Renal denervation

Clinical Policy ID: CCP.1283

Recent review date: 1/2026

Next review date: 5/2027

Policy contains: Renal sympathetic ablation; renal denervation; treatment-resistant hypertension.

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Coverage policy

Renal denervation for treatment-resistant hypertension is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Medically prescribed antihypertensive therapy.
- Standard medical treatment of underlying disorders.

Background

Hypertension is largely viewed as a major modifiable risk factor associated with mortality. The sympathetic nervous system is activated in stressful or emergency situations and often referred to as the fight-or-flight response. The kidneys play a major role in the response by increasing secretion of renin to activate a chemical chain reaction that changes the hemodynamic system of the body and provides the protective physiological response needed for a person to react. The systemic effects include arterial blood vessel constriction, increased heart rate, dilated pupils, and elevation of blood pressure (Sarathy, 2021).

Sympathetic hyperactivity-mediated resistant hypertension has been associated with multiple conditions, including but not limited to stroke, obstructive sleep apnea, metabolic syndrome, myocardial hypertrophy and heart failure, and cardiac dysrhythmias (Böhm, 2014; Hou, 2018; Sarathy, 2021). Renal injury or hypoxia can further result in systemic and renal sympathetic activity (Hou, 2018).

Renal denervation, also referred to as endovascular renal sympathetic ablation, is a minimally invasive percutaneous procedure that applies radiofrequency or focused ultrasound via a catheter inserted through the femoral artery to selectively engage the sympathetic nerve fibers surrounding the renal artery. The desired result is to interrupt the influence of the sympathetic reflexes on the kidney and systemic hemodynamics and provide a simple solution to the complex issue of hypertension (Azizi, 2023).

The procedure usually takes from 45 to 60 minutes when a single catheter is used, or less time with a multi-electrode or balloon catheter. Analgesia and sedation are required. Renal denervation has been proposed as a non-pharmacologic treatment for treatment-resistant hypertension, which is common in patients with pre-existing comorbid atherothrombotic disease and obesity, and for other sympathetically-driven conditions (Böhm, 2014).

In 2023, two renal denervation devices received pre-market approval for clinical use in the United States: Symplicity Spyral™ Renal Denervation System and Paradise® Ultrasound Renal Denervation System (U.S. Food and Drug Administration, 2023a, 2023b). The 2025 American Heart Association/American College of Cardiology (AHA/ACC) High Blood Pressure Guideline subsequently provided the first U.S. professional society recommendations for renal denervation, assigning a Class 2b recommendation ("may be reasonable") for carefully selected patients, while emphasizing that broader FDA-approved indications exceed the evidence base from clinical trials (Jones, 2025).

Findings

Evidence for renal denervation in treatment-resistant hypertension includes professional society statements, systematic reviews and meta-analyses, sham-controlled randomized trials, observational registries, and regulatory submissions. The body of evidence demonstrates that renal denervation produces statistically significant but modest reductions in blood pressure compared with sham procedures, with ambulatory systolic blood pressure reductions typically ranging from 3 to 6 mm Hg at two to six months. Serious procedural adverse events occur in fewer than 1% of patients. However, no randomized controlled trial has demonstrated that renal denervation reduces cardiovascular events such as stroke, myocardial infarction, or heart failure.

Guidelines:

Guidelines and consensus recommendations have consistently identified renal denervation as a potential adjunctive therapy for patients with resistant or uncontrolled hypertension, albeit with caution and calls for further evidence. Position statements from the Society for Cardiovascular Angiography and Interventions reported that

modest systolic blood pressure reductions of about 10 mm Hg can yield a 20% relative risk reduction in cardiovascular events, but also noted variable response rates (Swaminathan, 2023). The AHA/ACC guideline reports that only 60% to 70% of patients undergoing renal denervation experience a meaningful reduction in ambulatory systolic blood pressure of at least 5 mm Hg, and predictors of blood pressure response have not been consistently demonstrated across clinical trials (Jones, 2025).

The American Heart Association highlighted an average systolic blood pressure reduction of about 5 to 10 mm Hg, with approximately 60% to 70% of patients achieving at least a 5 mm Hg decrease by two to three months. Longer-term data from a global registry indicated sustained reductions of approximately 16 mm Hg in office measurements and 8 mm Hg by ambulatory monitoring over three years, with serious adverse events typically under 1% and no meaningful decline in renal function (Cluett, 2024; Carey, 2018). The European Society of Cardiology Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions cited durable 24-hour blood pressure reductions of clinically meaningful magnitude over up to three years without significant renal complications (Barbato, 2023).

