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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: Formal Request for a National Coverage Decision Reconsideration for Intracranial Stenting and Angioplasty

Dear Dr. Phurrough:

This letter is to formally request a National Coverage Decision reconsideration for intracranial stenting and angioplasty (*Manual Section Number, 20.7 Percutaneous Transluminal Angioplasty*). Intracranial stenting and angioplasty procedures fall within the statutorily defined Medicare coverage benefit categories for physician services and inpatient hospital services.

Boston Scientific Corporation recently received FDA approval of a Humanitarian Device Exemption (HDE) application for the Wingspan Stent System with Gateway PTA Balloon Catheter on August 3, 2005. This device 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% stenosis that are accessible to the system. Intracranial atherosclerotic disease is associated with a high risk of stroke and death, and patients currently have limited treatment options available.

As of this date, Boston Scientific has provided CMS with all of the supporting documentation needed for CMS to open a formal coverage request (*Federal Register, CMS-3062-N, Medicare Program; Revised Process for Making Medicare National Coverage Determinations*). We appreciate the opportunity to provide this information and work with CAG to assure the timely consideration and approval of this coverage request.

We appreciate your continued attention to addressing Medicare coverage for intracranial stenting with angioplasty. Please feel free to contact me anytime at 510.624.1215 or john.hernandez@bsci.com if you have any questions or comments regarding this letter or the enclosed materials.

Sincerely,

John Hernandez, PhD
Director, Reimbursement & Outcomes Planning
Boston Scientific Corporation

Cc: Marcel Salive, M.D., OCSQ
Joseph Chin, M.D., OCSQ
Sarah, McClain, OCSQ
Parashar Patel, Boston Scientific Corporation
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