Renal Denervation for Uncontrolled Hypertension Clinical Coverage Criteria

Description

Renal denervation is a minimally invasive procedure designed to lower blood pressure in patients whose hypertension remains elevated despite lifestyle changes and multiple medications. The procedure works by targeting and disrupting overactive sympathetic nerves associated with the kidneys, which play a key role in regulating blood pressure. Using a catheter (typically inserted through the femoral artery), energy such as radiofrequency or ultrasound is delivered to the renal arteries to ablate these nerves, thereby reducing the signals that contribute to elevated blood pressure.

Two renal denervation (RDN) devices are FDA-approved and have been assigned device pass-through payment status effective January 1, 2025 through December 31, 2027: The Paradise® Ultrasound RDN System (ReCor Medical, Inc.,) and the Symplicity Spyral™ RDN System (Symplicity Spyral™ Catheter).

Both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System are FDA-approved to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Both are RDN devices that use an endovascular approach to enter the renal arteries and ablate renal sympathetic nerves to achieve reductions in blood pressure.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus
☒ MassHealth ACO
☒ NaviCare HMO SNP
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care

Renal denervation for uncontrolled hypertension is covered for Fallon Medicare Plus, NaviCare and PACE members in accordance with NCD 20.40, and requires prior authorization. Refer to Medicare Variation section below for details.

Fallon Health Clinical Coverage Criteria

Fallon Health considers radiofrequency renal denervation and ultrasound renal denervation (collectively, RDN) for uncontrolled hypertension experimental/investigational and not medically necessary.

Fallon Health considers renal denervation for uncontrolled hypertension performed via retrograde ureteral approach using cystourethroscopy (0935T) experimental/investigational and not medically necessary.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for renal denervation for uncontrolled hypertension. Medicare has an NCD for Renal Denervation for Uncontrolled Hypertension, effective for dates on service on or after October 28, 2025 (Medicare Coverage Database search 05/19/2026). Coverage criteria for renal denervation (RDN) for uncontrolled hypertension are fully established in NCD 20.40; therefore, the Plan's coverage criteria are not applicable.

Radiofrequency renal denervation and ultrasound renal denervation (collectively RDN) are covered for the treatment of uncontrolled hypertension when coverage criteria in NCD 20.40 are met.

B. Coverage Criteria

RDN is covered for uncontrolled hypertension when furnished according to a Food and Drug Administration (FDA) market-authorized indication, and all the following conditions are met:

1. Patient Criteria

The patient meets all the following criteria:

(a) Diagnosis of uncontrolled hypertension (≥ 140 mm Hg systolic blood pressure and > 90 mm Hg diastolic blood pressure) despite active management by a clinician with primary responsibility for blood pressure management.

(b) Uncontrolled hypertension diagnosed using either ambulatory blood pressure monitoring or serial home blood pressure readings.

(c) On lifestyle modifications and stable doses of maximally tolerated guideline-directed medical therapy (GDMT), with assessment of adherence to the prescribed regimen, for at least six weeks before referral for RDN.

(d) As clinically appropriate, secondary hypertension must be evaluated and treated before determining that blood pressure remains uncontrolled. At a minimum, patients must be screened for primary aldosteronism, obstructive sleep apnea, and drug or alcohol induced hypertension before referral to RDN.

(e) The patient has no contraindications to RDN, consistent with the FDA labeling of the device used.

(f) The primary clinicians must coordinate management of the patient for a minimum of six months before referral for RDN, during which the patient had at least three encounters, with no more than two of the three encounters being virtual.

(g) No prior RDN procedure.

2. Physician Criteria

RDN is furnished by clinicians who meet the following criteria, as applicable:

(a) Clinicians referring Medicare beneficiaries must have longitudinal responsibility for hypertension management.

(b) Physicians performing RDN must have interventional and endovascular skills to perform effective RDN treatments. Additionally, they must be able to manage potential complications either themselves or with institutional support from colleagues who are immediately available to assist in emergency management.

(c) Physicians performing RDN without prior endovascular training or renovascular expertise must complete at least ten supervised cases of diagnostic/therapeutic renovascular procedures, half as primary operator. Additionally, they must complete at least five proctored RDN cases with each approved device used in their practice.

(d) Physicians performing RDN with prior endovascular training and active endovascular experience must complete at least five proctored RDN cases with each approved device used in their practice.

