Clinical Policy Bulletin:  
Radiofrequency Ablation of the Renal Sympathetic Nerve

Number: 0847

Policy

Aetna considers radiofrequency ablation of the renal sympathetic nerve experimental and investigational for the treatment of the following indications (not an all-inclusive list) because of insufficient evidence in the peer-reviewed literature.

- Hypertension
- Obstructive sleep apnea
- Ventricular tachycardia

See also: CPB 0820 - Carotid Sinus Stimulation for Hypertension

Background

Hypertension is an independent risk factor for cardiovascular disease. Treatment frequently includes administration or more drugs. Resistant hypertension is defined as blood pressure which remains above target levels despite use of maximum tolerated dose of antihypertensive medications, consisting of at least three different classes of drugs, including a diuretic. Radiofrequency (RF) ablation 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).

Selective renal sympathetic denervation interrupts the influence of the sympathetic nervous system on the kidney systemic hemodynamics. The sympathetic innervation of the kidney is implicated in the pathogenesis of hypertension through effects on renin secretion, increased plasma renin activity that leads to sodium and water retention, and renal blood flow. Renal sympathetic ablation is a minimally invasive procedure utilizing a RF catheter inserted through the femoral artery and selectively engaging the renal artery (Papadimitriou et al, 2011).

Krum et al (2009) performed a proof-of-principle trial of therapeutic renal sympathetic denervation in patients with resistant hypertension (i.e., systolic blood pressure greater than or equal to 160 mm Hg on 3 or more anti-hypertensive medications including a diuretic) to assess safety and blood-pressure reduction effectiveness. The investigators enrolled 50 patients from Australian and European centers; 5 patients were excluded for anatomical reasons (primarily due to dual renal artery systems). Patients received percutaneous RF catheter-based treatment between June 2007 and November 2008, with subsequent follow-up to 1 year. The effectiveness of renal sympathetic denervation with renal noradrenaline spillover...
assessed in a subgroup of patients. Primary endpoints were office blood pressure and safety data before the procedure at 1, 3, 6, 9, and 12 months after the procedure. Renal angiography was done before, immediately after, and 14 to 24 months after procedure, and magnetic resonance angiogram was assessed 6 months after procedure. Blood-pressure low effectiveness was analyzed using repeated measures ANOVA. In treated patients, baseline mean office blood pre 177/101 mm Hg (SD 20/15), (mean of 4.7 anti-hypertensive medications); estimated glomerular filtration rate was ml/min/1.73m(2) (SD 23); and mean reduction in renal noradrenaline spillover was 47 % (95 % confidence interval % to 65 %). Office blood pressures after procedure were reduced by -14/-10, -21/-10, -22/-11, -24/-11, and -27/-17 1, 3, 6, 9, and 12 months, respectively. In the 5 non-treated patients, mean rise in office blood pressure was +3/-2 +14/+9, and +26/+17 mm Hg at 1, 3, 6, and 9 months, respectively. One intra-procedural renal artery dissection o before RF energy delivery, without further sequelae. There were no other renovascular complications. The author concluded that catheter-based renal denervation causes substantial and sustained blood-pressure reduction, with no adverse events, in patients with resistant hypertension. They also stated that prospective randomized clinical trials needed to investigate the usefulness of this procedure in the management of this condition.

A prioritizing summary of the Australia and New Zealand Horizon Scanning Network on renal sympathetic denervation treatment of resistant hypertension concluded that based on the low level of available evidence, it would appear that denervation may be a viable option for the treatment of resistant hypertension (Mundy & Hiller, 2010). Blood pressure significantly lower after renal denervation than that measured at baseline; however, it is unclear whether this decrease is considered clinically significant. Finally, 12-month follow-up data were only reported for a small portion of the enrolled patients (22%) and in addition, six of the 45 patients were considered non-responders with non-significant reductions in blood pressure. The summary concluded that well conducted randomized controlled trial is needed to adequately investigate whether renal denervation is capable of producing a sustained lowering of blood pressure in hypertensive patients with resistant hypertension (Mundy & Hiller, 2010).

