CMS Grants New Technology Add-On Payment for Inpatient Use of Medtronic's Drug-Coated Balloon

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Decision Will Provide Patients with Additional Access to New Medical Device with Potential to Improve Standard of Care for Peripheral Arterial Disease in Vessels Above the Knee

DUBLIN -- August 3, 2015 -- Medtronic plc (NYSE: MDT) announced today that the U.S. Centers for Medicare and Medicaid Services (CMS) has granted a New Technology Add-on Payment (NTAP) for the company's IN.PACT® Admiral® drug-coated balloon (DCB) under the Medicare hospital inpatient prospective payment system (IPPS).

The NTAP will help reimburse hospitals for the incremental costs of using DCB and support patient access in the inpatient setting to this innovative medical technology, which represents a significant improvement to the standard of care for peripheral arterial disease (PAD) in vessels above the knee.

"Medtronic has been leading the efforts with CMS to enhance access to DCB technology for the Medicare population, based on the substantially improved clinical outcomes in patients with PAD in the superficial femoral artery (SFA) treated with the IN.PACT Admiral DCB technology, including significantly fewer repeat interventions and improved quality of life for these patients," said Brian Verrier, vice president and general manager of Peripheral Vascular, a business in Medtronic's Aortic and Peripheral Vascular division. "Today's decision will ultimately help to improve patient access to the IN.PACT Admiral DCB, which provides significant improvement to the standard of care."

For a new technology to qualify for an add-on payment in the inpatient setting it must demonstrate a substantial clinical improvement relative to predecessor technology and meet specific cost thresholds. The NTAP payment will provide hospitals with a payment, in addition to the DRG reimbursement, of up to 50 percent of the cost of DCB, and is expected to last for a period of two to three years. The NTAP for DCB is effective in CMS' fiscal year 2016 starting October 1, 2015 and has been assigned a maximum payment of $1,035.72 per case for FY 2016.

"The NTAP decision provides further validation of CMS' determination that the use of drug coated balloons significantly improves clinical outcomes for peripheral arterial disease patients," added Mark Turco, M.D., medical director, Aortic and Peripheral Vascular. "The IN.PACT Admiral DCB has demonstrated the best clinical outcomes ever reported for this disease state and has been proven to reduce the need for costly repeat procedures that are commonly associated with other available interventional therapies."

Earlier this year in February 2015 the Centers for Medicare and Medicaid Services (CMS) approved a transitional pass-through payment for the company's IN.PACT Admiral drug-coated balloon (DCB) under the Medicare hospital outpatient prospective payment system (OPPS) for patients treated in the outpatient setting.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

About the IN.PACT Admiral Drug Coated Balloon

The IN.PACT Admiral Drug Coated Balloon (DCB) is designed to reopen superficial femoral and popliteal arteries that have been narrowed or blocked by plaque. Once deployed in the artery, the balloon delivers a proven, safe and effective dose of the anti-restenotic drug paclitaxel to the artery walls. The drug aims to prevent the artery from narrowing again by minimizing scar tissue formation.

IN.PACT Admiral has incomparable clinical outcomes in the SFA, as evidenced by the published IN.PACT SFA 12-Month results and reinforced by results of the IN.PACT Global Study. The DCB arm of the IN.PACT SFA Trial demonstrated the lowest clinically-driven target lesion revascularization (CD-TLR) rate ever reported for an interventional treatment of PAD in the superficial femoral artery (SFA), with only 2.4 percent of patients treated with the IN.PACT Admiral DCB requiring a repeat procedure at one year, compared to one in five patients (20.6%) treated with percutaneous transluminal angioplasty (PTA).

The data also revealed the highest reported rates of primary patency, which measures sustained restoration of adequate blood flow through the treated segment of the artery. Based on Kaplan-Meier survival estimates for primary patency at 360 days, the data showed an 89.8 percent sustained restoration of blood flow in the DCB group compared to 66.8 percent for the PTA group. Using the trial's protocol definition, primary patency assessed at 12 months of follow up was 82.2 percent for the DCB group and 52.4 percent for the PTA group.

Subset analyses of data from the IN.PACT SFA Trial and the IN.PACT Global Study show consistent performance of the device in women, patients with diabetes and those with long lesions.

By reducing the need for repeat procedures, the new device is also proving to be economically attractive. Results from an interim economic analysis of the IN.PACT SFA Trial revealed that treatment with the IN.PACT Admiral DCB is cost-effective compared to balloon angioplasty from discharge through one-year of follow-up, indicating the potential to lower overall healthcare costs over the longer term.

ABOUT MEDTRONIC

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, 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.

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