HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Radiofrequency Ablation of the Renal Sympathetic Nerve

Policy MP-063

Origination Date: 08/28/2024

Reviewed/Revised Date: 08/28/2024

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Current Effective Date: 10/28/2024

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Hypertension is one of the most common health conditions diagnosed in adults, with approximately 4 of 5 of those diagnosed having uncontrolled 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. Drug resistant hypertension is defined as a systolic blood pressure ≥140 mmHg and diastolic blood pressure ≥90 mmHg on multiple occasions despite concurrent use of three antihypertensive agents of different classes taken at maximally tolerated doses and at appropriate dosing frequency, one of which should be a diuretic.

Radiofrequency ablation (RFA) of sympathetic nerve fibers around renal arteries has been proposed as a non-pharmacologic treatment to reduce blood pressure in drug resistant hypertension (Simonyi et al, 2013). RFA of the renal sympathetic nerves is a minimally invasive procedure performed percutaneously with access at the femoral artery by using a flexible catheter-based technology that is threaded into the renal artery. After appropriate positioning, a controlled low-power radio frequency energy is delivered to the arterial walls to thermally ablate the renal sympathetic nerves. RFA interrupts the influence of the sympathetic nervous system on the kidney and systemic hemodynamics. It 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.

Currently, only one RFA device has been approved by the U.S. Food and Drug Administration (FDA) for ablation of the renal sympathetic nerves as a treatment for hypertension. The Symplicity Spyral™ Renal Denervation System (Medtronic) which is a multi-electrode RFA catheter system designed to deliver 4-quadrant ablations.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans does not cover radiofrequency ablation of the renal sympathetic nerve as it is considered unproven and investigational for all indications, including but not limited to uncontrolled drug-resistant hypertension.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

Multiple systematic reviews with overlapping studies, 1 of which is a 2017 Cochrane review (Coppolino et al), summarizing the key randomized control trials (RCTs) evaluating renal denervation (RDN). The overall results vary depending on the inclusion of earlier, unblinded studies and controlled but nonrandomized studies, with some systematic reviews reporting significant improvements with RDN and some reporting no significant improvement. The Cochrane review reported that none of the trials was designed to evaluate clinical endpoints as primary outcomes. The evidence for clinical endpoints (e.g., all-cause mortality, hospitalization, cardiovascular events) was of low-quality. Comparisons of clinical outcomes in sham versus RDN groups showed no significant differences between groups in myocardial infarction (relative risk, 1.3; 95% CI, 0.5 to 3.8), ischemic stroke (relative risk, 1.1; 95% CI, 0.4 to 3.7), or unstable angina (relative risk, 0.6; 95% CI, 0.1 to 5.1). Also of note, most analyses included 6-month follow-up measurements, while a review by Chen et al (2017), calculated change in blood pressure for subgroups at 12-month follow-up. However, the 12-month analysis showed no difference at the longer follow-up.

A 2020 systematic review and meta-analysis (Stavropoulos et al) noted that despite the availability of a numerous anti-hypertensive agents, hypertension treatment and control rates remain low in many countries. The role of the sympathetic nervous system has long been recognized, but recent sham control RDN studies demonstrated conflicting results. The researchers investigated the outcomes of sham-controlled studies utilizing new technologies and procedures; 6 published randomized, sham-

controlled studies were included in this meta-analysis. Of those, 3 trials used the first-generation RF RDN device and technique and the other 3 used second-generation devices and techniques. A total of 981 patients with hypertension were randomized in all 6 trials to undergo RDN (n = 585) or sham procedure (n = 396). Overall, RDN resulted in a decrease of 24-hours systolic ambulatory blood pressure (ABP) by 3.62 mm Hg (95% CI: -5.28 to -1.96; I2 = 0%), compared to sham procedure (GRADE: low). Renal denervation also reduced day-time systolic ABP by 5.51 mm Hg (95% CI: -7.79 to -3.23; I2 = 0%), compared to sham procedure but not night-time systolic ABP. Office systolic blood pressure (SBP) was reduced by 5.47 mm Hg (95% CI -8.10 to -2.84; I2 = 0%), compared to sham control. Further analysis demonstrated that second-generation devices were effective in reducing blood pressure (BP), whereas the first-generation devices were not. Drawbacks of this study included the small number of the included RCTs (n = 6), the relatively small sample size (n = 981), the short-term follow-up period (up to 6 months), and small number of studies. The authors concluded that the results of this meta-analysis suggested that RDN worked in the short-term and may contribute to better management and control of uncontrolled hypertension. However, the effect was relatively small and most likely diluted by non-responders. Therefore, further, well-designed studies (larger, adequately powered RCTs) are needed to better-define the role of RDN in the treatment of hypertension in the general population.

