Medtronic News

Medicare Approves Transitional Pass-Through Payment for Outpatient Use of Medtronic Drug-Coated Balloon

CMS Decision Provides Supplemental Reimbursement to U.S. Hospitals for New Medical Device with Potential to Improve Standard of Care for Peripheral Arterial Disease in Upper Leg

DUBLIN - Feb. 19, 2015 - Medtronic plc (NYSE: MDT) announced today that the U.S. Centers for Medicare and Medicaid Services (CMS) has 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), removing a potential barrier to patient access to this new medical device, which represents a significant improvement to the standard of care for peripheral arterial disease in the upper leg.

This supplemental reimbursement provision takes effect on April 1, 2015 and will remain in effect for the following two to three years. It aims to cover the additional cost to U.S. hospitals for treating Medicare beneficiaries with the IN.PACT Admiral DCB in the outpatient setting. The Healthcare Common Procedure Coding System (HCPCS) code for this new device category will be C2623 (catheter, transluminal angioplasty, drug-coated, non-laser).

A similar supplemental payment to hospitals that treat Medicare beneficiaries with the device on an inpatient basis is currently under review by CMS, with a decision on a new technology add-on payment for the hospital inpatient prospective payment system (IPPS) expected over the summer.

Recently approved by the U.S. Food and Drug Administration (FDA) on the strength of clinical and economic data from multiple studies, the IN.PACT Admiral DCB offers patients a new therapy option that 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.

CMS agreed to establish a transitional pass-through payment for the IN.PACT Admiral DCB after determining that "use of the new device significantly improves clinical outcomes for a patient population as compared to currently available treatments."

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.

The IN.PACT Admiral 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.

The IN.PACT Admiral DCB received the CE (*Conformité Européene*) mark in 2009 and has been widely adopted by European physicians, leading the market with nearly 100,000 patients treated.

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 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.

- end -

Contacts:
Joe McGrath
Public Relations
+1-707-591-7367

Jeff Warren
Investor Relations
+1-763-505-2696

---

https://news.medtronic.com/2015-02-19-Medicare-Approves-Transitional-Pass-Through-Payment-for-Outpatient-Use-of-Medtronic-Drug-Coated-Balloon