Mahfoud et al (2011) described their first experience with a percutaneous treatment modality using renal artery RF a treatment option in patients with resistant hypertension, with a low-risk of serious adverse events. Selected patients were resistant to at least 3 types of anti-hypertensive medical therapy (office systolic blood pressure than or equal to 160 mm Hg; n = 9) or who did not tolerate medication (n = 2). Between July and November 2010, 11 patients received percutaneous RF treatment and were followed for 1 month after treatment. Urine and blood samples were taken to evaluate the effects on renal function and neurohumeral factors. No peri-procedural complications were noted. A reduction of mean office blood pressure was observed from 203/109 +/- 32 at baseline to 178/97 +/- 28/21 mm Hg at 1 month follow-up (mean difference 25 +/- 12 mm Hg, p < 0.01). The investigators also noted a significant decrease in aldosterone level (391 +/- 210 pmol/L versus 250 +/- 142 pmol/L; p = 0.03), but no decrease in plasma renin activity (190 +/- 134 fmol/L/s versus 195 +/- 163 fmol/L/s; p = 0.43). No change in renin was noted. The authors concluded that catheter-based renal denervation seems an attractive novel minimally invasive treatment option in patients with resistant hypertension, with a low-risk of serious adverse events.

Mahfoud et al (2011) summarized the expert consensus and recommendations of the working group 'Herz und Nie German Society of Cardiology (DGK), the German Society of Nephrology (DGfN) and the German Hypertension League (DHL) on renal denervation for anti-hypertensive treatment. Renal denervation was defined as a new, intervention approach to selectively denervate renal afferent and efferent sympathetic fibers. The authors noted that renal denervation has been demonstrated to reduce office systolic and diastolic blood pressure in patients with resistant hypertension as systolic office blood pressure greater than or equal to 160 mm Hg and greater than or equal to 150 mm Hg in patients with diabetes type 2, which should currently be used as blood pressure thresholds for undergoing the procedure. Exclusion criteria for the Symplicity studies. Therefor denervation should be only considered in patients with a glomerular filtration rate greater than 45 ml/min. Adequate qualification in both treatment of hypertension and interventional expertise are essential to ensure correct patient selection and procedural safety. The authors stated that long-term follow-up after renal denervation and participation in the Renal Denervation (GREAT) Registry are recommended to assess safety and efficacy after renal denervation over time.
Lobodzinski (2011) reviewed renal denervation system technology for treatment of drug resistant hypertension. The researchers described “an investigational device that is currently tested in an on-going clinical trial. The denervation uses the RF thermal ablation catheter attached to the RF generator. The RF catheter is inserted into the renal artery in the vicinity of the efferent and afferent parasympathetic innervations. Renal denervation is a minimal localized procedure and the procedural and recovery times are very short. The entire procedure takes about 40 minutes. Early clinical trials, the systolic blood pressure in 87% of patients who underwent the denervation procedure resulted in an average blood pressure drop of greater than 10 mm Hg. The procedure has no systematic side effects, and appears beneficial in the management of hypertension in patients refractory to pharmacological therapy.”

Patel and White (2012) stated that renal artery intervention to treat hypertension is one of the frontiers of ongoing research combating this epidemic. The investigators discussed recent data regarding renal artery angioplasty with stenting and catheter-based renal sympathetic denervation. They noted that despite progress in this field, large, multi-center randomized trials that compare these treatment modalities with medical therapy for hypertension are lacking.

Tam et al (2013) stated that resistant hypertension, defined as the failure to achieve target blood pressure despite use of 3 anti-hypertensive agents of different classes, is estimated to affect 20 to 30% of hypertensive patients. These patients are vulnerable to cardiovascular, cerebrovascular and renal complications. There is ample evidence that sympathetic nervous system hyperactivity contributes to the initiation, maintenance, and progression of hypertensive renal sympathetic nervous system, in particular, has been identified as a major culprit for the development and progression of hypertension, heart failure and chronic kidney disease in both preclinical and human studies. Traditional surgical sympathectomy proposed in the 1940s was halted due to unacceptable operative risk and the emergence of anti-hypertensive medications. The authors report that recently, catheter-based renal sympathetic denervation by RF ablation has shown encouraging intermediate-term results with minimal complications in patients with resistant hypertension.

