Boston Scientific

Boston Scientific Comments on CMS Proposal To Expand Coverage of Carotid Artery Stenting

NATICK, Mass., Feb. 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today commented on a proposed National Coverage Determination (NCD) released by the Centers for Medicare and Medicaid Services (CMS). Under the proposed policy, asymptomatic patients under age 80 who are at high risk for surgery and have 80 percent or greater carotid artery stenosis would be eligible for coverage outside of a post-market study or clinical trial as long as the procedure is performed using U.S. Food and Drug Administration (FDA)-approved Carotid Artery Stent (CAS) systems and embolic protection devices in a facility approved by CMS.

Boston Scientific supports the proposed expansion but also supports broader coverage.

"We are excited about the opportunity for expanded coverage for carotid stenting for asymptomatic patients at high risk for surgery," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "However, we believe that clinical data from our carotid stenting trials also supports expansion of coverage for high-risk symptomatic patients."

"This proposal comes on the heels of Boston Scientific's launch of the NexStent® Carotid Stent and the FilterWire EZ™ Embolic Protection System, two products that utilize state-of-the art technology to address the need for stroke protection in high-surgical risk patients with carotid artery stenosis," added Pedersen. "We look forward to continuing to provide CMS with data to support even broader coverage of carotid stenting."

Currently, Medicare only provides coverage for CAS to a small subset of high-risk Medicare beneficiaries who are symptomatic and have 70 percent or greater carotid artery stenosis. Under the proposed policy, other high-risk and non-high risk Medicare patients, including octogenarians, will be required to enroll in a category B investigational device exemption (IDE) clinical trial or an FDA-mandated post-approval study to access coverage for CAS.

The proposed coverage change reflects the medical community's growing acceptance of the procedure as a viable alternative to surgery for high-risk patients with carotid artery disease. If approved, coverage could be effective as early as May, 2007.

The carotid arteries are located on either side of the neck and are the main conduit through which blood flows from the heart to the brain. Plaque formation in these arteries can cause the arteries to harden and narrow, impeding blood flow and increasing the risk of stroke in affected patients. Stroke is a leading cause of severe, long-term disability in the U.S. Each year, approximately 700,000 Americans suffer from a stroke.

Until recently, the only option for physically widening the vessels was to perform carotid endarterectomy, a surgical procedure involving a vertical incision in the neck and artery and removal of the plaque from the vessel walls. CAS is a less-invasive procedure in which a stent-bearing catheter is guided through the femoral artery to the affected area of the carotid arteries. The stent is placed at the site of the blockage, where it expands and forces the walls of the arteries open, restoring the blood flow.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: http://www.bostonscientific.com/.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Dan Brennan
508-650-8538 (office)
617-459-2703 (mobile)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Paul Donovan, Media Relations, +1-508-650-8541, or mobile, +1-508-667-5165, or Dan Brennan, Investor Relations, +1-508-650-8538, or mobile, +1-617-459-2703, both of Boston Scientific Corporation

Web site: http://www.bostonscientific.com/

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