Medtronic News

CMS grants Transitional Pass-Through Payment for Medtronic Symplicity Spyral™ renal denervation catheter

The Symplicity ™ blood pressure procedure offers patients a new adjunct approach to lowering blood pressure

GALWAY, Ireland, Nov. 1, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced that the Centers for Medicare & Medicaid Services (CMS) has granted transitional pass-through (TPT) payment for the Medtronic Symplicity Spyral™ renal denervation (RDN) catheter, used in the Symplicity™ blood pressure procedure, under the Medicare Hospital Outpatient Prospective Payment System. TPT payment, which will be effective for up to three years beginning January 1, 2025, aims to support patient access to new and innovative technology, including devices granted Breakthrough Device Designations like the Symplicity Spyral RDN system.

"Receiving TPT approval for our RDN catheter is an important milestone for the Symplicity blood pressure procedure, as it will enable greater patient access to a breakthrough treatment by reducing cost barriers for healthcare systems," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. "Very few technologies achieve this qualification, and the core goals of fostering innovation and increasing access mirror Medtronic's desire to continue bringing Symplicity to even more patients suffering from uncontrolled high blood pressure. We look forward to continuing to work with CMS to establish coverage and expand patient access."

Hypertension, or high blood pressure, is the leading modifiable cause of heart attack, stroke, and death[1], and its prevalence is notably worse in underserved U.S. populations.[2] Despite available medications and lifestyle interventions, control rates remain low. The prevalence of hypertension underscores the importance for availability of adjunctive treatment options that patients may benefit from to better manage their blood pressure.

The purpose of the TPT program is to support access to newly approved innovative technologies where the costs to adopt them may otherwise inhibit patient access. The TPT program reduces barriers for Medicare beneficiaries to access critical healthcare innovations shortly after products receive FDA approval by providing hospitals with additional payments to cover their costs, while allowing CMS to collect necessary cost data to determine future outpatient payments.

Approved by the U.S. Food and Drug Administration (FDA) inNovember 2023, the Medtronic Symplicity Spyral RDN System is a minimally invasive procedure that delivers radiofrequency energy to nerves near the kidneys that can become overactive and contribute to high blood pressure. After sedation, the doctor inserts a single thin tube (known as a catheter) into the artery leading to the kidney. Once the tube is in place, the doctor administers energy to the system to calm the excessive activity of the nerves connected to the kidney. The tube is removed, leaving no implant behind.

Supporting TPT approval is the Medtronic SPYRAL HTN Global Clinical Program, which is the most comprehensive clinical program studying RDN in the presence and absence of medication, and in patients with both high and lower baseline cardiovascular risk. The Symplicity Spyral RDN System is approved for commercial use in more than 75 countries around the world and is backed by experience in more than 25,000 patients treated globally with the Symplicity blood pressure procedure. The Symplicity Spyral renal denervation system is limited for investigational use in Japan.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway,Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices,

surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on LinkedIn.

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] Bundy JD, Mills KT, Chen J, et al. Estimating the Association of the 2017 and 2014 Hypertension Guidelines With Cardiovascular Events and Deaths in US Adults: An Analysis of National Data. JAMA Cardiol. 2018 Jul 1;3(7):572-581.

[2] Aggarwal R, et al. Hypertension. 2021;78(6):1719-1726.

Contacts:

Krystin Hayward Leong	Ryan Weispfenning
Public Relations	Investor Relations
+1-508-261-6512	+1-763-505-4626

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