Molina Clinical Policy
Renal Denervation as a Treatment for Resistant Hypertension: Policy No. 390

Last Approval: 12/13/2023
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Resistant hypertension is defined as a systolic blood pressure ≥140 mmHg and diastolic blood pressure ≥90 mmHg on multiple occasions. Hypertension is one of the most common health conditions diagnosed in adults, with approximately 4 of 5 of those diagnosed having resistant hypertension (WHO 2023). Standard blood pressure lowering treatment includes lifestyle modification, such as dietary changes and exercise routines; and antihypertensive medications, which are frequently employed but can be ineffective due to either patient non-compliance or drug resistant hypertension. Due to the prevalence of resistant hypertension unresponsive to pharmaceuticals or lifestyle modification, increasing research has been conducted to explore procedure related blood pressure lowering techniques, such as neurotoxin injection into the renal artery, and ultrasound or radiofrequency ablation of the renal sympathetic nerves (Rey-Garcia and Townsend 2022).

Ablation of the renal sympathetic nerves is an interventional procedure that uses catheter-based technology to deliver either radiofrequency energy or ultrasound energy to thermally ablate the renal sympathetic nerves within the wall of the renal arteries. Renal denervation for the treatment of hypertension is assumed to decrease both the afferent sympathetic signals from the kidneys to the brain and the efferent signals from the brain to the kidneys. This decreases sympathetic activation, decreases vasoconstriction, and decreases activation of the renin-angiotensin system, which potentially lowers the blood pressure. Radiofrequency ablation and ultrasound ablation are minimally invasive procedures performed percutaneously with access at the femoral artery. A flexible catheter is threaded into the renal artery and a controlled low-power energy is delivered to the arterial walls to ablate the renal sympathetic nerves.

Regulatory Status
The FDA approved Medtronic Inc's (Santa Rosa, CA) Symplicity Spyral™ Renal Denervation System on November 17, 2023, and ReCor Medical Inc's (Palo Alto, CA) Paradise Ultrasound Renal Denervation System on November 07, 2023, under the product code QYI (ablation catheter, renal denervation). These are currently the only FDA approved devices for renal denervation. They are approved for the indication of reducing blood pressure as an adjunctive treatment in patients with hypertension nonresponsive to lifestyle modification and antihypertensive medications.

COVERAGE POLICY

Ablation of the renal sympathetic nerves, via radiofrequency or ultrasound, **may be considered medically necessary** for the treatment of resistant hypertension when **ALL** the following criteria are met:

1. The requested procedure is done utilizing an FDA approved device intended as an adjunctive treatment in Members with hypertension in whom lifestyle modification and antihypertensive medications have not adequately controlled Member's blood pressure; **AND**

2. Member is 18 years or older; **AND**

3. Member has a confirmed office systolic blood pressure ≥ 150 mmHg and <180 mmHg and a diastolic blood

pressure ≥ 90 mmHg on repeat occasions; **AND**

4. Member has a 24-hour Ambulatory Blood Pressure Monitoring average SBP ≥ 140 mmHg and < 170 mmHg; **AND**

5. Evidence or attestation from treating physician stating Member has been compliant with a three hypertensive medication class regimen (e.g., a diuretic, angiotensin 2 receptor blockers, angiotensin converting enzyme inhibitors) where not contraindicated or intolerable to Member for at least three months.

CONTINUATION OF THERAPY
Ablation of the renal sympathetic nerves, via radiofrequency or ultrasound, is intended as a one-time procedure and has not been studied for multiple procedures in a single patient.

LIMITATIONS AND EXCLUSIONS

1. Radiofrequency or ultrasound ablation of the renal sympathetic nerves is contraindicated if **ANY** of the following conditions are present:
    a. Renal artery diameter < 3 mm or > 8 mm
    b. Renal artery fibromuscular dysplasia
    c. Stented renal artery (< 3 months prior to RFA procedure)
    d. Renal artery aneurysm
    e. Renal artery diameter stenosis > 50%
    f. Actively pregnant or breastfeeding
    g. Presence of abnormal kidney (or secreting adrenal) tumors
    h. Iliac/femoral artery stenosis precluding insertion of the catheter
    i. Main artery length of less than 20mm for ultrasound ablation
    j. Active infection within previous 7 days prior to procedure

2. Radiofrequency or ultrasound ablation of the renal sympathetic nerves in the presence of the following conditions is considered **experimental, investigational, and unproven** based on insufficient evidence:
    a. Isolated systolic hypertension
    b. Prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation.
    c. Type 1 Diabetes Mellitus
    d. eGFR less than 45 mL/min/1.73 m^2
    e. Secondary hypertension
    f. Primary pulmonary hypertension
    g. Frequent intermittent or chronic pain that results in treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) for two or more days per week over the month prior to procedure.
    h. Stable or unstable angina within 3 months of procedure
    i. Myocardial infarction within 3 months of procedure
    j. Prior heart failure, cerebrovascular accident or transient ischemic attack, or atrial fibrillation

