answer in this quest for Medicare reimbursement remains elusive as the bar seems to keep moving out of reach, with CMS weakly responding that they need more data but never actually disclosing what data would satisfy them. It is a frustrating subjective process, without objective endpoints, that is putting some of our Medicare patients at a true disadvantage because they do not have a choice of therapies.

HISTORY OF MEDICARE COVERAGE OF CAS

Understanding the history of CMS’s reimbursement decisions for carotid artery endovascular intervention will help us to better comprehend the current conundrum faced by CMS in trying to work out how to cover this important service for our patients. Another reason to understand the past process was clearly stated by the Spanish-American philosopher, George Santayana: “Those who cannot remember the past are condemned to repeat it.”

Congress created a statutory mandate whereby National Coverage Decisions (NCDs) were intended to supplement the Social Security Act, which specified that no payment would be made for services that are not reasonable and necessary. Early NCDs denied payment when there was evidence of lack of effectiveness. In 1997, the Coverage and Analysis Group (CAG) was formed within CMS and was given sole responsibility for developing NCDs. The CAG has

**CMS CRITERIA FOR HIGH-SURGICAL-RISK PATIENTS**

- Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection) and would be poor candidates for CEA in the opinion of a surgeon.
- Significant comorbid conditions include, but are 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;
  - Previous radiation treatment to the neck;
  - Other conditions that were used to determine patients at high risk for CEA in the previous CAS trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.
moved away from accepting negative evidence and has begun to require some arbitrary level of evidence to justify coverage. This is a problem because the target in CAS has not been an objective one but a subjective one that proves difficult for CMS to explain other than the circular reasoning of not being “reasonable and necessary.”

Before the March 19, 2001 NCD, percutaneous transluminal angioplasty (PTA) was not covered for obstructive lesions of the carotid, vertebral, and cerebral arteries. Therefore, any services related to percutaneous therapies of these arteries, including services related to follow-up care and complications that require treatment during the same hospital stay in which the endovascular therapy was performed, were not covered services under Medicare.1 In the next several paragraphs, I will paraphrase the CMS 2001 document.

As early as 1980, there was consensus among CMS consultants and the agency that PTA for noncoronary vessels (primarily atherosclerotic lesions of the iliac, popliteal, and femoral arteries) was generally accepted and performed. In 1981, there was a request to assess the effectiveness of PTA in noncoronary vessels. At that time, there was no specific national coverage policy related to noncoronary vessels so that CMS contractors had discretion in determining coverage for these procedures. In May 1981, coverage of PTA for the treatment of atherosclerotic obstructions in the lower extremities became effective.

In 1984, the Office of Healthcare Technology provided CMS with an assessment titled, “Percutaneous Transluminal Angioplasty for Obstructive Lesions of the Aortic Arch Vessels.” The authors noted a high degree of success and a low complication rate with careful patient selection when PTA was performed by an experienced individual; however, the “treatment of patients with obstructive lesions of the aortic arch vessels with PTA is a relatively new procedure that lacks adequate long-term follow-up.” Upon review of this document, CMS issued a national noncoverage policy for PTA for treating obstructive lesions of the aortic arch vessels. Subsequently, CMS amended the PTA policy to cover the upper extremities (not including the head and neck).

In September 1995, CMS adopted a policy to reimburse for category B (nonexperimental/investigational) devices used under FDA protocols to provide Medicare beneficiaries with earlier access to the latest advances in medical technology while facilitating data collection through clinical trials. However, because of the noncoverage decision for PTA and carotid arteries, CMS was unable to reimburse for clinical trials. This led to the July 1, 2001 NCD that permitted limited coverage in the context of an FDA-approved category B investigational device exemption (IDE) trial. Next came a further modification on October 12, 2004 that permitted CMS coverage for carotid stenting in accordance with FDA postapproval protocols.

On March 17, 2005, CMS further expanded coverage for carotid stents with embolic protection to include high-surgical-risk symptomatic patients with > 70% stenosis treated with FDA-approved devices. They also specified coverage for high-surgical-risk asymptomatic patients with 50% to 70% stenosis in accordance with FDA category B IDE preapproval and postapproval studies. Coverage was also extended to high-surgical-risk asymptomatic patients with > 80% stenosis in accordance with FDA category B IDE preapproval and postapproval studies. Coverage was further restricted to procedures performed with FDA-approved carotid stents and embolic protection devices. The use of embolic protection devices was required by CMS, and if they could not be used, CMS required that the procedure be abandoned. CMS further specified which patients were at high surgical risk and would be poor candidates in the opinion of a surgeon (see sidebar titled CMS Criteria for High-Surgical-Risk Patients). Further mandates for coverage included what qualified as symptoms of a carotid stenosis (see CMS Definition of Symptomatic Carotid Stenosis), how stenoses should be measured (see CMS Guidelines for Carotid Stenosis Measurement), criteria for facility certification (see CMS

### CMS Definition of Symptomatic Carotid Stenosis

Symptoms of carotid artery stenosis include:

- 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);
- Patients who have had a disabling stroke (modified Rankin scale ≥ 3) are excluded from coverage.

