Medtronic News

Vertebral Augmentation for Spinal Fractures Continues to Be Covered by Noridian Administrative Services

Kyphon(R) Balloon Kyphoplasty is Among Treatments that Continue to be Covered by Major Medicare Administrative Contractor

MINNEAPOLIS, May 13, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today announced that Noridian Administrative Services, a major Medicare Administrative Contractor providing Medicare insurance coverage in 11 states, has issued a decision to continue coverage of vertebral augmentation for the treatment of spinal fractures. Medtronic is the leader in Kyphon(R) Balloon Kyphoplasty, a vertebral augmentation procedure for spinal fractures caused by osteoporosis and cancer, with over 900,000 fractures treated worldwide.

Noridian's decision affects both vertebral augmentation (balloon kyphoplasty) and vertebroplasty. The decision applies to Medicare patients in Alaska, Arizona, Idaho (Part A), Minnesota (Part A)*, Montana, North Dakota, Oregon, South Dakota, Utah, Washington and Wyoming. Noridian's coverage for the therapies remains positive but with greater specificity on documentation requirements and the required patient clinical care path prior to performing the procedure.

"We are pleased that Noridian has decided to join other major Medicare Administrative Contractors in continuing to cover Kyphon Balloon Kyphoplasty," said Alex DiNello, VP, Medtronic Spinal, which manufactures and markets Kyphon Balloon Kyphoplasty worldwide. "This coverage is important to the thousands of Medicare patients in 11 states who suffer back pain from these fractures and desire to be treated with clinically proven, minimally invasive Kyphon Balloon Kyphoplasty."

"We believe Noridian's positive decision on balloon kyphoplasty was based on positive input from physicians and national medical societies and on the strength of two recent studies supporting the benefits of Kyphon Balloon Kyphoplasty compared with non-surgical management," DiNello added.

In presenting its case for continued coverage to Noridian, Medtronic pointed out the results of the Fracture Reduction Evaluation1 (FREE) and Cancer Patient Fracture Evaluation2 (CAFE) studies along with other published clinical evidence on Kyphon Balloon Kyphoplasty. FREE showed that patients treated with Kyphon Balloon Kyphoplasty experienced statistically significant better back pain relief, improvement in quality of life and mobility, and greater satisfaction with their treatment on average over the 24-month study compared with patients receiving non-surgical care. CAFE indicated that cancer patients treated with Kyphon Balloon Kyphoplasty had clinically and statistically significant better improvements in back-specific function, back pain, and quality of life one month after treatment compared with those obtaining non-surgical care, who showed no significant improvement in these measures after one month.

The complication rate with Kyphon Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement leakage), including serious complications, and though rare, some of which may be fatal. This procedure is not for everyone. A prescription is required. Patients should consult their physicians for a complete list of indications, contraindications, benefits, and risks. Only patients and their physicians can determine whether this procedure is right for a particular patient.

About Kyphon Balloon Kyphoplasty
During the minimally invasive Kyphon Balloon Kyphoplasty procedure, working tubes are used to create small pathways into the fractured bone, generally on both sides of the vertebral body. Orthopedic balloons are inserted and then inflated inside the fractured bone in an attempt to return it to its correct position. Inflation and removal of the balloons create cavities in the vertebral body that are filled with bone cement, forming an "internal cast."

Balloon kyphoplasty differs from vertebroplasty, which is designed to stabilize the fracture without correcting vertebral body

deformity or providing a controlled fill and distribution of bone cement. With balloon kyphoplasty, inflation of the balloons compacts the cancellous bone, which may fill fracture lines. The presence of the space also allows a more viscous bone cement to be injected under manual pressure.

For more information on Kyphon Balloon Kyphoplasty, go towww.balloonkyphoplasty.com or www.spinalfractures.com. For more information on the FREE and CAFE studies, go to www.compressionfracturestudy.com.

Kyphon Balloon Kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

About the Spinal Business at Medtronic
The Spinal business is based in Memphis, Tenn. It is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. The Spinal business works with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for neurological, orthopedic, dental and spinal conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle-friendly surgical therapies. More information about the company and its treatment therapies can be found at www.medtronic.com and its patient-education Web sites, www.back.com, www.iscoliosis.com, www.maturespine.com and www.necksurgery.com.

ABOUT MEDTRONIC
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1 Boonen S, et al. Balloon Kyphoplasty for the Treatment of Acute Vertebral Compression Fractures: 2-year Results from a Randomized Trial. *J Bone Miner Res.* Published online on Feb 17, 2011.

2 Berenson J, et al. Balloon Kyphoplasty versus Non-surgical Fracture Management for Treatment of Painful Vertebral Body Compression Fractures in Patients with Cancer: A Multicentre, Randomised Controlled Trial. *Lancet Oncol*. 2011 Mar;12(3):225-35.

* Noridian administers Part A benefits in these states; WPS and Cigna administer Part B benefits

SOURCE: Medtronic, Inc.

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