SUMMARY OF MEDICAL EVIDENCE

Radiofrequency Ablation of the Renal Sympathetic Nerves
It is important to note that the failure of the Symplicity HTN-3 clinical trials (Bhatt et al 2014), and the ReSET trial (Mathiassen et al. 2016) led scientists to re-evaluate their working knowledge of the renal sympathetic nerve system, redesign the ablation catheter, apply a new technique in the RFA approach to include the main renal artery and branches with a lumen size of ≥3 mm, and employ more careful patient selection in subsequent clinical trials. These changes led to the success of subsequent Symplicity Spyral™ clinical trials (Rey-Garcia and Townsend 2022).

Mahfoud et al. (2022, 2018) conducted a multi-center, randomized, single blind, sham controlled, clinical trial to evaluate the effect of renal denervation on resistant hypertension in patients currently on antihypertension medications. During the enrollment period, 467 patients were screened with 80 ultimately meeting inclusion criteria of an office systolic blood pressure of between 150 mm Hg and 180 mm Hg and a diastolic blood pressure of 90 mm Hg or higher;

a 24 h ambulatory systolic blood pressure of between 140 mm Hg and 170 mm Hg at second screening; and were on one to three antihypertensive drugs with stable doses for at least 6 weeks. The 2018 publication of this study analyzed the first 80 patients randomly assigned to either renal denervation (38) or sham control (42). Patients, caregivers, and those assessing the blood pressure were blinded. Primary outcome was blood pressure change from baseline based on ambulatory blood pressure measurements 6 months post procedure. Patients underwent a one-time procedure with either the Symplicity Spyral™ multielectrode renal denervation catheter or a renal angiogram as the sham control, with office follow up visits at 1-, 3-, and 6-months post procedure. The change in blood pressure was significantly greater at 6 months in the renal denervation group than the sham-control group for office systolic blood pressure (difference –6·8 mm Hg, 95% CI –12·5 to –1·1; p=0·0205), 24 h systolic blood pressure (difference –7·4 mm Hg, –12·5 to –2·3; p=0·0051), office diastolic blood pressure (difference –3·5 mm Hg, –7·0 to –0·0; p=0·0478), and a 24h diastolic blood pressure (difference –4·1 mm Hg, –7·8 to –0·4; p=0·0292). There were no serious adverse events recorded in the trial. In 2022 the authors published an updated assessment that included the 24 and 36 month follow up of the original cohort. The previous results of statistically significant blood pressure reduction in the renal denervation group vs sham control group held in the long term follow up. The medication burden at 36 months was 2·13 medications (SD 1·15) in the renal denervation group and 2·55 medications (2·19) in the sham control group (p=0·26). At 36 months, the ambulatory systolic blood pressure reduction was -18·7 mm Hg (SD 12·4) for the renal denervation group (n=30) and -8·6 mm Hg (14·6) for the sham control group (n=32; adjusted treatment difference -10·0 mm Hg, 95% CI -16·6 to -3·3; p=0·0039). Treatment differences between the renal denervation group and sham control group at 36 months were -5·9 mm Hg (95% CI -10·1 to -1·8; p=0·0055) for mean ambulatory diastolic blood pressure, -11·0 mm Hg (-19·8 to -2·1; p=0·016) for morning systolic blood pressure, and -11·8 mm Hg (-19·0 to -4·7; p=0·0017) for night-time systolic blood pressure. There were no short-term or long-term safety issues associated with renal denervation.

Böhm et al. (2020) conducted a multi-center, randomized, single blind, sham controlled, clinical trial to evaluate the effect of renal denervation on resistant hypertension in patients who did not take antihypertensive medications. A total of 331 patients met the inclusion criteria of had office systolic blood pressure between 150 mm Hg and 180 mm Hg, an office diastolic blood pressure of at least 90 mm Hg, a mean 24-h systolic blood pressure between 140 mm Hg and 170 mm Hg using ambulatory blood pressure monitoring, and an absence of antihypertensive medications. Patients were randomly assigned to either renal denervation (166) or sham control (165), with patients, caregivers, and those assessing blood pressure masked as to which procedure was conducted. Those receiving renal denervation underwent a one-time procedure utilizing the Symplicity Spyral™ renal denervation system, and those receiving sham treatment underwent a renal angiography. The primary outcome was change in mean 24-h systolic blood pressure from baseline to 3 months after the procedure, adjusted for baseline 24-h systolic blood pressure. The treatment difference between the two groups for 24-h systolic blood pressure was -3·9 mm Hg (Bayesian 95% credible interval -6·2 to -1·6) and for office systolic blood pressure the difference was -6·5 mm Hg (-9·6 to -3·5). There were no short term serious adverse safety events recorded up to 3 months.