A May, 2012 National Institute for Health and Clinical Excellence guideline stated that “current evidence on percutaneous transluminal RF sympathetic denervation of the renal artery for resistant hypertension is from limited numbers of patients, there is evidence of efficacy in the short and medium term. There is inadequate evidence on efficacy in the long term and is particularly important for a procedure aimed at treating resistant hypertension. The limited evidence suggests a low risk of serious periprocedural complications, but there is inadequate evidence on long-term safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2012).

Esler et al (2012) noted that renal sympathetic nerve activation contributes to the pathogenesis of hypertension. In a multicenter, randomized trial, demonstrated that catheter-based renal denervation produced significant blood pressure lowering in treatment-resistant patients 6 months after the procedure compared with controls, which were medication-only patients. The authors presented longer-term follow-up, including 6-month crossover results, in a recent study. Eligible patients were on ≥3 antihypertensive drugs and had a baseline systolic blood pressure ≥160 mm Hg for type 2 diabetes). After the 6-month primary end point was met, renal denervation in control patients was permitted. Patients randomized to immediate renal denervation (n=47) were evaluated one year post-procedure an crossover patients were evaluated 6 months post-procedure. At 12 months after the procedure, the mean fall in blood pressure in the initial renal denervation group (-28.1 mm Hg; 95% confidence interval, -35.4 to -20.7; P<0.001) was similar to the 6-month fall (-31.7 mm Hg; 95% confidence interval, -38.3 to -25.0; P=0.16 versus 6-month change). Systolic blood pressure of the crossover group 6 months after the procedure was significantly lowered (from 190.0±166.3±24.7 mm Hg; change, -23.7±27.5; P<0.001). In the crossover group, there was 1 renal artery dissection during catheter insertion, before denervation, corrected by renal artery stenting, and 1 hypertensive episode, which resolved with medication adjustment. Control patients who crossed over to renal denervation with the Symplicity system had a similar drop in blood pressure similar to that observed in patients receiving immediate denervation. The authors conclude denervation provided safe and sustained reduction of blood pressure to 1 year.

Geisler et al (2012) conducted a study to assess cost-effectiveness and long-term clinical benefits of renal denervation in resistant hypertensive patients. The authors noted that in the Symplicity HTN-2 randomized controlled trial, catheter renal denervation (RDN) lowered systolic blood pressure by 32 ± 23 mm Hg from 178 ± 18 mm Hg at baseline. A s
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In a pilot study, Ott et al (2013) examined the effect of RDN in patients with treatment-resistant hypertension (TRH) to the established definition (Joint National Committee VII and European Society of Hypertension/European Society Cardiology guidelines), i.e., office blood pressure (BP) greater than or equal to 140/90 mm Hg (with at least 3 anti-hypertensive drugs, including a diuretic, in adequate doses) and confirmed by 24-hour ambulatory BP monitoring. In this study, there were 54 patients with moderate TRH (office BP greater than or equal to 140/90 mm Hg and less than 160/100 mm Hg and diagnosis confirmed by 24-hour ABPM of greater than or equal to 130/80 mm Hg) who underwent catheter-based RDN using the Symplicity catheter (Medtronic Inc., Mountain View, CA). Patients were treated with anti-hypertensive drugs on average. Office BP was significantly reduced by 13/7 mm Hg 6 months after RDN (systolic 6 mm Hg versus 138 ± 21 mm Hg, p < 0.001; diastolic: 83 ± 11 mm Hg versus 75 ± 11 mm Hg, p < 0.001). In patients who underwent ABPM 6 months after treatment, there was a reduction in average 24-hour ABPM of greater than or equal to 130/80 mm Hg) who underwent catheter-based RDN using the Symplicity catheter (Medtronic Inc., Mountain View, CA). Patients were treated with anti-hypertensive drugs on average. Office BP was significantly reduced by 13/7 mm Hg 6 months after RDN (systolic 6 mm Hg versus 138 ± 21 mm Hg, p < 0.001; diastolic: 83 ± 11 mm Hg versus 75 ± 11 mm Hg, p < 0.001). In patients who underwent ABPM 6 months after treatment, there was a reduction in average 24-hour ABPM of greater than or equal to 130/80 mm Hg (systolic: 150 ± 16 mm Hg versus 136 ± 16 mm Hg, p < 0.001; diastolic: 83 ± 10 mm Hg versus 76 ± 10 mm Hg, p < 0.001). In 51% of patients, office BP was controlled below 140/90 mm Hg after RDN. In addition, heart rate decreased from 63 ± 10 beats/min (p = 0.006). The authors concluded that these findings indicated that RDN may reduce office hour ambulatory BP substantially in patients with moderate TRH. The main drawbacks of this study were the lack of a control group and the relatively small sample size. These researchers stated that there is a need for a large-scale, prospective randomized, multi-center, controlled trial in this group of TRH patients to precisely define the therapeutic role of RDN.