3. Facility Criteria

The RDN device and related items and services are furnished at facilities meeting the following criteria:

(a) Facilities performing RDN must have a hypertension program with contributions from a hypertension clinician with longitudinal patient management responsibility, a hypertension navigator, and access to relevant medical specialties (e.g., internal medicine, endocrinology, sleep medicine, cardiology, and nephrology) as appropriate.

(b) Preprocedural imaging capabilities (e.g., ultrasound, Computed Tomography Angiography, Magnetic Resonance Angiography).

(c) An appropriate interventional cardiology or radiology suite.

4. CED Study Criteria

RDN is furnished in the context of a CMS-approved CED study.

A list of CMS-Approved CED studies that have been determined to meet the requirements for coverage under CED are listed on the CMS Coverage with Evidence Development website, under Renal Denervation for Uncontrolled Hypertension.

- Members undergoing radiofrequency renal denervation must be enrolled in the study investigating the Spyral device sponsored by Medtronic.
- Members undergoing ultrasound renal denervation must be enrolled in the study investigating the Recor Paradise System sponsored by Recor Medical.

C. Nationally Non-Covered Indications

RDN is not covered outside of a CMS-approved study.

D. Other

Nothing in this NCD would preclude coverage of RDN through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.

Documentation Requirements
In order to review for medical necessity, the following documentation must be provided.

- All clinical documentation pertinent to request in order to meet NCD criteria, including:
  - Diagnosis of uncontrolled hypertension; and
  - Documentation the patient meets the FDA market-authorized indications for use, with no contraindications for the device used; and
  - No prior RDN procedure has been performed; and
  - Documentation of lifestyle modifications and stable doses of maximally tolerated guideline-directed medical therapy (GDMT), with assessment of adherence to the prescribed regimen, for at least six weeks before referral for RDN; and
  - If clinically appropriate, documentation that secondary hypertension has been evaluated and treated before determining that blood pressure remains uncontrolled. At a minimum, patients must be screened for primary aldosteronism, obstructive sleep apnea, and drug or alcohol induced hypertension before referral to RDN.
- The name of the device that will be used; and,
- The NCT number for the CMS-approved CED study the member is enrolled in (enrollment is a requirement under the Medicare criteria).

Verve Renal Pelvic Denervation (RPD) System (formerly the Phoenix System; Verve Medical Inc.)
The Verve Renal Pelvic Denervation (RPD) System is currently not FDA approved. The Verve RPD System is a radiofrequency system that accesses the renal nerves via cystourethroscopy rather than via an arterial catheter. Results from the feasibility study in 18 patients were published in 2022 (Hering et al.).

Based on findings from the feasibility study, a sham-controlled pivotal trial is underway (ClinicalTrials.gov ID NCT07005050) to evaluate the safety and effectiveness of Verve Medicals renal denervation system in patients with uncontrolled hypertension despite drug therapy. The clinical trial started on 12/30/2025 and is expected to enroll 60 patients. Following completion of the 12-month assessments, sham treated subjects may receive open-label therapy if they meet the original inclusion/exclusion criteria, with all subjects followed for a total of 2 years.

NCT0700505 is a CMS approved Category B IDE Study (G240295), therefore, Fallon Health is responsible for payment for routine care items and services in the study and also for the cost of the device. Renal denervation for uncontrolled hypertension performed via retrograde ureteral approach using cystourethroscopy may be billed using CPT code 0935.

MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for renal denervation for uncontrolled hypertension, therefore, the Plan's coverage criteria are applicable (MassHealth website search 5/19/2026).

Exclusions

- Renal denervation as treatment for hypertension is considered experimental/investigational and not medically necessary for all indications. Renal denervation as treatment for hypertension is covered for Medicare members in accordance with NCD 20.40. Refer to Medicare Variation section above.

Summary of Evidence

CMS conducted a National Coverage Analysis for renal denervation for uncontrolled hypertension pursuant to a formal request submitted by Medtronic on December 12, 2024. The Proposed Decision Member was released on July 10, 2025 and the Final Decision Memo was released on October 28, 2025. NCDs are effective on the date the Final Decision Memo is released.

The following are excerpts from the National Coverage Analysis, Final Decision Memo available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=318.

Food and Drug Administration
On November 2, 2023, the Food and Drug Administration (FDA) approved ReCor Medical's Paradise® Ultrasound Renal Denervation System (RDN) premarket approval (PMA) application (P220023).