A 2021 network meta-analysis (Silverwatch et al) collected the results of 20 RCTs of varying approaches to RDN compared to sham or antihypertensive medications or one another. Trials enrolled participants with uncontrolled hypertension treated with radiofrequency main renal artery denervation (n=10 studies), radiofrequency of the main renal artery plus branches (n=4), radiofrequency of main renal artery plus antihypertensive therapy (n=5), ultrasound of the main renal artery (n=3), sham control (n=8), and antihypertensive therapy alone (n=9). The conclusion reach by the authors was that radiofrequency RDN had the greatest improvement in 24 ambulatory, daytime, and nighttime BPs compared to other interventions (p-scores ranging from 0.83 to 0.97), with significant effects found versus both sham and antihypertensive therapies. However, no significant difference in the effect of RDN on clinical outcomes was found. Further clinical outcome data is needed from future trials to further assess the efficacy and safety of RDN interventions.

The last systematic review examining RDN was a 2023 systematic review and meta-analysis (Fernandes et al) which examined the effect of catheter-based sham renal denervation (RDN) in hypertension (HTN). This review included 9 RCTs comprised of 674 individuals with hypertension who received sham RDN. The primary outcome was systolic and diastolic BP. The sham arms showed a significant decrease in ambulatory systolic and diastolic blood pressure of -3.41 mmHg and − 2.44 mmHg, respectively as well as in decreasing office systolic and diastolic BP by -5.52 mmHg and − 2.13 mmHg, respectively, in patients with hypertension. Some limitations of the review included the availability of a small number of randomized sham-controlled trials for RDN and the short follow-up time of patients submitted to this procedure, especially since unblinding of the intervention occurred between 8 weeks and 12 months, having an impact in the placebo effect and long-term outcomes. In conclusion, the authors found that despite recent data indicating that RDN might be an effective treatment for patients with resistant HTN when compared to a sham intervention, the results indicate that the sham intervention for RDN also has a significant effect on lowering office and ambulatory (24-h) BP in adult patients with hypertension. This highlights that BP itself might be sensitive to placebo-like effect and also brings further difficulties in establishing the BP lowering efficacy of invasive interventions due to the magnitude of the sham effect. Despite modestly favorable, short-term results for RDN as treatment of drug-resistant uncontrolled HTN from several trials, benefit from renal nerve denervation compared with a sham procedure has not been consistently established, nor has a durability of effect. It was felt that more robust studies with sufficient long-term follow-up to assess net health outcomes data are needed.

As for individual studies there have been several studies published on RDN and impact on health outcomes. In 2017, Townsend et al reported on findings from the unpowered, proof-of-concept SPYRAL HTN-OFF MED pilot trial, in which 80 patients were randomized to RDN (n=38) or sham treatment (n=42). Patients were followed for 3 months following a 3-4 week medication washout period. Eligibility criteria included mild to moderate hypertension defined as office systolic blood pressure (SBP) ≥150 mmHg and <180 mmHg and office diastolic blood pressure (DBP) ≥90 mmHg in addition to mean 24-h ambulatory SBP ≥140 mmHg and <170 mmHg. Both mean 24-h ambulatory and office blood pressure measurements significantly decreased from baseline in the RDN group at 3 months. No significant reductions in blood pressure were found in the sham control group. Between-group difference in blood pressure changes were also significant. Limitations included small sample size, short term (3 month) follow-up, and the method used in this trial might not be generalizable to other RDN technologies. Trial investigators concluded that these data provide biological proof of principle that RDN lowers BP in untreated hypertensive patients, supporting prior data regarding the correlation between reduction in sympathetic tone and blood pressure reduction. No composite safety events were reported through 3 months of the pilot study, defined as the composite of all-cause mortality, end-stage renal disease, embolic event resulting in end-organ damage, renal artery perforation requiring re-intervention, renal artery dissection requiring re-intervention, vascular complications, hospitalization for hypertensive crisis or emergency, or new renal artery stenosis >70%. Utilizing a Bayesian study design. However, due to the limitations of this report, further, well designed studies with longer follow-up times, larger populations and comparisons to other RDN technologies are necessary to demonstrate the findings of this trial.

