



February 12, 2025

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**RE: CAG-00470N Renal Denervation for Uncontrolled Hypertension**

The American College of Cardiology, the Society of Cardiovascular Angiography & Interventions (SCAI), and the Society for Vascular Medicine (SVM) support a National Coverage Determination (NCD) for renal denervation (RDN). Nearly half of the US adult population has hypertension, and despite the availability of medications and lifestyle interventions to manage hypertension, nearly 80% of these individuals do not achieve recommended blood pressure goals. This shortfall is due to several challenges associated with medical and lifestyle therapy, including the fact that many patients with elevated blood pressure who are still at substantial risk due to their hypertension have no or minimal symptoms, justifying the moniker “silent killer”. Further, the cost of medications, adverse side effects, limited access to healthcare, and poor adherence to prescribed treatment regimens compound the overall low rates of blood pressure control. While some of these barriers are addressable, there is clearly a need for additional solutions, like RDN, to help patients manage their blood pressure.

RDN is a minimally invasive procedure used to treat uncontrolled hypertension. It involves disrupting the nerves surrounding the renal arteries using a minimally invasive approach, thereby reducing sympathetic nerve activity and lowering blood pressure. During the procedure, a catheter is inserted into the femoral artery (future iterations will allow access via the radial artery) to access the arteries supplying the kidneys. Different methods, such as radiofrequency ablation or ultrasound, are then applied to target the sympathetic nerves that arborize the renal arteries to interrupt nerve signaling without injury to the arteries or other surrounding structures.

The totality of data supporting RDN is robust and demonstrates consistent reductions in blood pressure within treatment groups, above and beyond existing approved medical/lifestyle therapies. In addition to large study in real-world clinical practice, the evidence base is highlighted by multiple independent sham-controlled randomized trials that are extraordinarily challenging to conduct and infrequently implemented in cardiovascular device evaluation. Overall, these data support that RDN

can be a valuable addition to lifestyle changes and antihypertensive medications for managing uncontrolled hypertension.

High-quality, sham-controlled randomized trial evidence for both radiofrequency and ultrasound RDN demonstrates their effectiveness in reducing blood pressure in patients with uncontrolled and/or resistant hypertension. The SPYRAL HTN-ON MED trial showed that radiofrequency RDN significantly reduced office systolic blood pressure (oSBP) by 4.9 mmHg compared to sham therapy.<sup>1</sup> The SPYRAL HTN-OFF MED pivotal trial showed significant reductions in 24-hour and office blood pressure measurements with RDN compared to a sham procedure in the absence of antihypertensive medications.<sup>2</sup> Moreover, the Global SYMPPLICITY Registry (GSR) with data from over 3000 patients reported an average reduction of 8.9 mmHg in 24-hour systolic blood pressure (SBP) at three years.<sup>3</sup> The RADIANCE-HTN SOLO and RADIANCE II trials demonstrated a significant reduction in daytime ambulatory systolic blood pressure (ABPM) by 6.3 mmHg in patients with mild to moderate hypertension off medications.<sup>4, 5</sup> The RADIANCE-HTN TRIO trial confirmed the effectiveness of ultrasound RDN in patients with resistant hypertension on single-pill combination therapy.<sup>6</sup> Additionally, a comprehensive meta-analysis of ten trials comprising 2,478 patients found that RDN reduced 24-hour systolic blood pressure by 4.4 mmHg and office systolic blood pressure by 6.6 mmHg compared to sham procedures.<sup>7</sup> Both radiofrequency and ultrasound RDN have been supported by evidence for their safety and efficacy in managing uncontrolled blood

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<sup>1</sup> 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 randomised, sham-controlled trial. *The Lancet*. 2022; 399:1401-1410.

<sup>2</sup>Böhm M, Kario K, Kandzari DE, et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet* March 2020.

<sup>3</sup> Mahfoud F, Böhm M, Schmieder RE, Narkiewicz K, Ewen S, Ruilope L, Schlaich M, Williams B, Fahy M, Mancía G. Effects of renal denervation on kidney function and long-term outcomes: 3-year follow-up from the Global SYMPPLICITY Registry. *Eur Heart J*. 2019 Nov 1;40(42):3474-3482.