Recor Medical's Paradise ultrasound RDN device utilizes intra-arterial catheters to deliver ultrasound energy through the renal arterial wall to ablate the adjacent sympathetic nerves. The Paradise Ultrasound RDN System includes the Paradise Catheter with ultrasound transducer, Paradise Generator, Paradise Cartridge, and the Paradise Connection Cable. The Paradise Ultrasound RDN System is a catheter-based system that delivers ultrasound energy circumferentially to thermally ablate and disrupt renal sympathetic nerve activity to reduce systemic arterial BP.

On November 17, 2023, FDA approved Medtronic's Symplicity Spyral™ Renal Denervation System PMA application (P220026). The Symplicity Spyral rfRDN System consists of two main components: a single-use, disposable catheter (Symplicity Spyral multielectrode renal denervation catheter, also referred to as Symplicity Spyral catheter) and a reusable radiofrequency (RF) generator (Symplicity G3 Renal Denervation RF generator, also referred to as Symplicity G3 RF generator). The generator includes an optional remote control and power cord.

Medtronic previously studied an earlier version of their RDN device, the Symplicity Flex RDN, in a series of clinical trials: HTN-1 (Esler et al., 2014); HTN-2 (Esler et al., 2010, Esler et al., 2014, Esler et al., 2012); and HTN-3 (Bakris et al., 2015, Bhatt et al., 2014, Bhatt et al., 2022). HTN-3 was a multicenter, sham-controlled trial of 535 patients. It met its primary safety endpoint, but the primary and secondary effectiveness endpoints (a significant reduction in blood pressure compared to sham controls) were not met. Potential contributors to the nil result in HTN-3 include prescribed medication changes in 39% of patients during the study period, despite the protocol mandating no medication changes, and a larger than expected decrease in office and ambulatory systolic BP in the control group. Additionally, incomplete ablation might result in inadequate denervation and was cited as a potential contributor to the nil result in HTN-3.

Following HTN-3, Medtronic redesigned its RDN device with a spiral configuration of multiple RF electrodes to deliver more effective circumferential RDN. The Symplicity multi-electrode radiofrequency RDN system's safety and performance were tested in a prospective, non-randomized, open-label, feasibility study that enrolled 50 subjects (Whitbourn et al., 2015). The results of this feasibility study indicated that the Symplicity multi-electrode RDN system was associated with a statistically significant, although highly variable, reduction in office SBP (OSBP) from baseline at 12 months post-procedure (-19.2±25.2 mm Hg), with minimal complications.

The indication for both RDN devices is to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control BP.

Assessment of Evidence
CMS included seven RCTs considered as evidence consisted of various designs to evaluate renal denervation systems in patients with hypertension. Three trials—RADIANCE-HTN SOLO, RADIANCE-

HTN TRIO, and RADIANCE II—were randomized, double-blind, sham-controlled studies conducted at multiple centers across Europe and the United States. The REQUIRE trial, conducted in Japan and South Korea, was a randomized, single-blind, sham-controlled study. Additionally, two multicenter, sham-controlled, single-blind trials, SPYRAL HTN-OFF and SPYRAL HTN-ON, were conducted across the US, Canada, Japan, Europe, and Australia. The RADIOSOUND-HTN trial was a 3-arm study, conducted in Germany, comparing uRDN, and rfRDN ablation of either the main renal artery or of both the main renal artery, branches, and accessory arteries to each other.

The RADIANCE-HTN SOLO, RADIANCE-HTN TRIO, RADIANCE II, and REQUIRE trials evaluated the safety and efficacy of the uRDN system. These studies were conducted in groups of patients who were either not using (Off Med) or who were using (On Med) antihypertensive drugs.

The SPYRAL HTN-OFF and HTN-ON trials assessed the safety and efficacy of the rfRDN system, incorporating an adaptive Bayesian design with a pilot study followed by an expansion cohort. Like the RADIANCE trials, these studies were conducted in groups of patients who were either not using (Off Med) or who were using (On Med) antihypertensive drugs.

Finally, the RADIOSOUND-HTN trial employed a prospective, randomized design to directly compare the different renal denervation methods in patients with resistant hypertension. Participants who were considered medication-adherent were admitted into the study and continued with their antihypertensive medications during the trial, with therapeutic adjustments as needed.

Study quality for RCTs was assessed using the US Preventive Services Task Force's (USPSTF) Criteria for Assessing Internal Validity of Individual Studies. We rated the quality of the primary RCTs, and it should be noted that most studies were unblinded during the follow-up period, which could impact the findings. All Radiance trials were sponsored by Recor, and all SPYRAL trials were sponsored by Medtronic. REQUIRE was funded by JIMRO Co. and Korea Otsuka Pharmaceutical. RADIOSOUND-HTN was funded by the Leipzig Heart Institute. All studies except RADIOSOUND-HTN received editorial or trial design input or medical writing support from the manufacturers, and all studies had declarations of support (e.g., receiving speaker or consulting fees) from manufacturers for one or more authors.

