

Medtronic announces CMS national coverage analysis for Symplicity™ Spyral Renal Denervation System

- *National coverage analysis is the first-of-its kind for a minimally invasive, interventional treatment for high blood pressure*
- *Milestone is supported by large public health need and robust, long-term data from the SPYRAL-HTN global clinical program*

GALWAY, Ireland, Jan. 13, 2025 [/PRNewswire/](#) -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced that the Centers for Medicare & Medicaid Services (CMS) is opening a national coverage analysis (NCA) on renal denervation, a process that will allow the agency to review and develop a national Medicare coverage policy for renal denervation procedures for patients with hypertension. This national coverage analysis was initiated by CMS in response to Medtronic's request to support Medicare beneficiary access to the Symplicity™ Spyral renal denervation (RDN) system, used in the Symplicity blood pressure procedure.

"Hypertension is a global health epidemic that impacts a wide variety of patients," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. "As the leader in developing a minimally invasive treatment option for hypertension, Medtronic has been closely engaged with CMS to establish a national coverage pathway for Symplicity Spyral. We appreciate CMS' efforts in creating new pathways to expedite access to breakthrough technologies like Symplicity Spyral and look forward to our continued partnership in developing a national coverage policy."

CMS' action follows Medtronic's work with the agency to pilot the framework for the Transitional Coverage for Emerging Technologies (TCET) pathway to establish coverage for the Symplicity Spyral renal denervation system, a U.S. FDA-approved breakthrough device. As referenced in the CMS tracking sheet, the expected completion date for the national coverage analysis is October 11, 2025. Until a national coverage determination is put into effect, Symplicity blood pressure procedures will continue to be evaluated for coverage based on medical necessity for individual Medicare patients.

About the Symplicity Spyral renal denervation procedure

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 clinical program has demonstrated 18 mmHg office blood pressure reductions out to three years in a real-world setting,¹ has the longest and largest real-world registry² 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 over 4,000 patients in the presence and absence of medication, and with high baseline cardiovascular risk. The Symplicity blood pressure procedure 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 over 75 countries around the world.

About Hypertension

Hypertension, or high blood pressure, impacts more than 1 billion adults worldwide, 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 control¹ 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 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 Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomized, sham-controlled trial. *The Lancet*. 2022; 399:1401-1410.

² Mahfoud F, Mancía G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. *Hypertension*. 2023 Aug ;80(8):1759-177.

³ Kandzari DE et al. Long-term Safety and Efficacy of Radiofrequency Renal Denervation in the Presence of Antihypertensive Drugs: 24-Month Results from the SPYRAL HTN-ON MED Randomized Trial. TCT 2024

⁴ WHO. Hypertension fact sheet. September 13, 2019. Available at: <https://www.who.int/news-room/fact-sheets/detail/hypertension>. Accessed February 15, 2022.

⁵ Bhatt, D. et al, Long-term outcomes after catheter-based renal artery denervation for resistant hypertension: final follow-up of the randomised SYMPLICITY HTN-3 Trial. *The Lancet*. September 18, 2022. DOI:[https://doi.org/10.1016/S0140-6736\(22\)01787-1](https://doi.org/10.1016/S0140-6736(22)01787-1).

⁶ Mahfoud, F. et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. *Hypertension*. August 2023; DOI: 10.1161/HYPERTENSIONAHA.123.21283.

⁷ Mahfoud, F. et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. *The Lancet*. April 2022. [https://doi.org/10.1016/S0140-6736\(22\)00455-X](https://doi.org/10.1016/S0140-6736(22)00455-X)(opens new window)

⁸ Mahfoud, F. et al. Cardiovascular Risk Reduction After Renal Denervation According to Time in Therapeutic Systolic Blood Pressure Range. *Journal of the American College of Cardiology*. November 2022. <https://doi.org/10.1016/j.jacc.2022.08.802>

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