Ultrasound Ablation of the Renal Sympathetic Nerves

Aziz et al. (2023) conducted a multi-center, randomized, sham controlled, clinical trial to evaluate the effect of ultrasound renal denervation in patients with resistant hypertension despite medications. Two hundred and twenty-four patients with a seated office systolic blood pressure ≥140 mm Hg and diastolic blood pressure ≥90 mm Hg despite taking up to 2 antihypertensive medications, and an ambulatory blood pressure of 135/85 mm Hg or greater, and a blood pressure less than 170/105 mm Hg after a 4-week washout of their medications were eligible to participate in the study. Participants were randomized 2:1 to undergo ultrasound renal denervation or a sham procedure and were expected to abstain from antihypertensive medications until the 2-month follow-up unless prespecified BP criteria were exceeded and were associated with clinical symptoms. One hundred and fifty participants received ultrasound renal denervation and 74 underwent the sham procedure with results showing a reduction in daytime ambulatory systolic blood pressure was greater with ultrasound renal denervation (mean, −7.9 mm Hg [SD, 11.6 mm Hg]) vs the sham procedure (mean, −1.8 mm Hg [SD, 9.5 mm Hg]) (baseline-adjusted between-group difference, −6.3 mm Hg [95% CI, −9.3 to −3.2 mm Hg], P < .001), with a consistent effect of ultrasound renal denervation throughout the 24-hour circadian cycle. There were no major adverse events recorded in either group.

Aziz et al. (2021,2022) conducted a multi-center, randomized, single blind, sham controlled, clinical trial to evaluate ultrasound renal denervation in patients with persistent hypertension despite being on a regimen of three or more antihypertensive medications, including a diuretic. Eligible patients were switched to a once daily, fixed-dose, single-pill combination of a calcium channel blocker, an angiotensin receptor blocker, and a thiazide diuretic; then randomly

assigned to ultrasound renal denervation or a sham procedure if after 4 weeks of standardized therapy, patients with daytime ambulatory blood pressure of at least 135/85 mm Hg. A total of 136 participants were included in the study and 1:1 randomized to ultrasound renal denervation (n=69) or a sham procedure (n=67). Full adherence to the combination medications at 2 months among patients with urine samples was similar in both groups (42 [82%] of 51 in the renal denervation group vs 47 [82%] of 57 in the sham procedure group; p=0·99). Renal denervation reduced daytime ambulatory systolic blood pressure more than the sham procedure (-8·0 mm Hg [IQR -16·4 to 0·0] vs -3·0 mm Hg [-10·3 to 1·8]; median between-group difference -4·5 mm Hg [95% CI -8·5 to -0·3]; adjusted p=0·022); the median between-group difference was -5·8 mm Hg (95% CI -9·7 to -1·6; adjusted p=0·0051) among patients with complete ambulatory blood pressure data. The same patients were re-assessed six months post procedure. In the patients who had persistent elevation of blood pressure at 2 months post procedure, standardized stepped-care antihypertensive treatment escalation resulted in similar BP reduction in both groups at the six-month post procedure re-assessment. In the ultrasound renal denervation group, fewer additional medications required, and fewer patients received aldosterone antagonists at 6 months (26 of 65 [40.0%] vs 39 of 64 [60.9%]; P = .02). Despite less intensive standardized stepped-care antihypertensive treatment, mean daytime ambulatory blood pressure at 6 months was 138.3 (15.1) mm Hg with ultrasound renal denervation vs 139.0 (14.3) mm Hg with sham therapy (additional decreases of -2.4 [16.6] vs -7.0 [16.7] mm Hg from month 2, respectively), whereas home systolic blood pressure was lowered to a greater extent with ultrasound renal denervation by 4.3 mm Hg (95% CI, 0.5-8.1 mm Hg; P = .03) in a mixed model adjusting for baseline and number of medications. Safety profiles were similar between both groups.