<sup>4</sup> Azizi M, Schmieder RE, Mahfoud F, Weber MA, Daemen J, Davies J, Basile J, Kirtane AJ, Wang Y, Lobo MD, Saxena M, Feyz L, Rader F, Lurz P, Sayer J, Sapoval M, Levy T, Sanghvi K, Abraham J, Sharp ASP, Fisher NDL, Bloch MJ, Reeve-Stoffer H, Coleman L, Mullin C, Mauri L; RADIANCE-HTN Investigators. Endovascular ultrasound renal denervation to treat hypertension (RADIANCE-HTN SOLO): a multicentre, international, single-blind, randomised, sham-controlled trial. *Lancet*. 2018 Jun 9;391(10137):2335-2345. doi: 10.1016/S0140-6736(18)31082-1. Epub 2018 May 23. Erratum in: *Lancet*. 2018 Sep 8;392(10150):820.

<sup>5</sup> Azizi M, Saxena M, Wang Y, Jenkins JS, Devireddy C, Rader F, Fisher NDL, Schmieder RE, Mahfoud F, Lindsey J, Sanghvi K, Todoran TM, Pacella J, Flack J, Daemen J, Sharp ASP, Lurz P, Bloch MJ, Weber MA, Lobo MD, Basile J, Claude L, Reeve-Stoffer H, McClure CK, Kirtane AJ; RADIANCE II Investigators and Collaborators. Endovascular Ultrasound Renal Denervation to Treat Hypertension: The RADIANCE II Randomized Clinical Trial. *JAMA*. 2023 Feb 28;329(8):651-661. doi: 10.1001/jama.2023.0713. Erratum in: *JAMA*. 2023 Jun 13;329(22):1989.

<sup>6</sup> Azizi M, Sanghvi K, Saxena M, Gosse P, Reilly JP, Levy T, Rump LC, Persu A, Basile J, Bloch MJ, Daemen J, Lobo MD, Mahfoud F, Schmieder RE, Sharp ASP, Weber MA, Sapoval M, Fong P, Pathak A, Lantelme P, Hsi D, Bangalore S, Witkowski A, Weil J, Kably B, Barman NC, Reeve-Stoffer H, Coleman L, McClure CK, Kirtane AJ; RADIANCE-HTN investigators. Ultrasound renal denervation for hypertension resistant to a triple medication pill (RADIANCE-HTN TRIO): a randomised, multicentre, single-blind, sham-controlled trial. *Lancet*. 2021 Jun 26;397(10293):2476-2486. doi: 10.1016/S0140-6736(21)00788-1.

<sup>7</sup> Vukadinović D, Lauder L, Kandzari DE, Bhatt DL, Kirtane AJ, Edelman ER, Schmieder RE, Azizi M, Böhm M, Mahfoud F. Effects of Catheter-Based Renal Denervation in Hypertension: A Systematic Review and Meta-Analysis. *Circulation*. 2024 Nov 12;150(20):1599-1611.

pressure,<sup>8,9</sup> and observational and limited randomized trial data suggest that these benefits may be durable and safe in the long term.

RDN is an emerging therapy for hypertension treatment, offering an innovative approach to manage uncontrolled high blood pressure as a complement to medications and lifestyle interventions. There are other modalities of RDN being studied that are not yet FDA-approved that include ethanol-ablation as well as non-invasive techniques such as focused ultrasound and external high-intensity focused ultrasound. There is also an investigational approach that targets both the renal and hepatic arteries to enhance blood pressure reduction. Once FDA-approved, technologies that fall under the same class should be covered under the same NCD to ensure comprehensive treatment options for patients.

### **Patient Criteria**

**Patients with resistant hypertension, characterized by blood pressure that still exceeds 130/80 mm Hg despite being on three maximally tolerated medications from classes with proven outcomes (such as mineralocorticoid receptor antagonists, angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, calcium channel blockers, thiazide diuretics, and beta blockers), benefit from RDN. Additionally, patients with uncontrolled hypertension who have tried lifestyle modifications and antihypertensive medications but are either intolerant of additional medications or for whom escalation of medications is ineffective, and who are willing to undergo renal denervation after shared decision-making, are also suitable candidates.** When evaluating patients with elevated blood pressure who may be candidates for RDN, priority might be given to patients with higher cardiovascular risk (e.g., comorbidities of coronary artery disease, diabetes, prior transient ischemic attack/stroke, or chronic kidney disease), as they are likely to gain the most significant benefit from blood pressure reduction. CMS should not limit coverage to resistant hypertension or intolerance to medication alone. Given the additional populations and clinical scenarios where RDN can offer substantial benefits, coverage should reflect this broader applicability.