In 2018, Kandzari et al reported on initial findings from the unpowered SPYRAL HTN-ON MED pilot trial, in which 80 patients were randomized to RDN (n=38) or sham treatment (n=42). Eligibility criteria were consistent with those for the SPYRAL HTN-ON MED trial, but additionally required patients to be on 1-3 antihypertensive medications with stable doses at 50% or more of the maximum manufacturers recommended dosage for at least 6 weeks. Patients were knowingly screened for antihypertensive drug adherence and medications changes were not permitted through 6 months unless patients met pre-specified escape criteria (office systolic blood pressure [SBP] ≥180 mmHg or <115 mmHg with symptoms of hypotension). Baseline patient characteristics were similar except for a 19% higher incidence of obstructive sleep apnea in the sham control group. At 6 months for the overall population, the key efficacy outcome of mean 24-h SBP was significantly reduced by -9.0 mmHg with RDN, with a statistically significant between-group difference of -7.4 mmHg in favor of RDN. Between-group differences were also statistically significant for 24-h diastolic blood pressure (DBP), office SBP, office DBP, daytime SBP and DBP, and night-time SBP and DBP in favor of RDN. In contrast to prior findings from the SPYRAL HTN-OFF MED trial, no significant between-group differences were noted at 3 months. Medication adherence at 6 months was 60.5% and 64.3% in RDN and sham control groups, respectively. Importantly, between-group differences for 24-h SBP and DBP were only significant for the subgroup of non-adherent patients. Additionally, between-group differences for office SBP and DBP were not statistically significant in either adherent or non-adherent subgroup analyses.

In a 2019 retrospective review, Bolignano and Coppolino noted that hypertension remains a major public health problem and one of the most relevant causes of cardiovascular mortality and morbidity worldwide. Approximately 10% of hypertensive individuals are considered as "resistant" as they are unable to attain and maintain optimal BP values despite the concurrent use of 3 anti-hypertensive agents of different classes at optimal doses. As resistant hypertension conveys a higher risk of adverse outcomes, the search for effective treatments to properly manage this condition has progressively surged as a true health priority. The renal nerve plexus plays a central role in regulating arterial BP and renal sympathetic over-activity is a major component in the development and progression of hypertension. On these premises, minimally-invasive catheter-based devices for renal nerve ablation

have been developed and tested as an alternative treatment for resistant hypertension; however, clinical study results had been conflicting. These investigators provided a historical perspective on the scientific evidence forming the foundation of renal never ablation from accrued clinical evidence to possible future applications. The authors found that further research and clinical experience is needed to fully reveal limits and potential indications of this procedure.

Several studies in 2020 also looked at renal sympathetic denervation in the treatment of drug resistant hypertension. The first, a 2020 study (Liu et al) reported on renal sympathetic denervation (RSD) as a new method for the treatment of refractory hypertension (RH); however, few studies have focused on the effects of RSD on blood flow and the interaction between temperature field and flow field. These researchers designed a numerical simulation of electromagnetic field, flow field and temperature field coupling by finite element method. Numerical simulation results were verified by particle image velocimetry (PIV) and in-vitro experiment. From the simulation results, when the flow velocity increased to 0.05 m/s, the turbulence near the electrode disappeared and flow state became uniform laminar flow. With the increases of flow velocity (0 m/s to 0.1 m/s), temperature rise of the renal artery, the electrode tip and blood decreased from 13°C, 24°C and 5.4°C to 9.3°C, 9.7°C and 0.2°C, respectively. From PIV experiment and in-vitro experiment results, when the flow rate increased to 0.5 L/min, it appeared similar phenomenon with the velocity of 0.05 m/s in simulation. With the increases of flow rate (0 L/min to 0.8 L/min), temperature rise of 3 points decreased from 11.2°C, 20.5°C and 3.6°C to 7.8°C, 8.5°C, and 0.4°C, respectively. When the blood flow rate exceeded 0.5 L/min, there was no large velocity gradient and reflux area in the flow field, so there would be no hemolysis and thrombosis. Thus, the temperature field had less influence on the flow field. With the increase of flow rate, the temperature at all 3 points decreased. Consequently, the flow field had an effect on the temperature field; however, the central temperature of renal artery could still reach the treatment target in which temperature rose to be more than 6°C. In conclusion it was determined that the preliminary findings of this study verified the safety and effectiveness of RSD. However, further more robust studies are required to duplicate these findings.