Ultrasound Renal Denervation (RDN)
CMS identified four RCTs and numerous other studies evaluating the impact of uRDN on hypertension control.

The RADIANCE studies enrolled individuals aged 18 to 75 years with a documented history of hypertension, suitable renal anatomy for the renal denervation procedure confirmed by recent renal CTA (computed tomography angiography) or MRA (magnetic resonance angiography), and the ability to comply with study procedures. The studies RADIANCE-HTN SOLO (Azizi et al., 2018), RADIANCE-HTN TRIO (Azizi et al., 2021), and RADIANCE II (Azizi et al., 2023) were conducted at multiple centers across Europe and the United States. The REQUIRE trial was conducted in Japan and South Korea (Kario et al., 2022).

RADIANCE-HTN SOLO (Azizi et al., 2018; Azizi et al., 2019; Azizi et al., 2020): The studies reported uRDN efficacy in patients without antihypertensive drugs with mild-to-moderate hypertension (SOLO: Azizi et al., 2018; Azizi et al., 2019; Azizi et al., 2020) and Stage II hypertensive patients (RADIANCE II: Azizi et al., 2023). The SOLO trial reported significant daytime ASBP reductions of 6.3 mm Hg at 2 months versus sham (Azizi et al., 2018), and the effect persisted for up to 6 months (Azizi et al., 2019). After the first 2 months of follow-up, the participants were allowed to receive antihypertensive drugs if home BP control did not achieve the target range (home BP ≥135/85 mm Hg) according to the antihypertensive treatment escalation protocol. By 12 months, the differences were no longer significant (Azizi et al., 2020).

RADIANCE II (Azizi et al., 2023): The study had similar findings with a reduction in daytime ASBP in the RDN group versus sham (baseline-adjusted between-group difference, -6.3 mm Hg [95% CI: -9.3 to -3.2 mm Hg], $p < 0.001$) in Stage II hypertensive patients at two months. Unlike RADIANCE-HTN SOLO and TRIO trials, blinding was maintained until 12 months post-randomization, after which AHM was prescribed per community standard of care.

RADIANCE-HTN TRIO (Azizi et al., 2021; Azizi et al., 2022): This trial reported uRDN efficacy in patients on antihypertensive drugs with resistant hypertension and reported the mean difference in daytime ambulatory systolic pressure between uRDN and sham group of 4.5 mm Hg (95% CI: -8.5 to -0.3) at 2 months (Azizi et al., 2021). However, no significant reduction was noted in daytime ASBP at 6 months follow-up (baseline-adjusted mean difference between groups was 0.0 mm Hg (95% CI: -4.6 to 4.5; p = 0.65 in the per-protocol analysis; Azizi et al., 2022). Notably, from two to five months, if monthly home BP was ≥135/85 mm Hg, prespecified standardized stepped-care antihypertensive treatment, including an aldosterone antagonist, was started under blinding to the original treatment assignment.

REQUIRE (Kario et al., 2022): The trial in Japan and South Korea also focused on resistant hypertension patients undergoing uRDN or a sham procedure. At 3 months, there was no significant difference in BP reduction between the uRDN and the sham group, with both groups experiencing similar reductions in ambulatory, home, and office BP (p=0.971). This study highlighted the variability in response to uRDN and a greater-than-expected BP reduction in the sham group (Kario et al., 2022).

Based on this analysis, CMS concluded that the evidence for improved health outcomes in patients with hypertension is hypothesis-generating rather than definitive, and thus, this remains an important evidence gap for CED studies to address.

Radiofrequency Renal Denervation (RDN)
CMS identified two RCTs and numerous other studies evaluating the impact of radiofrequency RDN on hypertension control.

SPYRAL HTN-OFF MED (Böhm et al., 2020): This trial assessed whether radiofrequency RDN performed with the Symplicity Spyral catheter reduces blood pressure in patients not taking antihypertensive medication. At three months, the primary efficacy endpoint of change in average 24-hour SBP, adjusted for SBP at study entry, was -3.9 mm Hg (95% BCI: -6.2 to -1.6), and the secondary efficacy endpoint of change in average office BP, adjusted for office blood pressure at study entry, was -6.5 mm Hg (95% BCI: -9.6 to -3.5), with a 99.9% probability that radiofrequency RDN was superior to the sham procedure. This study does not reflect the real-world intended use of RDN because most patients will require AHMs despite radiofrequency RDN. The number of patients included in the study was small, and the average age was 52.5. Additionally, hypertension is a lifelong condition, and the follow-up period was very short due to safety and ethical concerns.