As stated in the 2023 *SCAI Position Statement on Renal Denervation for Hypertension: Patient Selection, Operator Competence, Training and Techniques, and Organizational Recommendations*,<sup>10</sup> RDN was initially tested in patients with resistant hypertension, where controlling blood pressure was challenging despite the use of at least three antihypertensive medications, including a diuretic. For patients who

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<sup>8</sup> Cluett JL, Blazek O, Brown AL, East C, Ferdinand KC, Fisher NDL, Ford CD, Griffin KA, Mena-Hurtado CI, Sarathy H, Vongpatanasin W, Townsend RR; American Heart Association Council on Hypertension; Council on Cardiovascular and Stroke Nursing; Council on the Kidney in Cardiovascular Disease; and Council on Peripheral Vascular Disease. Renal Denervation for the Treatment of Hypertension: A Scientific Statement From the American Heart Association. *Hypertension*. 2024 Oct;81(10):e135-e148.

<sup>9</sup> Fisher NDL, Kirtane AJ. Renal denervation for hypertension. *Nat Rev Cardiol*. 2025 Jan 2. doi: 10.1038/s41569-024-01104-z.

<sup>10</sup> Swaminathan RV, East CA, Feldman DN, Fisher ND, Garasic JM, Giri JS, Kandzari DE, Kirtane AJ, Klein A, Kobayashi T, Koenig G, Li J, Secemsky E, Townsend RR, Aronow HD. SCAI Position Statement on Renal Denervation for Hypertension: Patient Selection, Operator Competence, Training and Techniques, and Organizational Recommendations. *J Soc Cardiovasc Angiogr Interv*. 2023 Aug 21;2(6Part A):101121.

adhere to their medication regimen, these individuals have limited further medical treatment options and may benefit most from RDN. However, other groups, such as those who struggle with medication adherence, might also see significant benefits. Long-term follow-up has shown that reduced adherence to medication can negate the clinical benefits of blood pressure reduction. Many patients previously diagnosed with resistant hypertension are now more accurately identified as having 'apparent resistant hypertension,' as nearly half of these patients are not taking their prescribed medications one year later.

Patient preference plays a crucial role in selecting the most appropriate treatment strategy. For some, medication treatment is limited by side effects, while for others, nonadherence is due to cost, fear, or lack of understanding of the benefits. Importantly, a high burden of antihypertensive medications is associated with increased rates of nonadherence. Before referring a patient for RDN, a multi-disciplinary team should discuss the necessity of other efforts to control blood pressure, such as lifestyle modifications and optimizing medication regimens, in addition to the workup and management of secondary causes of hypertension.

Shared decision-making is essential in the context of RDN due to the variability in individual patient responses and the fact that it is a procedure (although minimally invasive). It involves a collaborative process where clinicians and patients work together to make informed decisions about treatment options and discuss medication adherence issues prior to referral for RDN. This approach ensures that patients understand the risks, benefits, alternatives, and potential outcomes of RDN, aligning the treatment with their preferences, values, and lifestyle.

For RDN to be effective, it is important to rule out conditions like white coat and secondary hypertension. . White coat hypertension should be ruled out by confirming elevated blood pressures outside of the provider's office. Secondary hypertension, caused by underlying conditions such as kidney disease or hormonal disorders, must be identified and managed appropriately. Comprehensive workup and exclusion of these conditions are needed to ensure that the treatment outcomes align with those demonstrated in clinical studies. Patients with renal artery stenosis, end-stage renal disease and fibromuscular dysplasia have been excluded from randomized trials and the safety and effectiveness of RDN in these patient populations is unknown. Those with treatable secondary causes of hypertension should not undergo RDN. Other secondary causes, like Cushing syndrome and thyroid disease, should be excluded if suspected. Common factors such as sleep apnea and obesity do not exclude patients from RDN, but optimization of these risk factors should be attempted prior to referral for RDN. There are limited data on RDN for certain subgroups, including those with stage 1 hypertension, end stage renal disease, and kidney transplant recipients.<sup>11</sup>

RDN is appropriate in the Medicare population. While the mean age of treated patients in randomized trials was mid 50's, studies have included patients aged 65 and older and found that the

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<sup>11</sup> Cluett JL, Blazek O, Brown AL, East C, Ferdinand KC, Fisher NDL, Ford CD, Griffin KA, Mena-Hurtado CI, Sarathy H, Vongpatanasin W, Townsend RR; American Heart Association Council on Hypertension; Council on Cardiovascular and Stroke Nursing; Council on the Kidney in Cardiovascular Disease; and Council on Peripheral Vascular Disease. Renal Denervation for the Treatment of Hypertension: A Scientific Statement From the American Heart Association. *Hypertension*. 2024 Oct;81(10):e135-e148.

effectiveness of the treatment does not diminish with age.<sup>12,13</sup> This is significant because older adults often have more complex health profiles and may be more resistant to traditional hypertension treatments.