The AHA/ACC High Blood Pressure Guideline provides the first U.S. guideline recommendations specifically addressing renal denervation (Jones, 2025). The guideline assigns a Class 2b recommendation (Level of Evidence B-R) stating that renal denervation "may be reasonable as an adjunct treatment" in carefully selected patients meeting specific criteria: office systolic blood pressure 140-180 mm Hg and diastolic blood pressure ≥90 mm Hg, estimated glomerular filtration rate ≥40 mL/min/1.73 m², and resistant hypertension despite optimal treatment or intolerable side effects to additional antihypertensive therapy. The guideline includes two Class 1 recommendations: (1) all patients being considered for renal denervation should be evaluated by a multidisciplinary team with expertise in resistant hypertension and renal denervation, and (2) shared decision-making should be employed to discuss benefits of blood pressure lowering and procedural risks compared with continuing medical therapy. The guideline notes that the risk of renal artery stenosis requiring intervention is approximately 0.2% per year, with highest risk within the first 6 months post-procedure.
Regulatory bodies have taken more conservative positions. The National Institute for Health and Care Excellence advised that percutaneous transluminal renal sympathetic denervation be performed only with specific governance, consent, and audit arrangements due to uncertainties in long-term benefit (NICE, 2023). Hypertension Canada did not recommend routine use, as the device was not approved in Canada, and advised that the procedure be limited to controlled clinical investigations (Hiremath, 2020).

Systematic Reviews:

A number of systematic reviews and meta-analyses have quantified the blood pressure-lowering effects of renal denervation, though effect sizes and consistency have varied. A meta-analysis of second-generation sham-controlled trials (n=1622) found statistically significant reductions in 24-hour ambulatory systolic blood pressure by -3.72 mm Hg (95% CI -5.44 to -2.00; p<0.001) and daytime systolic blood pressure by -4.10 mm Hg (95% CI -5.84 to -2.37; p<0.001). A 2025 network meta-analysis comparing renal denervation technologies (Tu, 2025) found that radiofrequency ablation of main renal arteries and branches reduced 24-hour ambulatory systolic blood pressure by -5.59 mm Hg (95% CI -8.00 to -3.18) versus sham, while ultrasound-based renal denervation achieved reductions of -4.48 mm Hg (95% CI -6.51 to -2.45). Radiofrequency ablation of main arteries alone showed smaller, non-significant reductions (-2.00 mm Hg, 95% CI -4.30 to 0.30), and alcohol-mediated denervation demonstrated limited efficacy (-1.80 mm Hg, 95% CI -5.00 to 1.40). Reductions in office systolic blood pressure were also statistically significant in this analysis (-6.04 mm Hg, 95% CI -11.31 to -0.78; p=0.024), though the effect was less pronounced than for ambulatory measures; nighttime reductions did not reach statistical significance (Dantas, 2024). Another quantitative review of 15 randomized studies (n=2581) also reported statistically significant reductions in systolic and diastolic blood pressure across ambulatory, office, and

home measurements (Mufarrih, 2024). The 2025 network meta-analysis found no significant differences in safety outcomes across renal denervation technologies, with all modalities demonstrating comparable adverse event profiles to sham procedures (Tu, 2025). A comprehensive systematic review analyzing 25 randomized controlled trials (16 included, n = 2268) demonstrated clinically meaningful reductions in office and ambulatory systolic blood pressure across multiple subgroups (Sharp, 2024). Similarly, a meta-analysis focusing on ultrasound-based renal denervation reported mean systolic and diastolic reductions of approximately 2 to 4 mm Hg across office, daytime, nighttime, and home measurements (Maia, 2024).

Other syntheses have yielded more mixed results. A systematic review and meta-analysis of six studies (n=989) found no statistically significant difference in 24-hour ambulatory or office blood pressure compared to sham, with low certainty of evidence (Ahmed, 2023). Earlier systematic reviews and meta-analyses offered inconsistent support for renal denervation in treatment-resistant hypertension (Fadl Elmula, 2015; Shafi, 2016) and for related conditions such as Type 2 diabetes and obstructive sleep apnea (Pan, 2015; Shantha, 2015). A Cochrane review reported low- to moderate-quality evidence that did not clearly support long-term benefits (Coppolino, 2017). Additional meta-analyses published subsequently confirmed that renal denervation could safely reduce blood pressure compared to sham, but noted challenges with medication adherence and the need for improved trial design (Agasthi, 2019; Cheng, 2019; Liu, 2019; Lobo, 2019). A 2025 systematic review specifically examining renal denervation combined with antihypertensive medications (Adnan, 2025) found significant reductions in 24-hour ambulatory systolic blood pressure, daytime ambulatory systolic blood pressure, office systolic blood pressure, and office diastolic blood pressure compared to sham plus medications, supporting the role of renal denervation as an adjunct to pharmacotherapy rather than a replacement.

