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Medtronic issues statement on the U.S. Centers for Medicare & Medicaid Services proposed National Coverage Determination for Symplicity Spyral™ renal denervation (RDN) system

Medtronic plc, a global leader in healthcare technology, today announced that the Centers for Medicare & Medicaid Services (CMS) posted the proposed National Coverage Determination (NCD) on renal denervation, applicable to the Symplicity Spyral™ renal denervation (RDN) system. This proposed NCD initiates a 30-day public comment period, with the final NCD posting expected on or before October 8, 2025.

"We are pleased to see CMS' proposed National Coverage Determination for the Symplicity Spyral renal denervation system," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "This milestone is an important step towards expanding patient access to this innovative treatment for hypertension, a public health crisis in the U.S."

Jason continued: "The proposed NCD from CMS – as it stands today – will provide many U.S. Medicare patients in need with access to RDN. We recognize and thank CMS for their ongoing efforts in creating new pathways to expedite access to breakthrough technologies."

Until a final NCD is announced, coverage for the Symplicity Spyral renal denervation system for Medicare patients remains on a case-by-case basis.

About the Symplicity Spyral renal denervation system

The Symplicity Spyral RDN system, approved by the U.S. Food and Drug Administration (FDA) in November 2023, is an innovative, minimally invasive procedure that delivers radiofrequency energy to nerves near the kidneys that can become overactive and contribute to high blood pressure. Symplicity Spyral is the only commercially available RDN device with the breadth of durable, consistent, long-term data and single catheter design. The SPYRAL HTN-ON MED study showed 24-month office systolic blood pressure reduction of 17.4 mmHg (Spyral patients) through two years and significantly greater reduction versus sham.[1] The SPYRAL HTN clinical program has the longest and largest real-world registry[2] and the largest dataset showing long-term reductions without the need for additional

medication.[2-3]

The Medtronic SPYRAL HTN global clinical program is the most comprehensive clinical program studying RDN in more than 4,000 patients in the presence and absence of medication, and with high baseline cardiovascular risk. The Symplicity RDN system has demonstrated sustained and durable drops in blood pressure out to three years in randomized control and real-world registry trials.[5-8]

The Symplicity RDN system is approved for commercial use in more than 75 countries around the world.

About Hypertension

Hypertension, or high blood pressure, is a global health crisis, and is the leading modifiable cause of heart attack, stroke, and death.[4] Despite available treatment with medications and lifestyle changes, blood pressure remains uncontrolled for many patients. Nearly 80% of adults with hypertension do not have it under control[1] and half of hypertension patients become non-adherent to medication within one year.[4-5]

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(opens new window) and follow Medtronic on LinkedIn(opens new window).

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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