Another 2020 study (Versaci et al) examined initial studies on RDN for the treatment of non-controlled arterial hypertension (HTN) via RF ablation of renal arteries and found that RDN appears to be an effective therapeutic strategy to reduce arterial BP. Nonetheless, the 1st randomized study, SYMPLICITY-HTN-3, failed to demonstrate a clear benefit for RND over the control group. Technologic evolution, with the introduction of new 2nd generation multi-electrode devices, allowed deep energy delivery along the full circumference of the vessel. Two recent randomized studies involving patients assuming (SPYRAL HTN-ON MED) or not (SPYRAL HTN-OFF MED) anti-hypertensive pharmacotherapy, demonstrated the safety and efficacy of RDN using 2nd generation systems for RF ablation. Another recent randomized study demonstrated that RDN with US (RADIANCE-HTN SOLO) of the main renal arteries led to a significant BP reduction compared to the control group. The authors concluded that even though these studies have shown a significant reduction in arterial BP values after RDN, it is necessary to analyze these results with caution taking into account the limitations due to the small sample size and short-term follow-up. Thus, larger trials, with a greater number of recruited patients and longer follow-ups, are needed to better define the role of this procedure in controlling arterial BP values and in reducing the number of antihypertensive drugs and their adequate dose for long-term control of BP.

The last study from 2020 Böhm et al stated that catheter-based renal denervation has significantly reduced blood pressure in previous studies. Following a positive pilot trial, the SPYRAL HTN-OFF MED (SPYRAL Pivotal) trial was designed to examine the efficacy of renal denervation in the absence of antihypertensive medications, in which pilot trial data (n=80) was used as an informative prior and combined with data from an additional 251 subjects to constitute an overall primary analysis population

(N=331). Patients were randomly assigned to either RDN (n=166) or sham procedure (n=165). Significant between-group differences were found for the primary 24-h SBP and secondary office SBP endpoints in favor of RDN at 3 months. These primary and secondary endpoints were each met with a posterior probability of superiority greater than 0.999 with a treatment difference of -3.9 mmHg and 6.5 mmHg, respectively. Superiority of RDN was confirmed via both Bayesian and frequentist statistical methods. One composite safety event was reported in each study arm, neither of which were attributed to the device or trial procedures. Longer-term follow-up for the full cohort of pilot plus pivotal trial patients found that at 6 months, significant differences in 24-h SBP and office SBP were no longer observed, likely as a result of trial participants beginning or resuming antihypertensive medications at 3 months follow-up. By 12 months, the sham control group had a superior 24-h SBP, although no between-group differences were reported at 1 year post-treatment for office SBP. The authors concluded that the SPYRAL Pivotal Trial showed the superiority of catheter-based renal denervation compared with a sham procedure to safely lower BP in the absence of anti-hypertensive medications.

In a 2021 study, Haribabu et al noted that hypertension is one of the most important risk factors for cardiovascular disease, which is the leading cause of mortality. The World Health Organization (WHO) estimated that in 2019 more than 1.13 billion individuals worldwide were suffering from hypertension. Despite the advances in new medical therapies, control of hypertension remains suboptimal. Treatment with RDN was primarily developed to treat resistant hypertension (RH) and is a potential method for treating congestive heart failure, diabetes, and chronic renal failure. RDN entails passing a catheter into the renal arteries and ablating their sympathetic nerves using radiofrequency or ultrasound energy. Despite promising results in initial trials, RDN failed to achieve its efficacy endpoints as a treatment RH; however, the recent series of successful trials showed that RDN is back as a serious therapeutic alternative. The authors reviewed the current state-of-the-art RDN devices including Symplicity Flex, Symplicity Spyral, Vessix, EnligHTN, Iberis, TIVUS system, and Paradise. They also provided an in-depth review of future RDN devices that include Cryo-RDN, Golden Leaf Catheter, Synaptic, SyMapCath, ConfidenHT System, and Grizzly Microwave Ablation system.