Randomized Controlled Trials and Device-Specific Evidence:

Randomized controlled trials have shown varied results, influenced by population characteristics, procedural techniques, and study design. The foundational SYMPLICITY trials established early evidence for renal denervation. SYMPLICITY HTN-1 (n=45) and SYMPLICITY HTN-2 (n=106) reported significant short- to medium-term office-based systolic blood pressure reductions, though these effects were smaller or inconsistent when assessed with ambulatory monitoring (Krum, 2014; Esler, 2014). The larger, sham-controlled SYMPLICITY HTN-3 trial (n=535) met safety endpoints with a major adverse event rate of only 1.4%, but failed to demonstrate statistically significant differences in blood pressure reduction compared to the sham group (Bakris, 2014; Bhatt, 2014). These studies indicated that baseline blood pressure, patient characteristics such as ethnicity and renal function, and technical proficiency might affect outcomes, prompting calls for improved trial designs and methodology (Lobo, 2015; White, 2014).

More recent trials have examined novel technologies, particularly the Paradise Ultrasound Renal Denervation System. The RADIANCE-HTN SOLO, TRIO, and RADIANCE II trials demonstrated significant reductions in daytime ambulatory systolic blood pressure at two months compared to sham, with a pooled difference of -5.9 mm Hg (95% CI -8.1 to -3.8; $p<0.001$) across the three cohorts (Azizi, 2018, 2019, 2021, 2022, 2023; Kirtane, 2023). These reductions persisted at six months, sometimes with fewer antihypertensive medications. However, the REQUIRE study (n = 143) in Japan and South Korea did not find a significant difference at three months compared to sham, potentially due to unexpected blood pressure reductions in the control group (Kario, 2022). Ongoing RCTs (SPYRAL HTN-OFF MED Pivotal and SPYRAL HTN-ON MED Expansion) are designed to address prior limitations and clarify the efficacy of renal denervation (Böhm, 2020).

Other Study Types:

Observational studies and registries have generally reported durable blood pressure reductions and favorable safety profiles. Data from global registries have shown sustained office-based systolic blood pressure reductions

of approximately 16 mm Hg and ambulatory reductions of about 8 mm Hg over three years, with serious adverse events typically under 1% and no meaningful renal function deterioration (Cluett, 2024; Lee, 2019; Rodriguez-Leor, 2020; Naduvathumuriyil, 2020). Pooled analysis of the RADIANCE clinical trial program demonstrated that blood pressure reductions achieved at 2 months were maintained at 6 months following medication escalation in both treatment and sham groups, with the between-group difference persisting (Azizi, 2022). The AHA/ACC guideline notes that follow-up duration in clinical trials remains relatively short (2-3 months in most sham-controlled trials), and longer-term cardiovascular outcome data are lacking (Jones, 2025). Cost-effectiveness analyses, such as one by Geisler (2012), suggested potential economic value if these blood pressure reductions translate into fewer cardiovascular events. However, without definitive evidence linking renal denervation to improved long-term outcomes (e.g., stroke, myocardial infarction, heart failure), cost-effectiveness remains theoretical.

In 2026, we added two systematic reviews examining renal denervation technologies and combination therapy with antihypertensive medications (Tu, 2025; Adnan, 2025) and incorporated the 2025 American Heart Association scientific statement on renal denervation and recent systematic reviews. (Cluett, 2024) (Dantas, 2024.

References

On December 6, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “renal denervation,” “ablation,” “sympathectomy,” and “treatment resistant hypertension.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/2016: initial review date and clinical policy effective date: 2/2017

1/2018: Policy references updated.

1/2019: Policy references updated and policy ID changed.

1/2020: Policy references updated.

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

1/2024: Policy references updated.

1/2025: Policy references updated.

1/2026: Policy references updated.

Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1283. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
0338T	Transcatheter renal sympathetic denervation; unilateral
0339T	Transcatheter renal sympathetic denervation; bilateral
C1736	Catheter, ablation, renal denervation, FDA approved (Paradise System)