### **Institution & Operator Criteria**

Institutions interested in providing RDN therapy for managing uncontrolled and resistant hypertension need several key components. First, they require a clinician with expertise in hypertension management and access to resources for screening, testing, and treating hypertension is required. This clinician should also be responsible for the shared decision-making and long-term care of hypertensive patients referred for RDN.

As outlined in the SCAI position paper,<sup>14</sup> a dedicated hypertension program is important. Alternatively, the institution should have access to the necessary expertise and services of such a program. This program should manage hypertensive patients comprehensively, including performing serial blood pressure measurements, serologic and imaging tests to rule out secondary hypertension causes, and abdominal imaging to evaluate renal artery anatomy. The program must also provide intensive follow-up during and after the RDN procedure to monitor for complications and manage antihypertensive therapy adjustments.

A multidisciplinary team should be established to manage potential RDN patients. Depending on geography and local practices, this may include a clinical hypertension navigator (physician, advanced practice provider, or registered nurse) and specialists from various fields such as nephrology, endocrinology, general cardiovascular medicine, vascular medicine, primary care, interventional cardiology, interventional radiology, vascular surgery, invasive nephrology and/or other appropriately trained interventionalists. The team should ensure appropriate patient selection, management, and treatment, with support staff like triage nurses, pharmacy specialists, and nutritionists providing patient-centered care. The institution should also maintain or participate in a quality registry of RDN patients and have the necessary infrastructure and equipment for evaluating, treating, and managing patients.

The operators performing RDN must be credentialed interventional specialists. These specialists should possess current interventional or endovascular experience, ensuring they are proficient in navigating, treating and addressing complications in the renal arteries. Additionally, they must undergo device-specific training, which may include didactic modules covering theoretical aspects, hands-on simulation training to practice the procedure in a controlled environment, and/or

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<sup>12</sup> Mahfoud F, Mancia G, Schmieder R, et al. Renal denervation in high-risk patients with hypertension. *J Am Coll Cardiol.* 2020;75(23):2879–2888.

<sup>13</sup> Ziegler AK, Bertog S, Kaltenbach B, et al. Efficacy and safety of renal denervation in elderly patients with resistant hypertension. *Catheter Cardiovasc Interv.* 2015;86(2):299–303.

<sup>14</sup> Swaminathan RV, East CA, Feldman DN, Fisher ND, Garasic JM, Giri JS, Kandzari DE, Kirtane AJ, Klein A, Kobayashi T, Koenig G, Li J, Secemsky E, Townsend RR, Aronow HD. SCAI Position Statement on Renal Denervation for Hypertension: Patient Selection, Operator Competence, Training and Techniques, and Organizational Recommendations. *J Soc Cardiovasc Angiogr Interv.* 2023 Aug 21;2(6Part A):101121.

proctored cases. This comprehensive training ensures that specialists are well-prepared and competent in performing RDN, ultimately contributing to better patient outcomes.

### **CED Requirements**

Coverage with Evidence Development (CED) is an extremely powerful mechanism offering significant value to payers, clinicians, and patients. CED has been demonstrated to be a technique that promotes the diffusion of diverse innovative cardiovascular technologies and services into the marketplace while simultaneously promoting timely clinical safety and effectiveness evaluations. The societies support the use of CED to provide Medicare beneficiaries with prompt access to newer technologies and services when early evidence suggests, but does not yet convincingly demonstrate, a net benefit for beneficiaries.

Professional societies have been instrumental in data collection for CED through registries. The National Cardiovascular Data Registry (NCDR) is uniquely positioned to collaborate with stakeholders on RDN real-world data collection, while minimizing the burden on hospitals. Leveraging its extensive experience and resources, the NCDR can streamline the data collection process, providing valuable insights to assess the reasonableness and necessity of treatments for regulatory decision-making.

RDN is a reasonable and effective treatment option for older adults within the Medicare population, providing a valuable alternative for managing uncontrolled and resistant hypertension when traditional treatments are insufficient. The societies support Medicare coverage of RDN and appreciate the opportunity to provide feedback on the National Coverage Analysis. Please direct any questions or concerns to Amanda Stirling, Regulatory Affairs Associate, at 202-375-6553 or [astirling@acc.org](mailto:astirling@acc.org).

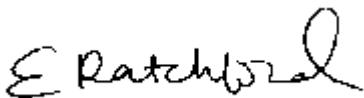
Sincerely,



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