In 2022 Rao and Krishnan issued an update on the available evidence regarding the short- and long-term safety and effectiveness of RDN in the treatment of hypertension and the role of renal sympathetic nerves in the pathophysiology of hypertension, along with its future perspectives. RDN is a percutaneous endovascular catheter-based neuromodulation approach that enables ablation of renal sympathetic nerve fibers within the adventitial layer of the renal arteries using RF (most extensively studied), US energy, or neurolytics (e.g., alcohol). In the past 10 years, advancements in procedural techniques and well-designed sham-controlled studies employing 24-hour ambulatory BP monitoring have shown that RDN has an excellent safety profile and resulted in a modest reduction of BP, in a wide range of hypertensive phenotypes (mild-to-resistant), irrespective of anti-hypertensive medication use and this effect is sustained over a 3-year period. Superiority of a particular RDN modality has not been yet established. The authors concluded that despite strong evidence showing the safety and effectiveness of RDN, current data does not support its use as a primary approach in the treatment of hypertension due to its modest treatment effect and concerns regarding its long-term sustainability. Furthermore, the authors noted that perhaps the best use of RDN is in hypertensives intolerant to anti-hypertensive medications or as an adjunct to aldosterone antagonists in the management of resistant hypertension. Additionally, patient selection will be critical to show a meaningful benefit of RDN. Therefore, future well-designed studies are required to determine predictors and measures of response to RDN, long-term effectiveness given question of renal nerve regeneration, comparison of available technologies, safety in patients with advanced kidney disease, and improvement in patient QOL measures.

In a 2022 randomized, single-blind, sham-controlled trial, Mahfoud et al reported on long-term outcomes from the SPYRAL HTN-ON MED pilot trial through 36 months. Medication adjustments were permitted after 6 months and patients were unblinded and permitted to crossover after 12 months. No significant between-group differences were reported at 12 months, which investigators attributed to a higher medication burden in the sham control group as confirmed by 2 out of 4 post-hoc analyses. Progressive and sustained reductions in blood pressure were noted over time, with significant between-group differences at 24 and 36 months in favor of RDN. Between 6 and 36 months, mean 24-h SBP was reduced by an additional 5.9 mmHg with RDN. Nonetheless, during this period, the mean number of antihypertensive medications prescribed for patients in both RDN and sham control groups increased by approximately 1 additional medication. Sham control measurements at 36 months included 13 imputed crossover patients' blood pressure measurements from the last observation prior to the RDN procedure. Between-group differences in mean office SBP lost statistical significance at 24 months without imputation. Additionally, both mean 24-h and office SBP between-group differences lost statistical significance without imputation at 36 months. At 36 months, 6 (20%) of 30 patients in the RDN group and 1 (3%) of 32 patients in the sham control group had mean 24-h SBP <130 mmHg and DBP <80 mmHg (p=.05). However, between-group differences for the proportion of patients achieving target 24-h blood pressure were not statistically significant at 24 months. One composite safety event was reported in RDN and sham control arms through 36 months, occurring at 427 days and 693 days post-procedure, respectively. Changes in eGFR, serum creatinine, sodium levels, and potassium levels from baseline to 24 and 36 months were not significantly different between groups. The authors concluded that overall, study interpretation is complicated by short-term blinded follow-up and imputation of excluded crossover patient data. It is unclear which patients are most likely to derive benefit and whether such benefit is clinically meaningful in the context of increased medication use over time. Therefore, further studies with even longer follow-up are needed to determine the full efficacy of RDN with antihypertensive medications.

