

## U.S. Centers for Medicare & Medicaid Services finalizes National Coverage Determination for the Medtronic Symplicity Spyral™ renal denervation (RDN) system

Symplicity blood pressure procedure is now covered for qualifying Medicare patients

GALWAY, Ireland, Oct. 28, 2025 [/PRNewswire/](#) -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced that the Centers for Medicare & Medicaid Services (CMS) has released the final National Coverage Determination (NCD) on renal denervation, applicable to the Symplicity Spyral™ renal denervation (RDN) system, also known as the Symplicity blood pressure procedure. This final determination will now provide Medicare patients with access to the Symplicity blood pressure procedure for the treatment of uncontrolled hypertension, or high blood pressure.

"We are very pleased with the final national coverage determination, which opens up patient access to renal denervation with the Symplicity Spyral RDN system, a safe and durable blood pressure-lowering procedure for patients who have not succeeded with medication or lifestyle changes alone," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "This milestone enables physicians to offer patients more choices when managing hypertension, potentially leading to better outcomes for a population in urgent need of new options. We congratulate CMS and recognize all the work it took to get to this point."

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. 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.

"We're proud to be at the forefront of expanding access to minimally invasive therapies and advancing hypertension treatment," said Skip Kiil, executive vice president and president of the Medtronic Cardiovascular portfolio. "This determination represents a significant opportunity to improve care for patients and opens a novel and meaningful market for Medtronic, positioning our renal denervation technology as one of the most exciting growth drivers for the company. Our commercial teams will be actively leveraging this milestone, collaborating closely with healthcare providers and hypertension centers as we accelerate the adoption of this transformative growth opportunity for Medtronic."

Symplicity Spyral is available in major centers across the U.S., including large integrated delivery networks as part of their hypertension care offerings.

Medtronic will continue working with physician partners and healthcare providers as they adopt the technology to support patient access.

The Symplicity Spyral RDN system is approved for commercial use in nearly 80 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.<sup>1</sup> 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<sup>1</sup> and 50% of hypertension patients become non-adherent to medication within one year.<sup>2</sup>

## About the SPYRAL HTN Global Clinical Program

The Medtronic SPYRAL HTN global clinical program is the most comprehensive clinical program studying RDN in more than 5,000 patients in the presence and absence of medication, and with high baseline cardiovascular risk, and is backed by experience in over 30,000 patients globally.<sup>3-10</sup> The Symplicity Spyral RDN system has demonstrated sustained and durable drops in blood pressure out to three years in randomized control and real-world registry trials.<sup>11-13</sup> Symplicity Spyral is the only commercially available RDN device with the breadth of durable, consistent, long-term data and single catheter design.<sup>4, 5, 8, 10, 14</sup>

## 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 (NYSE: MDT), visit [www.Medtronic.com](http://www.Medtronic.com) and follow Medtronic on [LinkedIn](https://www.linkedin.com/company/medtronic).

**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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<sup>1</sup> WHO. Hypertension fact sheet. September 25, 2025. Available at: <https://www.who.int/news-room/fact-sheets/detail/hypertension>.

<sup>2</sup> Berra E, Azizi M, Capron A, et al. A. Evaluation of Adherence Should Become an Integral Part of Assessment of Patients With Apparently Treatment-Resistant Hypertension. *Hypertension*. 2016 Aug;68(2):297-306.

<sup>3</sup> Medtronic data on file, RDN Catheter Historical Data, Feb 2025. Data includes both Symplicity Flex and Symplicity Spyral.

<sup>4</sup> Kandzari DE, Townsend RR, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. 2023 Nov 7;82(19):1809-1823.

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- <sup>8</sup> Townsend RR, Mahfoud F, Kandzari DE, et al. Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN-OFFMED): a randomised, sham-controlled, proof-of-concept trial. Lancet. November 11, 2017;390(10108):2160–2170.
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- <sup>10</sup> Mahfoud F, Schlaich M, Schmieder RE, et al. Long-term outcomes in ESC guideline-recommended patients for RDN from Global SYMPLICITY Registry DEFINE. EuroPCR 2025.
- <sup>11</sup> 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
- <sup>12</sup> 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: DOI: [10.1016/S0140-6736\(22\)01787-1](https://doi.org/10.1016/S0140-6736(22)01787-1)
- <sup>13</sup> 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.
- <sup>14</sup> Mahfoud F, et al. Long-term outcomes in ESC guideline-recommended patients for RDN from Global SYMPLICITY registry DEFINE. EuroPCR 2025

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