SPYRAL HTN-ON MED (Kandzari et al., 2023): This trial assessed whether radiofrequency RDN performed with the Symplicity Spyral catheter reduces blood pressure in patients taking antihypertensive medications. At six months (Kandzari et al., 2023), no between-group differences existed for the primary endpoint of 24-hour ABSP (MD: -0.03 mm Hg; 95% BCI: -2.82 to 2.77 mm Hg). The secondary effectiveness endpoint was the baseline-adjusted change in OSBP from baseline to 6 months post-procedure. In the rfRDN group, there was a greater reduction in OSBP at 6 months vs. the sham group (MD: -4.9 mm Hg; 95% BCI: -7.9 to -1.9), but this reduction is just below what is considered clinically meaningful. In a small subset of the original study (Mahfoud et al., 2022), there were modest BP reductions at 36 months in 24-hour ASBP in the radiofrequency RDN group (n=30) compared to sham (n=32), but there were no differences in OSBP (MD: -8.2; 95% CI: -17.1 to 0.8, p=0.073). While this on-medication trial better reflects real-world differences, the study did not meet its primary endpoint at six months and marginally met it at six months in an underpowered study. AHM changes during the final three months of the six-month pivotal study complicate the interpretation of the results. Like the SPYRAL HTN-OFF MED study, the follow-up of the full cohort was brief, and longer-term outcomes were examined in a small patient cohort.

Based on this analysis, CMS concluded that the evidence for improved health outcomes for patients with hypertension is hypothesis-generating, not definitive, and so this remains an important evidence gap for CED studies to address.

Head-to-Head Comparison of Ultrasound RDN and Radiofrequency RDN
RADIOSOUND-HTN (Fengler et al., 2023) was a head-to-head comparison of three different techniques of RDN in patients with resistant hypertension: rfRDN (main artery: RFM-RDN: n=39) as the reference standard, rfRDN (main and branch arteries; RFB-RDN: n=39), and uRDN (USM-RDN: n=42). Key inclusion criteria for the RADIOSOUND-HTN trial were patients diagnosed with resistant hypertension

with daytime SBP >135 mm Hg on ABPM, with a renal artery diameter of ≥5.5 mm for at least 1 of the main renal arteries. Use of AHM was required to be stable for at least 4 weeks. Patients then underwent ABPM to exclude those with white-coat hypertension. Exclusion criteria were age ≥75 years, pregnancy, life expectancy <6 months, evidence for secondary hypertension, participation in any other randomized clinical trial, known renal artery stenosis or anatomy unsuitable for interventional RDN, and any main renal artery diameter <4.0 mm. The trial was conducted at a single center in Germany (Fengler et al., 2019).

RDN lowered BP across all groups at all time points. At 3 months, daytime systolic and diastolic BP decreased significantly in the overall cohort by 9.5 (SD: 12.3) and 6.3 (SD: 7.8) mm Hg, respectively ($p<0.001$ for both) and within each treatment group ($p<0.001$) (Fengler et al., 2019). This effect was maintained at 6- and 12-month follow-up ($p<0.001$) (Fengler et al., 2023).

At 3 months, ultrasound RDN was found to be more effective than radiofrequency RDN (Daytime ASBP MD: -6.7 mm Hg; 98.3% CI: -13.2 to -0.2, adjusted p=0.043). radiofrequency RDN did not differ between uRDN (Daytime ASBP MD: -4.9 mm Hg; 98.3% CI: -11.5 to 1.7; p=0.22) or by rfRDN approach (Daytime ASBP MD: -1.8 mm Hg; 98.3% CI: -8.5 to 4.9; p>0.99). Rates of response to RDN were similar across treatment groups. There were several peri-procedural adverse events, including transient renal artery spasm, a symptomatic groin hematoma, and a pseudoaneurysm. The authors reported that all events were resolved. During the 3-month follow-up period, two patients in the rfRDN group experienced symptomatic hypotension. Three patients (main artery rfRDN: 1; main and branch arteries radiofrequency RDN: 2) experienced symptomatic hypertension that required medical treatment. A patient in the rfRDN group experienced acute decompensated heart failure, which required hospitalization. Finally, one patient in the rfRDN group died from acute aortic dissection 2 months post-procedure. Examination of this patient's angiogram suggested no evidence of dissection at the time of the procedure. No adverse events were reported in the ultrasound RDN group, and there were no renal vascular complications or instances of renal stenosis.

