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August 14, 2007

Steve Phurrough, MD, Director
Coverage and Analysis Group
Office of Clinical Standards & Quality (OCSQ), Mailstop C1-09-06
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: NCD Reconsideration Request for Intracranial Stenting and Angioplasty

Dear Dr. Phurrough:

Boston Scientific Corporation formally requests a reconsideration of the National Coverage Determination (NCD) for intracranial stenting and angioplasty (*Manual Section Number, 20.7 Percutaneous Transluminal Angioplasty*). Since CMS last considered coverage for intracranial stenting and angioplasty, new clinical evidence has become available on interventional therapy for intracranial atherosclerotic disease (ICAD).

The Wingspan® Stent System with Gateway™ PTA Balloon Catheter is indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy in intracranial vessels with greater than or equal to 50 percent stenosis that are accessible to the system. On August 3, 2005, the FDA granted approval of this intracranial stent system via the Humanitarian Device Exemption (HDE) application process. The device has demonstrated strong technical results and positive clinical outcomes for patients unresponsive to medical therapy in both the original HDE study and real world clinical experience.

Specifically, the Wingspan HDE Study showed promising positive clinical outcomes at long-term follow-up in a patient population at major risk for stroke and death. About seven percent of the study population (3/43) exhibited ipsilateral stroke or death at six months.[1] Two recently presented Wingspan real world clinical registries have also reported similarly strong results at acute and longer term clinical follow-up.[2,3,4]

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[1] Bose A et al. A Novel, Self-Expanding, Nitinol Stent in Medically Refractory Intracranial Atherosclerotic Stenoses: The Wingspan Study. *Stroke*. May 2007; 38.
[2] Fiorella D et al. U.S. Multi-center Experience with the Wingspan Stent System for the Treatment of Intracranial Atheromatous Disease. Periprocedural Results. *Stroke*. March 2007; 38: 881-887.
[3] Albuquerque F et al. Preliminary Multicenter Experience with the Wingspan Stent for the Treatment of Intracranial Stenosis (presented at International Stroke Conference, February 2007).
[4] Zaidat O et al. NIH Funded Multi-Center Registry on the Use of Wingspan Intracranial Stent for High Risk Patients with Symptomatic Intracranial Arterial Stenosis (presented at International Stroke Conference, February 2007).

We believe that sufficient clinical evidence exists on improvements in health outcomes to show that intracranial stenting and angioplasty is reasonable and necessary for Medicare coverage in medically refractory ICAD patients with greater than or equal to 50 percent stenosis. We continue to be receptive, however, to the use of coverage with evidence development (CED) for intracranial stenting and angioplasty. Under CED, as defined in the July 9, 2007 decision memorandum on Clinical Trial Policy (CAG-00071R), CMS may determine, through the NCD process, that intracranial stenting and angioplasty are reasonable and necessary when provided in a clinical study that meets the requirements defined in that NCD.

Boston Scientific had previously recommended the concept of extending Medicare coverage of intracranial stenting and angioplasty through the use of CED. We believe that providing coverage under CED for intracranial stenting and angioplasty would allow Medicare beneficiaries "access to technologies with proven benefit…under closer supervision than other covered services" and "ensure...the development of evidence to evaluate coverage"[5]. Since BSC believes that CMS has the authority to allow Medicare coverage of intracranial stenting and angioplasty when performed within a clinical observational study, we welcomed CMS's July 9, 2007 decision to reiterate its authority with respect to CED. As noted in the July 2007 decision memo, "CED is…conditional on meeting standards for clinical research that ensures patient protection and the development of evidence to evaluate coverage".

As noted in the November 6, 2006 decision memorandum, the population indicated for the Wingspan® Stent System "needs access to technologies with proven benefit….and that the use of these devices in the Medicare population be under closer supervision than other covered devices." CMS agreed with commenters that "limited coverage of the Wingspan system in a clinical study…would provide greater patient supervision," and accordingly, CMS "determined that intracranial stenting with PTA is covered when furnished in accordance with…Category B IDE clinical trials."

While the November 2006 decision extended coverage for future IDE studies, the currently indicated HDE population (patients with intracranial atherosclerotic disease, refractory to medical therapy in intracranial vessels with greater than or equal to 50 percent stenosis that are accessible to the system) remains ineligible for Medicare coverage. Therefore, the November 2006 decision does not provide a pathway for future research and understanding of stenting and angioplasty for the HDE population.

In short, we believe that providing coverage under CED for intracranial stenting and angioplasty for the indicated population would allow beneficiaries access to technologies with proven benefit…under closer supervision than other covered services" and "ensure…the development of evidence to evaluate coverage". We believe that CMS has the authority, which was reiterated in the July 2007 decision memo, to apply CED for intracranial stenting and angioplasty.

Boston Scientific has developed a draft observational study protocol that we believe would satisfy CMS's CED requirements. For example, the study type (observational) is appropriate because of the limitations associated with clinical research of such a small group of patients who have already failed all other appropriate therapies. Therefore a randomized comparative study is inappropriate in this case. We look forward to reviewing the protocol with CMS as you reconsider coverage for intracranial stenting and angioplasty.

[5] November 6, 2006 Decision Memorandum for Intracranial Angioplasty and Stenting, (CAG-00085R2), Centers for Medicare and Medicaid Services

We note that intracranial stenting and angioplasty falls within statutorily defined Medicare coverage benefit categories for inpatient hospital services and physicians' services. Further, the attached dossier includes all of the necessary supporting documentation required for CMS to open formal coverage reconsideration *(Federal Register, CMS-3062-N, Medicare Program; Revised Process for Making Medicare National Coverage Determinations;* see attached Table of Contents*)*. In addition to resubmitting materials from our prior September 2005 NCD request, we are also including new clinical evidence now available (See Attachment D).

Given CMS's extensive recent review of the ICAD evidence in the previous NCD, we appreciate your timely reopening and finalization of Medicare coverage of intracranial stenting and angioplasty consistent with CED. As noted, we have already developed a draft study protocol for your consideration, and we are hopeful that the NCD process could be completed within 2 to 3 months given that the primary unresolved issues surround the details of the appropriate clinical studies within which coverage would be available. As a next step, we will request a meeting with CMS to work collaboratively on obtaining feedback on the current draft protocol for a prospective, observational study of ICAD stenting and angioplasty.

We appreciate your continued attention to Medicare coverage for intracranial stenting with angioplasty. I will contact you in the coming days regarding scheduling a meeting to discuss the prospective, observational study. Please feel free to contact me at (508) 650-8681, if you have any questions or comments.

Sincerely,

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Boston Scientific Corporation

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