GUIDANT

March 31, 2006

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Marcel Salive, M.D., M.P.H.
Director, Division of Medical and Surgical Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Carotid Artery Stenting with Embolic Protection:
Request for Reconsideration of the CAS Coverage Issues Manual (CAG-00085R)

Dear Drs. Phurrough and Salive,

I am writing to formally request a revision of the Coverage Issues manual as it relates to carotid artery stenting (CAS) with embolic protection.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research facilities in the states of Minnesota, California, and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leader in the research, development, and manufacturing of medical technologies used primarily in treatment of cardiovascular and vascular illnesses. Guidant develops technologies that offer physicians and patients options to improve their health status and quality of life. In addition to receiving the first FDA approval of a carotid stent, Guidant has played a major role in sponsoring research on the clinical outcomes of carotid stenting. We are a sponsor of the ongoing randomized controlled CREST trial in collaboration with the National Institutes of Health to study carotid stenting in moderate and low risk patients. We also sponsored the ARCHeR clinical trail to evaluate carotid artery stenting in high-surgical risk patients and, more recently, the landmark CAPTURE post market registry, the largest, rigorous 'real world' experience of carotid stenting in high surgical risk patients. Guidant is continuing its commitment to evidence-based medicine with the recent initiation of the CAPTURE 2 registry, an unprecedented scale post market study of carotid stenting in high surgical risk patients.

Effective March 17, 2005, Medicare determined that the evidence was adequate to conclude that CAS with embolic protection is reasonable and necessary for the following:

1. Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq$ 70%;
2. Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70% OR patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq$ 80% may be covered in accordance with FDA approved protocols governing Category B IDE clinical trial regulation (42 CFR405-201), or as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.1)

Guidant appreciates CMS' recognition of the strength of evidence supporting CAS. Coverage for post-approval studies has supported continued expansion of the pool of clinical evidence, particularly as it relates to asymptomatic patients. This new evidence will benefit CMS, providers and patients so the option of CAS can be considered for a broader group of patients outside of clinical studies. Currently the large number of Medicare patients in Group (2) above must have access to and consent to enrollment in an FDA-approved study protocol. In addition, as FDA often limits the total number of providers in a study, as well as the number of cases performed per provider and the overall number of patients who can be treated, unfortunately, the result is that Medicare beneficiaries have limited access to a less-invasive technology that may be an important option that needs consideration.

Guidant Endovascular Solutions is requesting the following changes to the CAS coverage policy:

- Provide coverage of CAS for the treatment of carotid artery disease in high surgical risk patients who are symptomatic with ≥50% stenosis or asymptomatic ≥80% stenosis and determined by the treating physician to require carotid revascularization.
- Remove the language in the current policy stating the patient be a poor candidate for CEA 'in the opinion of a surgeon'.

The above proposed revisions would expand coverage to all patients at high-risk for surgical treatment consistent with FDA-approved labeling and would eliminate the requirement for many patients to be enrolled in an FDA-approved study. Further, the proposed revision would eliminate confusing language about whether a surgical consult must be obtained as a prerequisite for CAS. Clinical studies have defined high surgical risk thus this language is unnecessary and confusing.

This request is for expansion of coverage under the current benefit categories, hospital inpatient and physician services. Medicare beneficiaries comprised 81% of the post market CAPTURE study participants and over 72% of the ARCHeR IDE clinical trial enrollment.

Guidant's request for reconsideration is based on new and growing evidence from three Guidant sponsored studies, as well as important new evidence from other published studies. This includes a large, multicenter European study which has documented the stroke risk of over 1000 asymptomatic patients in a multi-year follow-up. This study includes a large number of patients with severe stenosis as well as those with comorbidities that not only place the patient at high surgical risk, but that are also associated with increased stroke risk.