In a research letter, 6- and 12-month follow-up data were reported for the head-to-head comparisons (Fengler et al., 2023). At 6 months, ASBP reduction from baseline varied across the treatment arms, with ultrasound RDN producing a statistically greater effect than rfRDN (uRDN: -12.1 mm Hg; SD: 11.5; main artery radiofrequency RDN: -6.0 mm Hg; SD: 11.0; main and branch arteries rfRDN: -4.8 mm Hg: SD: 12.1; p=0.017 for between-group comparison; Fengler et al., 2023). Given the wide variability around the point estimates for each treatment, this may not be a clinically meaningful difference. At 12 months, there were no longer any between-group differences in ASBP (Fengler et al., 2023). Harms were not reported.

Limitations of Evidence

CMS found relatively few randomized trials (n=7), and most were funded by each device's manufacturer. Only one poor-quality study directly compared ultrasound RDN and radiofrequency RDN, and the sample sizes in this study were fewer than 50 patients per arm. RCTs were conducted in multiple countries, including the US, the UK, Germany, France, the Netherlands, Poland, Belgium, Japan, and Korea, but detailed analyses of the US data reflective of the US population are lacking. Analyses of the SPYRAL HTN-ON trial reported on the US population subgroup, but the analysis is not comprehensive (Townsend et al., 2024; Kandzari et al., 2025).

Patient selection across all trials was highly selective, with a range of 35% (REQUIRE) to 6% (RADIOSOUND-HTM) of patients who were screened ultimately being enrolled. Overall, sample sizes in the RDN studies were relatively small when considering how common HTN is as a condition. Strict inclusion/exclusion criteria may limit applicability to the Medicare population, particularly older patients, those from different racial and ethnic groups, and those with multiple comorbidities.

Primary endpoints in each trial were assessed at a relatively short follow-up (2-3 months), and most trials did not maintain blinding long-term. Additionally, variations in AHM standardization, differences in medication treatment load, and measures of medication treatment adherence could contribute to the observed variability of the outcome measures across studies.

These studies were not powered to assess long-term health outcomes. Because HTN treatment is often lifelong and BP is a surrogate outcome, long-term follow-up and demonstration of improved health outcomes are very important. These studies only measured BP and were not designed to capture long-

term health sequalae of HTN, including preventing hypertension-associated end-organ damage and survival. Since hypertension treatment is usually required for life, long-term studies are needed to demonstrate the durability of treatment and improved health outcomes.

In addition to the above-identified limitations of the reviewed studies, other evidentiary gaps raised in the literature include patient selection and facility/operator experience, which strongly influence the benefit and utility of RDN. A volume-outcomes association has been demonstrated for most invasive procedures, especially during the earlier stages of technology adoption. Operators should have expertise in renal vascular anatomy (for instance, the presence of accessory or aberrant renal arteries), prompt recognition and management of potential complications, including vascular access complications and renal arterial injuries such as dissection, embolization, or perforation. Careful selection of patients who may benefit from the procedure through a multidisciplinary team approach that includes an HTN expert in a specialized center is also an important consideration. Such centers should be able to thoroughly evaluate patients for secondary causes of hypertension. For instance, up to 10% of patients with stage 1 hypertension and between 20% and 25% with stage 2 or resistant hypertension may have evidence of primary aldosteronism (O'Malley et al., 2023). Some patients may be misdiagnosed (white coat HTN, high-salt diet, incorrect BP recording technique). Such centers should also be proficient in the judicious pursuit and interpretation of 24-hour ambulatory BP recordings. Assessment for medication adherence through direct questioning and biochemical screening of serum or urinary drug levels (now available in clinical practice) may be necessary. The assessment and treatment of obstructive sleep apnea is another important factor in addressing apparent treatment-resistant hypertension.

Conclusions

Collectively, these trials demonstrate that second-generation RDN devices are effective for lowering BP in some, but not all, patients with hypertension, achieving modest reductions comparable to those seen with a single antihypertensive medication. The findings also suggest that RDN is safe, with minimal impact on renal function and consistent efficacy across the studied patient populations and device types. The benefit of these devices is mainly that they function as an “always on” treatment, which is useful for patients who may have difficulty adhering to or have contraindications to medical treatment; they do not appear to produce side-effects that challenge some medication options.