National and Specialty Organizations

The **European Society of Cardiology (ESC)** Council on Hypertension and the **European Association of Percutaneous Cardiovascular Interventions (EAPCI)** published an updated clinical consensus statement regarding the use of renal denervation for managing hypertension in adults (Barbato et al. 2023). The consensus statement cites recent studies that have proven the safety, efficacy, and sustained long-term effects of renal denervation for the treatment of hypertension. The ESC and EAPCI make the following recommendations:

- "Renal denervation may be used in adult patients with uncontrolled resistant hypertension (office blood pressure ≥140/≥90 mmHg confirmed by 24-hour ambulatory systolic blood pressure ≥130 mmHg or daytime systolic blood pressure ≥135 mmHg) treated with ≥ 3 anti-hypertensive drugs and an eGFR ≥ 40 mL/min/1.73 m^2.
- Renal denervation may be a possible treatment option for patients unable to tolerate antihypertensive drugs in the long term or patients who express a preference to undergo renal denervation in a tailored, shared decision-making process.
- The patient's global cardiovascular risk should be evaluated, accounting for hypertension-mediated organ damage and cardiovascular complications. High cardiovascular risk favors the use of renal denervation.
- In the absence of evidence, it is not advised to perform renal denervation in kidney transplant recipients or patients with severely impaired kidney function (KDIGO stage G4 and G5), including patients with fibromuscular dysplasia, untreated secondary hypertension, a single functioning kidney or who require hemodialysis.
- Preprocedural planning should include non-invasive renal artery imaging to anticipate anatomical peculiarities…and screen for anatomical ineligibility criteria, such as untreated severe atherosclerotic renal artery disease or fibromuscular dysplasia.
    - Selective renal angiography immediately before renal denervation remains the gold standard since computed tomography angiography or magnetic resonance angiography may miss some renal artery abnormalities which preclude renal denervation, such as fibromuscular dysplasia.
    - The choice of imaging modality should be based on patient characteristics (e.g., obesity), expected image quality, availability, and local expertise.
- With current-generation renal denervation devices, femoral arterial access is needed, ideally using sonographic guidance. Successful hemostasis with closure devices is advisable to shorten hospital stays, especially in patients with uncontrolled hypertension who are overweight or obese.
- At the end of the renal denervation procedure, angiography of the renal arteries should be performed to assess potential renal parenchymal or arterial injuries.
- A follow-up duration of 8 to 12 weeks was sufficient to demonstrate the blood pressure-lowering efficacy of renal denervation in the absence of antihypertensive medications. In contrast to antihypertensive

medications where no further blood pressure decrease is seen after 8 to 12 weeks, sustained and meaningful blood pressure reductions were documented up to 36 months after renal denervation independently from concomitant antihypertensive medication burden."

The **National Institute for Health and Care Excellence (NICE)** published an interventional procedures guidance for percutaneous transluminal renal sympathetic denervation for resistant hypertension (NICE 2023). The guidance makes the following recommendations:

- "Evidence suggests that there are no major safety concerns in the short team, and complications are well recognized such as renal artery damage.
- Reductions in blood pressure have been noted in the short- and medium-term; however, "[renal denervation] should only be used with special arrangements" as there are uncertainties regarding long-term outcomes and complications.
- Healthcare organizations should make systems available for clinicians to collect and report outcome and safety data.
- "Further research should include randomized controlled trials or analysis of registry data."

The **European Society of Hypertension (ESH)** published guidelines for the management of arterial hypertension that were endorsed by the **International Society of Hypertension (ISH)** and the **European Renal Association (ERA)** (Mancia et al. 2023). The guidelines recommend the following:

- "Renal denervation should be based on the procedures that applied radiofrequency energy to main, accessory, and distal arteries, or high frequency unfocused ultrasound energy to main and accessory arteries.
- Evidence exists that renal denervation using radiofrequency and ultrasound energy reduces blood pressure significantly in hypertensive patients in the absence of antihypertensive medication.
- No solid predictor of future blood pressure reduction after renal denervation has been identified, with the exception of pretreatment blood pressure."
- Complications have been limited to access-site vascular complications, such as bleeding, hematomas, and fistulas. However, complications are limited to a study group with an eGFR > 40 ml/min/1.73 m^2.
- Studies focused on long-term outcomes are needed to assess nerve regrowth associated with renal denervation.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	Description
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural road mapping 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 road mapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/13/2023 Policy reviewed and coverage criteria updated from E/I/U to cover renal denervation in the appropriate settings. Coverage

	criteria, continuation of therapy, and limitations/exclusions all updated. IRO peer review December 2023.
12/14/2022	Policy reviewed and updated. No changes in coverage criteria; updated references
12/08/2021	Policy reviewed and updated. No changes in coverage criteria; updated professional society guidelines section (added: AHA and Eighth Joint National Committee) and updated references. Converted to new format.
12/09/2020	New policy. IRO Peer Review: 11/6/2020. Practicing physician board-certified in Internal Medicine, Cardiovascular Disease.

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