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EDITOR'S PAGE

Catch-22: Carotid Stenting Is Safe and Effective (Food and Drug Administration) But Is it Reasonable and Necessary (Centers for Medicare and Medicaid Services)?

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It is time once again for the Centers for Medicare and Medicaid Services (CMS) to reconsider the National Coverage Determination (NCD) for carotid artery stenting (CAS) in light of: 1) the completion of CREST (Carotid Revascularization Endarterectomy vs. Stenting Trial), the largest prospective, multicenter, randomized controlled trial of carotid endarterectomy (CEA) versus CAS in average surgical risk patients (1); 2) approval by the U.S. Food and Drug Administration (FDA) of CAS systems for *symptomatic* and *asymptomatic* patients; and 3) publication of 2 multisocietal professional guideline documents supporting CAS as an appropriate alternative to CEA with a Level I recommendation in *symptomatic* patients, and a Level II recommendation in *asymptomatic* patients (2,3). The timing of this determination is critical to patient access for CAS, as several industry-sponsored post-market extension studies have closed (CABANA [Carotid Stenting Boston Scientific Surveillance Program], Boston Scientific Corp., Maple Grove, Minnesota) or will be closing soon (CHOICE [Carotid Stenting For High Surgical-Risk Patients; Evaluating Outcomes Through The Collection Of Clinical Evidence], Abbott Vascular, Santa Clara, California), putting Medicare beneficiaries in a difficult position.

To understand the importance of the upcoming coverage decision by CMS, we need to review the history of CAS reimbursement. As philosopher George Santayana said "those who cannot remember the past are condemned to repeat it (4)." The standard to be met for CMS coverage is "*reasonable and necessary*," which stakeholders struggle to understand because it has never been defined. The fact that 2 government agencies (FDA = safe and effective; and CMS = reasonable and necessary) have distinctly different mandates has the makings of a "Catch-22" situation.

In the mid-1980s, the CMS issued a national noncoverage decision for angioplasty of obstructive lesions of the carotid, vertebral, and cerebral arteries (5). In 2001 and 2004, the NCD was expanded to allow coverage for CAS as part of an FDA-approved Category B Investigational Device Exemption (IDE) trial, and to FDA-sanctioned post-approval trials. In 2005, the CMS further expanded coverage to include high surgical risk symptomatic patients with 70% to 99% carotid artery stenosis treated with FDA-approved devices. In October of 2008, the CMS declined to expand coverage for high surgical risk seniors, stating there was inadequate peer-reviewed literature to support such a change. Following the publication of studies with over 8,000 high surgical risk patients in 2009, (SAPPHIRE Worldwide [Stenting and Angioplasty With Protection in Patients At High-Risk for Endarterectomy], Cordis Corp., Miami Lakes, Florida [n = 2,001] [6], CAPTURE-2 [Carotid RX ACCULINK(TM)/ACCUNET(TM) Post-Approval Trial to Uncover Unanticipated or Rare Events], Abbott Vascular, Santa Clara, California [n = 4,175], and EXACT [Emboshield and Xact Post Approval Carotid Stent Approval, Abbott Vascular] [n = 2,145] [7]), with excellent results, the CMS reopened the carotid NCD for the seventh time but once again failed to expand coverage.

We can no longer rely on a decreasing number of FDA-sanctioned trials for coverage of our patients, because too many Medicare patients do not qualify for these clinical trials.

To break this log jam, and reach the CMS bar of "reasonable and necessary," some have proposed linking expanded coverage of CAS with a mandate for patient data collection.

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There are multiple special interest groups (physicians [surgeons, neurologists, cardiologists, and radiologists], the medical device industry, and health insurers) trying to influence the government to expand or restrict CAS coverage. The fact that there is such strong disagreement on both sides of the CAS versus CEA controversy among physician stakeholders is strong evidence for equipoise (8,9). However, given our responsibility as physicians to provide the best care for patients, we must put aside our "personal interests." The published, peer-reviewed evidence supports CAS as a reasonable alternative to CEA in both high and average surgical risk patients as reflected in the American Heart Association (AHA) and American Stroke Association (ASA) guidelines document (3) and the broad multisociety guidelines endorsed by 14 stakeholder professional societies (2). The largest randomized trial of CAS versus CEA ever performed showed no difference in the overall stroke rate between CAS and CEA (1). With increasing experience, there has been dramatic improvement in CAS outcomes over time (9–11). As responsible physicians, we know that procedures such as CEA and CAS have better outcomes when patients are carefully selected, and experienced and skilled operators perform the procedures in experienced centers. To take advantage of this opportunity for tailored therapy in the patients most likely to benefit requires the ability to choose between CEA or CAS.

The debate about effective alternatives for the treatment of carotid artery stenosis has moved beyond revascularization, as some contend that improved medical therapy is now equivalent, if not superior, to revascularization (11). While this hypothesis is attractive, the current evidence is far from conclusive. There are no randomized, multicenter, prospective trials of optimal medical therapy (including pill counts for patient compliance, rates of treatment to goal, or independent medical therapy adjudication committees) as primary treatment for "revascularization-eligible" patients. A major change in evidenced-based stroke prevention strategies will require clinical trial data. The short-cut of simply extrapolating data from atherosclerotic coronary artery trials could lead to serious errors.

To break this log jam, and reach the CMS bar of "*reasonable and necessary,*" some have proposed linking expanded coverage of CAS with a mandate for patient data collection. For example, *symptomatic* patients with carotid stenosis ≥50% by angiography (or ≥70% by ultrasound, magnetic resonance angiography [MRA], or computed tomography angiography [CTA]), would be eligible for reimbursement for CAS with: 1) mandatory facility certification by an independent accrediting organization; 2) participation in a national prospective registry with collection of minimum data elements (i.e., National Institutes of Health Stroke Scale [NIHSS] determination before and at 30 days following the procedure, and minimum facility and operator experience); and 3) site- and operator-level outcomes analyses required for reporting and accreditation.

Asymptomatic patients with carotid stenosis ≥60% by angiography (or ≥70% by ultrasound, or ≥80% by MRA or CTA) would be held to a higher bar for reimbursement. In addition to the requirements for symptomatic patients, centers that treat *asymptomatic* patients would also be subjected to an independent audit, by an accrediting body, to verify the accuracy of the reported data. Similar to post-market surveillance studies, approximately 1 in 10 records (10%) would be audited. Sites with data quality problems would be reported to the appropriate independent accrediting body, potentially resulting in loss of CAS privileges.

We can no longer rely on a decreasing number of FDA-sanctioned trials for coverage of our patients, because too many Medicare patients do not qualify for these clinical trials. The patient's plight is similar to the ancient mariner's "water, water, everywhere and not a drop to drink." While there are multiple FDA-approved "safe and effective" CAS systems available, only a tiny fraction of Medicare patients are covered by the CMS "reasonable and necessary" standard. We have multispecialty guidelines supporting CAS as an alternative to CEA in selected patients (2,3). The largest randomized carotid stenosis trial ever performed (CREST) supports equivalence for CEA and CAS (1). This begs the question: what more can be done?

Has CMS raised the bar of "reasonable and necessary" to unattainable levels, hiding behind a shield of physician disagreement to "ration healthcare" by denying expansion of CAS coverage to be equivalent with CEA? Or is this simply the CMS using the "Catch-22," to deny American seniors access to therapy they should "reasonably and necessarily" have available to them?

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