However, the current evidence is inadequate to fully assess which patient, practitioner, or facility characteristics predict the most successful patient outcomes from RDN. Studies of RDN with an active comparator or larger studies of head-to-head comparisons of RDN devices are needed. While one study found a greater BP reduction for ultrasound RDN at 3 months compared to radiofrequency RDN (with and without branch artery treatment), the differences were no longer evident at 12 months (Fengler et al., 2023; Fengler et al., 2019). Additionally, studies enrolling patients that better reflect real-world individuals are needed to understand the risks/benefits of this technology when combined with other AHTs. One recent analysis suggests that BP reductions after RDN may be dependent on baseline BP, with higher baseline BPs associated with larger BP reductions (Ziegler et al., 2024). Even so, many patients with severe, resistant hypertension will continue to require multiple AHTs after RDN. For context, adding one AHT can similarly achieve 4 to 6 mmHg in ambulatory SBP (equivalent to 7-10 mm Hg reduction in OSBP) with RDN. In particular, spironolactone reduced 12-week averaged home SBP by 8.7 mm Hg compared with placebo among patients with treatment-resistant HTN (Williams et al., 2015).

Future studies are needed to better define the most appropriate population(s) for RDN (resistant HTN, isolated systolic HTN, early HTN, high lifetime cardiovascular risk, etc.) and whether this BP reduction translates into improvements in surrogate markers (such as left ventricular hypertrophy) or hard clinical endpoints (such as major adverse cardiovascular events, stroke, etc.) as has been noted with studies of antihypertensive medications. Patients with features of sympathetic overactivity, including combined systolic-diastolic hypertension, orthostatic hypertension, and elevated renin levels, may benefit more from RDN. In contrast, the procedure may have less effectiveness for the treatment of isolated systolic hypertension because the mechanism of hypertension is mainly driven by aortic stiffening rather than sympathetic overactivity (Vongpatanasin and Addo, 2024). Additionally, given that a significant proportion of patients do not respond to RDN, statistical models are needed to define the predictors of treatment response.

Evidence-Based Guidelines

CMS identified two professional society guidelines relevant to managing resistant HTN with RDN.

2023 European Society of Hypertension (ESH) Guidelines for the Management of Arterial Hypertension (Mancia et al., 2023).

- "RDN can be considered as a treatment option in patients with an Estimated Glomerular Filtration Rate (eGFR) >40 ml/min/1.73 m2 who have uncontrolled BP despite the use of antihypertensive drug combination therapy, or if drug treatment elicits serious side effects and poor quality of life (Class of recommendation II, Level of evidence B)."
- "RDN can serve as an additional treatment option for patients with true resistant hypertension if their eGFR is greater than 40 ml/min/1.73 m2 (Class of Recommendation II, Level of Evidence B)."
- "Patient selection for RDN should involve a shared decision-making process, ensuring that patients receive objective and comprehensive information about the procedure (Class of Recommendation I, Level of Evidence C)."
- "To ensure optimal outcomes, "RDN should only be performed in experienced specialized centers to guarantee appropriate selection of eligible patients and completeness of the denervation procedure (Class of Recommendation I, Level of Evidence C)."

2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC/NMA/PCNA/. Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (Jones et al., 2025).

- "In carefully selected patients with systolic and diastolic hypertension (office SBP 140 – 180 mm Hg and DBP > 90 mm Hg) and eGFR > 40 mL/min/1.73 m2 who have resistant hypertension despite optimal treatment, or intolerable side effects to additional antihypertensive drug therapy, renal denervation (RDN) may be reasonable as an adjunct treatment to BP medications and lifestyle modifications to reduce BP." (Class of Recommendation 2b, Level of Evidence B-R)"All patients with hypertension who are being considered for RDN should be evaluated by a multidisciplinary team with expertise in resistant hypertension and RDN." (Class of Recommendation I, Level of Evidence B-NR)
- "For patients with hypertension for whom RDN is contemplated, the benefits of lowering BP and potential procedural risks compared with continuing medical therapy should be discussed as part of a shared decision-making process to ensure patients choose the therapy that meets their expectations (Class of Recommendation I, Level of Evidence C-EO)."

Verve Renal Pelvic Denervation (RPD) System (formerly the Phoenix System; Verve Medical Inc.)
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Results from the feasibility study in 18 patients were published in 2022 (Hering et al.).

