Centers for Medicare and Medicaid Services conducts a medical evidence development and coverage advisory committee meeting on carotid atherosclerosis: Executive summary

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Most clinicians are aware that a national coverage determination (NCD) for carotid angioplasty and stenting (CAS) exists that restricts reimbursement for CAS in Medicare beneficiaries to patients with high-grade symptomatic carotid stenosis who are at high risk for carotid endarterectomy (CEA). Coverage is also in place for patients being enrolled in appropriate clinical trials of CAS. Publication of the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) in mid-2010 engendered renewed debate about CEA vs CAS, and it was anticipated that there would be yet another application to the Centers for Medicare and Medicaid Services (CMS) for reconsideration of the NCD relative to CAS. In anticipation of same, the SVS Board of Directors voted 21 of 22 at its June 2011 meeting against any change in the current NCD for CAS.

An application for such reconsideration was submitted, but denied by CMS. Rather, CMS convened a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on January 25, 2012, to allow a current deliberation of the state of the art technology and science referable to carotid bifurcation atherosclerosis. The MEDCAC differs substantially from a reconsideration of coverage determination and, in this case, was built around seven research questions. The MEDCAC consists of a panel of experts who, after reviewing the pertinent literature and submitted commentary by interested stakeholders, and after hearing testimony from invited speakers and at-large presentations, held a panel vote on the research questions.

Also germane to the timing of the MEDCAC was the fact that five different international practice guidelines were published during calendar year 2011 referable to carotid disease management. The Society for Vascular Surgery (SVS) both endorsed the multispecialty practice guidelines published in January 2011 and updated its own practice guidelines, in the September 2011 *Journal of Vascular Surgery*.

Given that management of carotid disease is a core element of vascular surgical practice, SVS had a major presence at the MEDCAC in the form of a comprehensive written document individually considering the research questions and constituting the bulk of the present communication. In addition, SVS executive committee members and delegates presented six "at-large" presentations at the MEDCAC addressing various aspects of carotid disease management. MEDCAC invited speakers were chosen to represent a spectrum of specialties and viewpoints referable to carotid disease (neurology, interventional cardiology, and vascular surgery) with such invited speakers allotted 20 minutes to present to the panel. The panel chairman repeatedly emphasized to all presenters and the panel that the essence of the meeting of the MEDCAC was a consideration of the *available evidence* rather than individual clinician experience or bias, or both.

The SVS presentations, written commentary, and in fact, the invited presentation of a vascular surgery representative (Wesley Moore, MD), were entirely consistent with the SVS updated practice guidelines. Similar to the posture of the MEDCAC panel, SVS practice guidelines reflect best available evidence and consider the relevant clinical outcomes to be periprocedural stroke and death.

The MEDCAC panel votes on the six research questions were concordant with SVS position statements on the important elements of the natural history of high-grade asymptomatic carotid stenosis and the prediction of adverse events after CEA. The most striking concordance between the SVS position and the MEDCAC panel vote related to

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the treatment of symptomatic carotid stenosis, where the panel favored CEA as the optimal treatment strategy for such patients. In the realm of asymptomatic patients, the research questions were parsed into consideration of procedural risk for CEA and also qualifying patients by whether they are at high risk for stroke.

Management of asymptomatic patients is influenced by claims that optimal medical therapy has substantially reduced the stroke risk associated with asymptomatic carotid stenosis; however, this contention remains unproven by the best available evidence, particularly in patients with high-grade stenosis, wherein intervention would be considered by SVS guidelines. Although multiple practice guidelines published in 2011 support the performance of CEA in appropriately selected asymptomatic patients, the MEDCAC panel had low confidence about the role of any intervention vs optimal medical therapy in patients with asymptomatic carotid stenosis. SVS supports the position that future trials in asymptomatic patients should include an optimal medical therapy arm. SVS has also identified further research in the realm of asymptomatic carotid stenosis as its number 1 clinical research priority.

The further course and outcomes of the CMS MEDCAC are not clearly defined at the moment. Obviously, it will be a repository of information (the intent of this SVS document) should CMS choose to reopen the issue of the NCD for CAS.