### CMS Guidelines for Carotid Stenosis Measurement

- The degree of carotid artery stenosis should be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the medical records.
- If the stenosis is measured by ultrasound before the procedure, then 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 be performed.
In December of 2007, CMS received a joint request from multiple specialty societies to revise the current Medicare policy and extend coverage to “patients who are at high risk for CEA due to defined anatomic factors and who have either symptomatic carotid artery stenosis of 50% to 69% (or greater) or asymptomatic carotid artery stenosis of > 80%.” The requestors stated: “There is compelling clinical rationale and need for patients in the anatomic group defined above to have access to CAS. These patients do not have an acceptable surgical option, due to their anatomic conditions, which inherently preclude or severely limit safe surgical access.” They also “recommend that CMS’s new coverage policy mandate participation in robust data registries such as NCDR’s CARE registry. High-quality audited data generated by such registries will help CMS assess the wisdom of our requested coverage expansion and may provide some guidance for future decisions regarding coverage.”

In October 2008, after review of the currently available information, including a negative technology assessment from the private insurer Blue Cross/Blue Shield, CMS decided not to expand coverage because there was not enough peer-reviewed literature (CAG-00085R6).

In early 2009, after publication of three large registry trials (SAPPHIRE Worldwide [n = 2,001],3 CAPTURE-2 [n = 4,175],4 and EXACT [n = 2,145]4 totaling more than 8,000 new high-surgical-risk patients, CMS reopened the carotid coverage decision for the seventh time (CAG-00085R7). These new patients were treated by a cross-section of experienced and less-experienced operators with neurologic confirmed outcomes in patients < 80 years of age consistent with the AHA benchmarks of a 30-day stroke and death rate of ≤ 3% in asymptomatic patients and ≤ 6% in symptomatic patients. CMS’s proposed decision memo, dated September 10, 2009, states that no expansion in coverage is warranted, but the language regarding embolic protection is modified to include both proximal and distal FDA-approved devices.

CONCLUSION

It is difficult to understand CMS’s reasoning at this point. Limiting our discussion to patients considered to be at high surgical risk, with symptomatic lesions > 50% and asymptomatic lesions ≥ 80% by angiography, seems to be supported by an aggregate of more than 10,000 patients studied. More than 8,000 patients reported this year show the ability to meet the AHA benchmark for 30-day stroke and death rates in a population of patients similar to ACAS and NASCET (ie, < 80 years). No one is suggesting that CAS be required—only that it be considered a possible alternative by the patient and his physician.

We currently have a major problem with what appears to be overzealous government regulation of medical prac-
tions to market their CAS devices, only to find that the manufacturers succeeded in obtaining labeling indica-

outcomes for this patient-friendly, less-invasive procedure.

This is a Catch-22 for industry, which invests millions of dollars in technology to improve the quality of the individual interventionists and the program as a whole.

Given that it is unlikely that industry will continue to fund more trials and that it is perhaps unethical to further randomize high-surgical-risk patients, we should be asking the question of whether CMS should be paying for carotid stenting in high-risk patients. Certainly, it is not clear that an operation in a higher-risk patient is “reasonable and necessary.” Perhaps vascular surgeons would be more willing to consider CAS as an alternative to CEA if their ability to perform surgery on high-risk patients was limited.

Currently, there are Medicare patients who fall between the coverage cracks. They are at increased risk for a carotid surgical procedure (not necessarily contraindicated), but due to various other factors, they do not qualify for any of the current categories of reimbursement. These Medicare patients are being asked to pay out of pocket for the CAS procedure because it is not covered by CMS. This clearly seems to be an unreasonable stance given the data. A major lesson in this journey has come from the turf battles over carotid stenting between the vascular surgeons and radiologists; when doctors disagree, regardless of the reasons, government tends to do nothing. Until the physician specialties can resolve their differences and speak with a unified voice, its unlikely that significant expansion of CAS coverage will occur, and patients will continue to suffer from lack of choice of reasonable treatments.

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