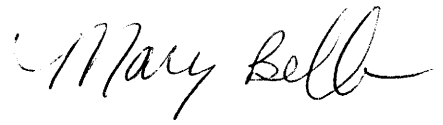
Consistent with CMS' request that new evidence be made public, both the ARCHeR and CAPTURE manuscripts have been submitted to leading peer review journals. The ARCHeR manuscript has been accepted for publication by the Journal of Vascular Surgery and publication is pending. Early results from the CREST lead-in cohort were published in the Journal of Vascular Surgery in 2004 and have been presented regularly at clinical conferences. In addition to submission of the manuscript, results from the first 2500 patients of the CAPTURE study were recently presented at the American College of Cardiology, March 2006.

The attached Summary of New Clinical Evidence presents an overwhelming body of data supporting CAS as an option for high surgical risk patients with significant carotid artery stenosis – both symptomatic and asymptomatic. Substantial new evidence has been accumulated subsequent to the March 2005 CMS coverage decision. Included in this evidence is the ACSRS asymptomatic study supporting at least a 4.5% per year stroke risk in patients with both comorbidities and severe stenosis that are treated with best medical therapy. Further, recent studies of CAS clearly support the safety of the procedure, its ability to prevent stroke over a multi-year period and the ability of established training and credentialing programs to ensure that the procedure can be performed safely by a wide group of operators from a variety of disciplines.

There is an urgent public health need to provide further options for these underserved asymptomatic ($\geq$ 80% stenosis) and symptomatic (50-70% stenosis) high surgical risk patient populations. CAS as a treatment option is reasonable and necessary and should not be delayed any further.

I would be pleased to provide you with any additional information that would be of assistance during your review. We would like to present this new evidence to CMS at your earliest convenience as a part our formal request for Reconsideration to the Committee. If you have any questions about this request please contact me at 408-845-2203.

Sincerely,



Mary Bellack
VP, Regulatory, Clinical & Quality
Guidant Endovascular Solutions

Attachment: Summary of New Clinical Evidence

cc: Sarah McClain, CMS
ARCHeR, CAPTURE Executive Committees

Abbott

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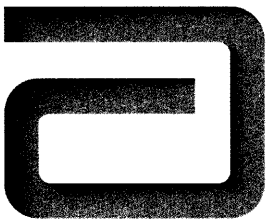

June 14, 2006

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. Phurrough,

During our June 5 call, we agreed to get back to you regarding an acceptable date for initiation of the reconsideration process that takes into account the need for public access to data from the ARCHeR and CAPTURE studies. In a subsequent e-mail Dr. Salive clarified that *all* data or information provided or discussed in our request that currently is not publicly available needs to be made available to the public before or with the release of a decision memorandum. Dr. Salive also indicated that our request would be considered complete after we provided a specific timeframe in which all data will be made publicly available.

As detailed in our letter of May 22 and the accompanying table, data and information from the vast majority of studies cited in our request are already publicly available. With regard to the ARCHeR and CAPTURE studies, we are now able to confirm that we expect these two studies to be published in peer-reviewed journals during the next six months. An ARCHeR manuscript has been accepted by the Journal of Vascular Surgery and we expect it to be published in August. We have submitted the CAPTURE manuscript to the Journal of the American College of Cardiology and expect that it will be published during the next 6 months. Given submission status, we have discussed with the manuscript authors our plan to authorize CMS to make this information public should publication not occur within the next 6 months (which is extremely unlikely). As such, we are now authorizing CMS to open the coverage decision with the agreed upon understanding that data or information provided or discussed in our request, including that related to ARCHeR and CAPTURE, that has not been made public by the posting date of the proposed decision memorandum, can be made available for public review by CMS by attaching the information to the proposed decision memorandum.

We will follow up to arrange a brief call to determine if our request is now considered complete and to discuss next steps.

Sincerely,

Barbara J. Calvert

Barbara J. Calvert
Director, Medical Products Reimbursement

cc: Mary Bellack-VP and General Manager, Carotid/Neurovascular
Abbott Vascular Solutions

Marcel Salive, M.D., M.P.H.
Director, Division of Medical and Surgical Services