Why the US Center for Medicare and Medicaid Services Should Not Extend Reimbursement Indications for Carotid Artery Angioplasty/Stenting

Anne L. Abbott, MD, PhD, FRACP1, Mark A. Adelman, MD2, Andrei V. Alexandrov, MD3, Henry J. M. Barnett C. C., MD4, Jonathan Beard, FRCS, ChM, Med5, Peter Bell, MD, FRCS6,7, Martin Björck, MD, PhD8, David Blacker, MD, FRACP9, Clifford J. Buckley, MD, FACS10,11,12, Richard P. Cambria, MD13,14, Anthony J. Comerota, MD, FACS, FACC, RVT15, E. Sander Connolly Jr, MD16, Alun H. Davies, MA, DM, FRCS, FHEA, FEBVS, FACPh17, Hans-Henning Eckstein, MD, PhD18,19, Rishad Faruqi, MD, FACS20,21,22, Gustav Fraedrich, MD23, Peter Gloviczki, MD24, Graeme J. Hankey, MD, FRACP25, Robert E. Harbaugh, MD, FAANS, FACS, FAHA26,27,28, Eitan Heldenberg, MD29, Steven J. Kittner, MD, MHP30, Timothy J. Kleinig, PhD, FRACP, MBBS31,32, Dimitri P. Mikhailidis, MSc, MD, FRSPH, FCP, FFPM, FRCPath33, Wesley S. Moore, MD34, Ross Naylor, MD, FRCs35, Andrew Nicolaides, MS, FRCS, PhD36, Kosmas I. Paraskevas, MD37, David M. Pelz, MD, FRCPC38, James W. Prichard, MD39, Grant Purdie, MD, FRACP40, Jean-Baptiste Ricco, MD, PhD41, Thomas Riles, MD42, Peter Rothwell, MD, PhD, FRCPE, FMedSci43, Peter Sandercock, MA, DM, FRCPE, FMedSci44, Henrik Sillesen, MD, DMSc45, J. David Spence, MBA, MD, FRCPC, FAHA, FCAHS46,47, Francesco Spinelli, MD48, Aaron Tan, FRACP49, Ankur Thapar, MBBS, MRCS50, Frank J. Veith, MD42,50,51, and Wei Zhou, MD52,53

1 Baker IDI Heart & Diabetes Institute and Florey Neuroscience Institutes, Melbourne, Australia
2 Vascular and Endovascular Surgery, New York University Langone Medical Center, New York, NY, USA
3 Comprehensive Stroke Center, University of Alabama Hospital, South Birmingham, AL, USA
4 University of Western Ontario, Toronto, Ontario, Canada
5 Sheffield Vascular Institute, Northern General Hospital, Sheffield, United Kingdom
6 University of Leicester, Leicester, UK
7 University of Leicester Hospitals, Osadby, Leicester, United Kingdom
8 Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, Uppsala, Sweden
9 Department of Neurology, Sir Charles Gairdner Hospital, Nedlands WA, Australia
10 Texas A&M Health Sciences Center College of Medicine, TX, USA
11 Department of Surgery; Director Division of Vascular Surgery, Scott and White Health Care Systems, TX, USA
12 Central Texas Veterans Health Care System, TX, USA
13 Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, Boston, MA, USA
14 Harvard Medical School, Boston, MA, USA
15 Jobst Vascular Institute, The Toledo Hospital, Toledo, OH, USA
16 Department of Neurological Surgery, Columbia University, New York, NY, USA
17 Imperial College School of Medicine, Level 4, Charing Cross Hospital, London, UK
18 Technische Universität München, Germany
19 Department of Vascular and Endovascular Surgery, *Klinikum rechts der Isar der Technischen Universität München* München, Germany
20 Department of Surgery, Stanford University, Stanford, CA, USA
21 Department of Surgery, University of California, San Francisco, CA, USA
22 Department of Vascular and Endovascular Surgery, Kaiser Permanente Medical Center, Santa Clara, CA, USA
23 Department of Vascular Surgery, Medical University, Innsbruck, Austria
24 Division of Vascular and Endovascular Surgery, Mayo Clinic, Rochester, MN, USA
25 Royal Perth Hospital and University of WA, Australia
26 Penn State Institute of the Neurosciences, PA, USA
27 Department of Neurosurgery, Penn State University, MS Hershey Medical Center, Hershey, PA, USA
28 Department of Engineering Science and Mechanics, Penn State University, MS Hershey Medical Center, Hershey, PA, USA
29 Assaf Haroef Medical Center, Zerifin, Tel Aviv University, Israel
30 University of Maryland School of Medicine, Baltimore, MD, USA
31 Neurology Department, Royal Adelaide and Lyell McEwin Hospitals, Adelaide, SA, Australia
32 University of Adelaide, SA, Australia
33 Department of Clinical Biochemistry (Vascular Disease Prevention Clinics), Royal Free Hospital Campus, University College London Medical School, University College London (UCL), Pond Street, London, UK
A potential crisis looms in the United States—related to the proposal for the US Center for Medicare and Medicaid Services (CMS) to allow wider indications for government reimbursement for carotid angioplasty/stenting (CAS). We, the undersigned, are writing to advise CMS to reject this proposal based on overwhelming evidence that it would have serious negative health and economic repercussions for the United States and any other country that may follow such inappropriate action. The purpose of this message is not to advise on existing CMS policy. Instead, we wish to advise that current Medicare coverage for CAS should not be extended to routine practice management of asymptomatic carotid stenosis or symptomatic carotid stenosis where the patient is considered at “low/average risk” of complications from carotid endarterectomy (CEA). We understand that, currently, CMS covers the cost of CAS for the indications listed below (the National Coverage Determination [NCD] for Percutaneous Transluminal Angioplasty [PTA] March 5, 2010):

1. Concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials.
2. Concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing postapproval studies.
3. Concurrent with the placement of an FDA-approved carotid stent with an FDA-approved or -cleared embolic protection device for the patients who are at high risk of CEA and who also have symptomatic carotid artery stenosis >70%.
4. Patients who are at high risk of CEA and have symptomatic carotid artery stenosis of 50% to 70%, in accordance with the Category B IDE clinical trials or in accordance with the NCD on carotid artery stenting postapproval studies.
5. Patients who are at high risk of CEA and have asymptomatic carotid artery stenosis >80%, in accordance with the Category B IDE clinical trials regulation or in accordance with the NCD on CAS postapproval studies.

According to the same NCD, patients at high risk of CEA are defined as having significant comorbidities and/or anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection), so that they would be considered poor candidates for CEA. Significant comorbid conditions include but are not limited to:

- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) <30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis;
- prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk of CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Over the last 2 to 3 years, the available evidence to direct current best stroke-prevention management of carotid stenosis has been reviewed by a number of leading academic clinicians. Current routine practice management of carotid stenosis is based on the results of randomized trials of medical (noninvasive) intervention alone versus additional CEA for patients with symptomatic or asymptomatic carotid stenosis. In these trials, patients were randomized up to 30 years ago (1981-1994 and 1983-2003, respectively). Overall, an average annual stroke prevention benefit of about 3.0% was measured

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34 Division of Vascular Surgery, The David Geffen School of Medicine at UCLA, Los Angeles, CA, USA
35 Clinical Sciences Building, Leicester Royal Infirmary, Leicester, UK
36 Vascular Diagnostic Centre, Imperial College, London, UK
37 Department of Vascular and Endovascular Surgery, Klinikum Nürnberg Süd, Germany
38 Departments of Medical Imaging and Clinical Neurological Sciences, University of Western Ontario, London, Ontario, Canada
39 Yale Medical School, New Haven, CT, USA
40 The Queen Elizabeth Hospital, Adelaide, SA, Australia
41 Vascular Surgery Service, University of Poitiers, France
42 Department of Surgery at New York University School of Medicine, New York, NY, USA
43 Nuffield Department of Clinical Neurosciences (Clinical Neurology), University of Oxford, John Radcliffe Hospital, Oxford, UK
44 Department of Clinical Neurosciences, Western General Hospital, Edinburgh, UK
45 Department of Vascular Surgery, Rigshospitalet, University of Copenhagen, Denmark
46 Neurology and Clinical Pharmacology, University of Western Ontario, Ontario, Canada
47 Stroke Prevention & Atherosclerosis Research Centre, Robarts Research Institute, London, Ontario, Canada
48 Department of Cardiovascular and Thoracic Sciences, University of Messina, Messina, Italy
49 Royal College of Surgeons, Charing Cross Hospital, London, UK
50 Vascular Surgery, Cleveland Clinic and Lerner School of Medicine of Case Western Reserve University, Cleveland, OH, USA
51 Department of Surgery, F. Edward Hebert School of Medicine, Uniformed Services, University of the Health Sciences, Riverdale, NY, USA
52 Vascular and Endovascular Surgery, Stanford University, CA, USA
53 Vascular Section, Division of Vascular and Endovascular Surgery, Palo Alto VA Health Care System, Stanford, CA, USA

Corresponding Author:
Anne L. Abbott, Baker IDI Heart & Diabetes Institute 75 Commercial Road, Melbourne, 3004, Australia
Email: anne.l.abbott@gmail.com
for operated patients with moderate or severe [70%-99% North American Symptomatic Carotid Endarterectomy Trial (NASCET) equivalent] symptomatic carotid stenosis and about 0.5% to 1% for operated patients with moderate or severe (50%-99% NASCET equivalent) asymptomatic carotid stenosis compared to patients who received medical intervention alone. More recently, trials of CAS versus CEA (without a medical intervention-only arm) were performed, demonstrating that the perioperative stroke risk is about twice as high with stenting when compared with CEA (see below). These trials were most likely designed assuming medical intervention has not changed since the randomized surgical trials, aiming to find at least an equivalent CEA stroke prevention benefit. However, it is now clear that the stroke prevention efficacy of medical intervention has steadily and significantly improved over the last 30 years and continues to improve,10-14 consistent with other observed falls in risk of stroke,15-17 heart attack, and sudden death.18 Currently used benchmarks for a stroke prevention benefit from CEA over medical intervention (a 30-day procedural risk of stroke/death of 3% for asymptomatic carotid stenosis19 or 6% for symptomatic carotid stenosis)20 are outdated. Therefore, the demonstration of stroke prevention equivalence between CAS and CEA using these benchmarks (even if this had been achieved) would be insufficient to justify a current, routine practice indication for CAS.