Based on findings from the feasibility study, a sham-controlled pivotal trial is underway (ClinicalTrials.gov ID NCT07005050) to evaluate the safety and effectiveness of Verve Medicals renal denervation system in patients with uncontrolled hypertension despite drug therapy. The clinical trial started on 12/30/2025 and is expected to enroll 60 patients. Following completion of the 12-month assessments, sham treated subjects may receive open-label therapy if they meet the original inclusion/exclusion criteria, with all subjects followed for a total of 2 years.

Analysis of Evidence (Rationale for Determination)

In the National Coverage Analysis for Renal Denervation for Uncontrolled Hypertension, CMS concluded that the totality of the evidence supports that RDN devices are a promising therapeutic technology that, combined with lifestyle changes and anti-hypertensive medications, could lead to meaningful improvement of health outcomes for certain Medicare beneficiaries with hypertension.

However, important questions remain, such as:
Question 1: Can the improved blood pressure control seen in trials be replicated in the real world with community-based physicians treating patients with uncontrolled hypertension?
Question 2: Which patient subgroups are most likely to benefit from RDN?
Question 3: Can all populations demonstrate benefit over a longer time? This is an important consideration as RDN is a permanent procedure.

Thus, CMS believes CED is the most appropriate NCD policy for RDN devices because it simultaneously covers these technologies while collecting and analyzing more data to fill evidence gaps to answer key questions.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Renal denervation for uncontrolled hypertension is covered for Fallon Medicare Plus, NaviCare and PACE members under Coverage with Evidence Development (CED) effective for dates of service on or after 10/28/2025.

All claims (professional and facility) for renal denervation for uncontrolled hypertension must be submitted with:

- ICD-10-CM Diagnosis code Z00.6 and one of the following diagnosis codes: I10, I11.0, I11.9, I12.0, I12.9, I13.0, I13.10, I13.11, I13.2, I15.0, I15.1, I15.2, I15.8, I15.9, I16.0, I16.1, I16.9, I1A.0.
- Value code D4 with the 8-digit National Clinical Trial (NCT) Identifier.
- Modifier Q0 or condition code 30, as appropriate

CPT codes 0338T and 0339T describe transcatheter renal sympathetic denervation via a percutaneous arterial approach to the renal arteries, which align with procedures performed using the Medtronic Symplicity and Recor Paradise systems, respectively.

CPT code 0935T describes renal sympathetic denervation via cystourethroscopy, using the Verve Medical, Inc. Verve Renal Pelvic Denervation (RPD) System. This device is not currently FDA-approved.

C Codes

C1735 and C1736 are OPPS pass-through devices paid separately when provided integral to a surgical procedure on the Medicare OPPS or ASC list, specifically, 0338Tor 0339T. Physicians cannot be paid for HCPCS C1735 or C1736.

Section 1833(t)(6)(D)(ii) of the Act requires the Plan to deduct from pass-through payments for devices an amount that reflects the device portion of the APC payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-through payments for the applicable pass-through device. The device offset amount for the CPT codes that are paired with HCPCS code C1735 is being updated to $0.00, effective January 1, 2026. The device offset amount for the CPT codes that are paired with HCPCS code C1736 is being updated to $0.00, effective January 1, 2026.

Code	Description
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral
0935T	Cystourethroscopy with renal pelvic sympathetic denervation, radiofrequency ablation, retrograde ureteral approach, including insertion of guide wire, selective placement of ureteral sheath(s) and multiple conformable electrodes, contrast injection(s), and fluoroscopy, bilateral
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components Note: Device code for Medtronic's Symplicity Spyral™ Renal Denervation System
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single

	use system components Note: Device code for Recor Medical's Paradise® Ultrasound Renal Denervation

ICD-10-CM Diagnosis codes
ICD-10-CM classifies hypertension by type as essential or primary (categories I10-I13), secondary (category I15), hypertensive crisis (category I16), and resistant (category (I1A).

Code	Description
I10	Essential (primary) hypertension
I11.0	Hypertensive heart disease with heart failure
I11.9	Hypertensive heart disease without heart failure
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end-stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease or end-stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end-stage renal disease
I15.0	Renovascular hypertension
I15.1	Hypertension secondary to other renal disorders
I15.2	Hypertension secondary to endocrine disorders
I15.8	Other secondary hypertension
I15.9	Secondary hypertension, unspecified
I16.0	Hypertensive urgency
I16.1	Hypertensive emergency
I16.9	Hypertensive crisis, unspecified
I1A.0	Resistant hypertension

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Policy history

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Review/Approval(s):	Technology Assessment Committee: 05/29/2026 (policy origination). Utilization Management Committee: 06/16/2026: (policy origination; approved).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.