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Society of Interventional Radiology
*The vision to heal*

August 8, 2025

Lori Ashby, Lead Analyst
Steven Farmer, MD, PhD, Lead Medical Officer
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

**Re: Proposed decision memo for renal denervation for uncontrolled hypertension, dated July 10, 2025**

Dear Ms. Ashby and Dr. Farmer,

The Society of Interventional Radiology (SIR) is a professional medical association representing over 8,000 members, including U.S. physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. SIR supports the proposed National Coverage Determination (NCD) and appreciates the thoughtful approach taken in the decision memo. We value the recognition of the clinical complexity and variability within the Medicare population with uncontrolled hypertension, as well as the emphasis on ensuring patients have received appropriate, guideline-directed care before consideration for renal denervation (RDN). Outlined below, we seek to provide clarity and strengthen the proposed NCD.

**Patient Criteria**

The current coverage criteria in the decision memo state that patients must have "(a) Diagnosis of uncontrolled hypertension (>140/90 mm Hg) despite active management by a clinician with primary responsibility for blood pressure management." As written, this may be interpreted to mean that patients must exceed both the systolic and diastolic thresholds. To align with the American Heart Association's 2024 definition of Stage 2 hypertension, as referenced by CMS on page 10 of the draft NCD (Table 1: Categories of BP in Adults), we recommend revising the language to:

**"(a) Diagnosis of uncontrolled hypertension (defined as a systolic blood pressure >140 mm Hg or a diastolic blood pressure >90 mm Hg) despite active management by a clinician with primary responsibility for blood pressure management."**

This clarification would ensure consistency with established clinical guidelines and prevent unnecessary exclusions from coverage.

According to the current coverage criteria, as stated above, the patient must have uncontrolled hypertension (> 140/90 mm Hg). This procedure should not be restricted to stage 2 hypertension; **we recommend that CMS extend therapy to stage 1 hypertension, with a target blood pressure of 130/80**

**mmHg, for patients with persistent blood pressure above this level, particularly those at increased cardiovascular risk.**

A substantial number of patients continue to have blood pressure readings above 130/80 mmHg despite receiving optimal medical therapy. Evidence demonstrates that even modest reductions in systolic blood pressure lead to meaningful decreases in cardiovascular events.

The decision memo currently includes the following coverage criterion: "(e) Patient has no contraindication to RDN, including estimated Glomerular Filtration Rate (eGFR) < 40, pregnancy, fibromuscular dysplasia, stented renal artery (< 3 months before RDN), renal artery aneurysm, significant renal artery stenosis (> 50%), or known kidney or secreting adrenal tumors."

**SIR recommends that CMS simplify the eGFR threshold to better align with current FDA-approved device labeling and allow for future updates as evidence evolves. Notably, an eGFR < 40 is not listed as a contraindication in the labeling for the Paradise or Spyral device; rather, it reflects an unstudied population. Adjusting this language would maintain patient safety while supporting broader clinical applicability as more data become available.**

The current coverage criteria outlined in Decision Memo (f) — which require that primary clinicians manage the patient for a minimum of six months before referral for RDN, including at least three encounters with no more than one being virtual — place an unrealistic burden on both patients and providers. In the context of nationwide physician shortages and prolonged wait times to see hypertension specialists, such requirements may delay necessary treatment and exacerbate disparities in care.

**We strongly recommend modifying the criteria to require a minimum of 90 days of management, with at least two encounters, no more than one of which is virtual, prior to referral for RDN. This adjustment maintains appropriate safeguards while facilitating more timely access to care. Restricting access to care, particularly for Medicare beneficiaries, undermines efforts to improve population health outcomes. Broadening access to renal denervation (RDN) is critical to addressing persistent gaps in hypertension control.**

The current CED study criteria state that patients must be "(c) On stable doses of maximally tolerated guideline-directed medical therapy (GDMT), including lifestyle modifications, for at least 3 months before referral for RDN." **SIR recommends that CMS clarify whether the term "maximally tolerated" is intended to mean "optimally tolerated."**

In clinical practice, "optimally tolerated" is often viewed as a more patient-centered standard, recognizing individual variability in response, side effects, and comorbid conditions. Reframing this language to "optimally tolerated" would more accurately reflect real-world treatment decisions and promote appropriate, individualized care before considering renal denervation.

**Physician Criteria**

Under the proposed Physician criteria, physicians without prior endovascular training or renovascular expertise must complete at least ten supervised diagnostic/therapeutic renovascular procedures—half

as primary operator—and a minimum of five proctored RDN cases with each approved device (c). Physicians with prior endovascular training and active experience must complete at least five proctored RDN cases with each approved device (d).

SIR recommends that CMS clarify whether these training and proctoring requirements apply to **all** approved RDN devices on the market or only to the **specific device(s)** a physician intends to use in clinical practice. Given the procedural and technical differences across RDN systems, we believe it is most appropriate—and practical—for physicians to be trained and proctored only on the device(s) they will use. This approach maintains high standards of procedural competency while avoiding unnecessary redundancy and administrative burden.

**Facility Criteria**

3. Facility Criteria (a): The current requirement that facilities performing RDN maintain a multidisciplinary hypertension program—including a hypertension clinician with longitudinal management responsibility, **a hypertension navigator**, and input from various medical specialties (e.g., internal medicine, endocrinology, cardiology, nephrology)—is well-intentioned but may be impractical in many settings.

While we support the inclusion of dedicated blood pressure management as a key component of care, mandating a hypertension navigator is an unrealistic expectation for most facilities, particularly given workforce constraints. We recommend that the criteria allow for flexibility in how comprehensive hypertension management is achieved, without requiring specific roles that may not be feasible to implement universally.

SIR appreciates the opportunity to provide meaningful feedback on the CMS proposed decision memo for renal denervation in the treatment of uncontrolled hypertension. If you have any questions, please do not hesitate to contact SIR's Senior Manager of Health Policy and Economics, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

Robert A. Lookstein, MD, FSIR
President, Society of Interventional Radiology

Cc: Eve Lee, MBA, CAE
Chief Executive Officer, Society of Interventional Radiology