In a 2022 single-blind, multicenter, sham-controlled, randomized clinical trial, Bhatt et al reported on the 36-month follow-up results of the industry-sponsored SYMPLICITY HTN-3 trial, previously described as Medtronic’s pivotal trial in the U.S. which failed to meet its primary and secondary efficacy endpoints. The original primary endpoint was the change in systolic BP from baseline to 6 months for the RDN group compared with the sham control group. Following the initial 6-month follow-up, participants were unmasked and those in the sham group who met the inclusion criteria (office BP ≥160 mm Hg, 24 h ambulatory systolic BP ≥135 mm Hg, and still prescribed three or more antihypertensive medications) could cross over to receive renal artery denervation. Changes in BP up to 36 months were analyzed in the original RDN group and in the sham control group, including those who crossed over to RDN and those who did not (remained in the control group). The study’s safety endpoints were the incidence of all-cause mortality, end stage renal disease, significant embolic event, renal artery perforation or dissection requiring intervention, vascular complications, hospitalization for hypertensive crisis unrelated to non-adherence to medications, or new renal artery stenosis of more than 70% within 6 months. Follow-up data from 36-months were available for 219 individuals in the original RDN group (originally, n=364), 63 in the crossover group, and 33 in the control group (originally, n=171). At 36 months, the change in office systolic BP and 24 h ambulatory systolic BP was significantly lower in the RDN group ($p \leq 0.0001$, for both outcomes). In conclusion, the authors found that the rates of adverse events were similar across treatment groups. However, given the trials failure to meet its original primary and secondary endpoints, and the high rate of attrition at 36 months, further study is needed.

In a 2023 prospective, randomized, single-blinded, sham procedure-controlled, multi-center trial, Wang et al investigated the safety and effectiveness of targeted renal sympathetic denervation in patients with essential and uncontrolled hypertension and titled it the "Sympathetic Mapping/Ablation of Renal

Nerves Trial" (SMART). RDN is proposed as a durable and patient compliance independent treatment for hypertension; however, 20% to 30% of non-responder patients after RDN treatment weakened the therapeutic effect, which may be due to blind ablation. The renal nerve mapping/selective ablation system developed by SyMap Medical Ltd (Suzhou), China, has the function of mapping renal sympathetic/parasympathetic nerve sites and selectively removing renal sympathetic nerves and is expected to meet the urgent unmet clinical need of targeted RDN. This study is the 1st clinical registry trial using a targeted RDN for the treatment of uncontrolled hypertension; the dual-endpoint design can answer the question of how many anti-hypertensive drugs can be reduced in patients following RDN. The trial is registered on clinicaltrials.gov NCT02761811.

The American Heart Association (AHA), American College of Cardiology (ACC), and American Society of Hypertension (ASH; 2015) issued joint guidelines on the treatment of hypertension in patients with coronary artery disease. The guidelines noted the Symplicity HTN-3 trial did not find a significant benefit from RDN and stated that additional randomized controlled trials would be needed. The AHA, ACC, and 9 additional specialty societies (2018) published joint guidelines on the prevention, detection, evaluation, and management of high blood pressure in adults. In discussing resistant hypertension, the guidelines indicated that studies using catheter ablation of renal sympathetic nerves "have not provided sufficient evidence to recommend the use of these devices." The AHA (2018) published a Scientific Statement on the detection, evaluation, and management of resistant hypertension. The AHA Statement discussed the lack of benefit found in the Symplicity HTN-3 trial, as well as its methodological limitations. The statement also referred to the more recent positive data from the SPYRAL HTN-OFF MED trial, but noted that because the enrolled patients did not have resistant hypertension, "at best, this represents a proof-of-principle study demonstrating the role of the renal sympathetic nervous system in hypertension." The statement concluded that "the role of device based sympatholytic treatments, as with renal denervation and baroreceptor stimulation, awaits clarification." As of 2024 the guidelines state that “radiofrequency ablation of renal sympathetic nerves has recently gained attention for its ability to reduce BP in those with resistant hypertension. A small study has demonstrated the ability of renal denervation to induce LV hypertrophy regression and to improve LV systolic and diastolic function. However, in the first large-scale clinical trial of renal denervation in patents with resistant hypertension, with an appropriate control group, namely a sham procedure (Renal Denervation in Patients With Uncontrolled Hypertension [SYMPLICITY HTN-3]), there was no significant difference between the 2 groups in the reduction of SBP, which leaves the future of renal denervation in the management of hypertension uncertain. The impact of renal denervation in HF patients is also unclear, and future randomized trials are needed to clarify its role in this patient population.”

Applicable Coding

CPT Codes

Non-covered codes

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 ; bilateral

HCPCS Codes

No applicable codes

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