Medtronic News

Medtronic Announces Medicare Coverage Decision for the First and Only Leadless Pacemaker Available for Use in the U.S.

CMS Decision Expands Patient Access to the Micra®Transcatheter Pacing System (TPS), the World's Smallest Pacemaker

DUBLIN - Jan. 26, 2017 - Medtronic plc (NYSE: MDT) today announced that the U.S. Centers for Medicare and Medicaid Services (CMS) will cover leadless cardiac pacemakers, as outlined in the agency's final National Coverage Determination (NCD). This decision will provide Medicare patient access to leadless pacemakers, consistent with the FDA-approved labeling for the devices, through Medicare's policy of Coverage with Evidence Development (CED).

"Medtronic is pleased with the CMS decision to cover leadless pacemakers, which will allow broad patient access to this novel, minimally invasive pacemaker technology through an innovative approach to evidence and data collection to address research questions identified by CMS," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "We are working closely with CMS to ensure patient access to the Micra TPS as quickly as possible under this decision."

CED is a Medicare policy through which additional evidence must be collected as a condition of coverage. The leadless pacemaker decision will provide coverage for leadless pacemakers when procedures are performed in FDA-approved studies of leadless pacemakers and prospective longitudinal studies approved by CMS. Under the policy, Medtronic will seek coverage of the existing FDA-approved Micra Post-Approval Study (PAS) as a well as a new study being finalized to track longitudinal data on Micra patients in the Medicare population. Coverage for Micra will become effective upon approval of these studies by CMS.

Approved by the U.S. Food and Drug Administration (FDA) in April 2016 for patients who need a single-chamber pacemaker, the Micra TPS is the first and only leadless pacemaker approved for use in the U.S. The miniaturized device was recently named at the top of US News & World Report's list of "2016's Biggest Achievements in Medicine."

Comparable in size to a large vitamin, the Micra TPS is less than one-tenth the size of traditional pacemakers, yet delivers the most advanced pacing technology to patients via a minimally-invasive approach. During the implant procedure, it is attached to the heart with small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device.

Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to such leads and pocket are eliminated - as are any visible signs of the device.

The Micra design incorporates a retrieval feature which can be enabled, if necessary; however, the device is designed to be left in the body. For patients who need more than one device, the miniaturized Micra TPS can be permanently turned off, allowing it to remain in the body so a new device can be implanted without risk of electrical interaction.

The Micra TPS is the first and only leadless pacing system to be approved for both 1.5 and 3 Tesla full-body magnetic resonance imaging (MRI) scans. It is designed to allow patients to be followed by their physicians and send data remotely via the Medtronic CareLink® Network. Remote monitoring of Micra devices is expected to be available later this year.

In November 2015, preliminary results from the Medtronic Micra TPS Global Clinical Trial, published in the *New England Journal of Medicine,* showed the Micra TPS was successfully implanted in 99.2 percent of patients and that the system met its safety and effectiveness endpoints with wide margins. In August 2016, new long-term data presented in a late-breaking clinical trial at the European Society of Cardiology congress continued to reinforce these results, demonstrating consistent and sustained outcomes from early performance through 12-month follow-up.

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

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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:

Ryan Mathre
Public Relations
+1-763-514-9625

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2017-01-26-Medtronic-Announces-Medicare-Coverage-Decision-for-the-First-and-Only-Leadless-Pacemaker-Available-for-Use-in-the-U-S