The inappropriateness of the recent push for widening CMS coverage for carotid stenting is particularly evident with respect to asymptomatic carotid stenosis because the randomized surgical trial stroke prevention benefit from CEA was so small and conditional. However, the most recent standardized measurements of the average annual rate of ipsilateral stroke among patients receiving medical intervention alone approximate only 0.5%.11,21-23 This is about 3 times lower than for randomized surgical trial CEA patients;5 about 5 times lower than randomized surgical trial nonoperated patients,5 3 times lower than CREST stented patients,24 and about half the rate of CREST CEA patients.10,11,24 The push for routine practice stenting for asymptomatic carotid stenosis is based largely on the recently published CREST results,24 and perhaps other clearly flawed randomized data,25,26 comparing CEA with CAS (without a medical intervention-only arm) and implications of “equivalence” with CEA.27 As mentioned, such equivalence, even if supported by the data, would not be sufficient to justify a current, routine practice indication for CAS for asymptomatic carotid stenosis.

However, to add insult to injury, an equivalent stroke prevention benefit between CAS and CEA has not been demonstrated. Carotid angioplasty/stenting in CREST,24 large registries, and population-based studies28-30 has been associated with about double the periprocedural rate of stroke or death compared to CEA. Further, in CREST, among asymptomatic patients, the rate of periprocedural stroke/death or later ipsilateral stroke projected for 4 years was 4.5% for 594 patients who had CAS and 2.7% for the 587 who had CEA (67% higher, \( P = .07 \)). This outcome measure reached statistical significance when symptomatic patients were added (6.4% vs 4.7%, 36% higher, \( P = .03 \)). The inclusion of higher risk symptomatic patients, and larger sample sizes, allows easier detection of statistically significant differences. Supporters of routine CAS for asymptomatic carotid stenosis have tried to use a higher incidence of periprocedural myocardial infarction (including minor infarction) associated with CEA to justify a higher stroke/death risk with CAS.31 However, this is invalid and distracting because the aim of invasive carotid intervention is to prevent stroke. Further, in CREST, at least, a larger proportion of patients who suffered periprocedural myocardial infarction associated with CAS (compared to CEA) died during follow-up.32 More importantly, procedure-associated myocardial damage would be prevented entirely if unnecessary CEA and CAS interventions were not performed in the first place. In addition, it should also be noted that CAS has higher procedural costs compared to CEA.33

The current situation regarding CEA and CAS for patients with asymptomatic stenosis in the United States is unjustified and outdated. Up to about 90% to 95% of these procedures are being performed for asymptomatic carotid stenosis,29,34 exposing patients to unnecessary risk and causing unjustified expenditure of at least 1 to 2 billion US health care dollars each year.10,12,35-38 at a time when the health care costs need to be justified.39 Despite no previous CMS coverage for routine practice CAS for asymptomatic carotid stenosis, rates of CAS procedures are increasingly dramatically, especially among cardiologists.40,41 Extending the approved indications for CAS will open the floodgates for widespread CAS and expose patients to unnecessary risk and greatly increase unjustified health expenditure.35

Broadening the indications for CAS reimbursement for symptomatic carotid stenosis is also inappropriate. The request for such broadening of reimbursement will, once again, be based on the CREST trial conclusions24 and the recently published American Heart Association (AHA) Guideline (approved by 13 other organizations),27 which states that “CAS is an alternative to CEA for the treatment of symptomatic carotid stenosis . . . .” Equivalence of the two procedures is implied.42,43 Unfortunately, the actual CREST data,44 most other randomized trial data,45-47 meta-analyses,48,49 and registry data28-30 do not justify this presumed equivalence of CAS and CEA for symptomatic carotid stenosis.50,51 In symptomatic patients, CAS, overall, is associated with about double the 30-day, 120-day, 6-month, and/or 4-year risk of stroke or death compared to CEA. The excessive CAS procedural risk of stroke or death is particularly notable in patients over 70 years of age,52 yet not confined to the oldest age groups.44 Carotid angioplasty/stenting is also associated with a much higher periprocedural risk of brain-imaging-detected ischemic lesions than CEA53 and a higher incidence of carotid restenosis.54-56 No studies have shown CAS is better than CEA in preventing stroke in patients with symptomatic carotid stenosis and procedural costs are significantly higher with CAS.33 Thus, the extension of Medicare reimbursement to routine treatment of “low” and “standard” CEA risk patients with symptomatic carotid stenosis is not currently justified.

Thus, in summary, at this time, the evidence does not support broadening reimbursement for CAS to routine management of patients with asymptomatic carotid stenosis or patients...
with symptomatic carotid stenosis considered at “low or standard” risk from CEA. It is acknowledged that this situation may change in the future.

**Authors’ Note**


**Authors’ Disclosures**

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Abbott et al


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