Fadl Elmula et al (2014) examined the BP-lowering effect of RDN versus clinically adjusted drug treatment in true resistant hypertension by excluding patients with confounding poor drug adherence. Patients with apparent TRH (n = 65) were referred for RDN when office systolic BP (SBP) greater than 140 mm Hg, despite maximally tolerated doses of greater than or equal to 3 antihypertensive drugs including a diuretic. In addition, ambulatory daytime SBP greater than 135 mm Hg after witnessed dosing of anti-hypertensive drugs was required, after which 20 patients had normalized BP and were excluded. Patients with TRH were randomized and underwent RDN (n = 9) performed with Symplicity Catheter System versus clinically adjusted drug treatment (n = 10). The study was stopped early for ethical reasons because RDN had uncertain BP-lowering effect. SBP and diastolic BP in the drug-adjusted group changed from 160 ± 14/88 ± 13 mm Hg (± SD) at baseline to 132 ± 14/80 ± 13 mm Hg at 6 months (p < 0.0005 and p = 0.02, SBP and diastolic BP, respectively) and in the RDN group from 156 ± 14/88 ± 13 mm Hg at baseline to 140 ± 12/82 ± 13 mm Hg at 6 months (p < 0.0005 and p = 0.006, SBP and diastolic BP, respectively).
15 to 148 ± 7/89 ± 8 mm Hg (p = 0.42 and p = 0.48, SBP and diastolic BP, respectively). Systolic BP and diastolic BP significantly lower in the drug-adjusted group at 6 months (p = 0.002 and p = 0.004, respectively), and absolute change in systolic BP was larger in the drug-adjusted group (p = 0.008). Ambulatory BP measurements changed in parallel to office BP measurements. The authors concluded that these findings suggested that adjusted drug treatment has superior BP-lowering effects compared with patients with true TRH.

Bhatt et al (2014) stated that prior unblinded studies have suggested that catheter-based RDN reduces blood pressure in patients with resistant hypertension. These investigators designed a prospective, single-blind, randomized, sham-controlled trial. Patients with severe resistant hypertension were randomly assigned in a 2:1 ratio to undergo RDN or a sham procedure. Before randomization, patients were receiving a stable anti-hypertensive regimen involving maximally tolerated doses of at least 3 drugs, including a diuretic. The primary efficacy end-point was the change in office SBP at 6 months; a secondary efficacy end-point was the change in mean 24-hour ambulatory SBP. The primary safety end-point was a composite outcome of end-stage renal disease, embolic events resulting in end-organ damage, renovascular complications, or hypertensive crisis 1 month or new renal-artery stenosis of more than 70% at 6 months. A total of 535 patients underwent randomization. The mean (± SD) change in SBP at 6 months was -14.13 ± 23.93 mm Hg in the denervation group as compared with -12.39 mm Hg in the sham-procedure group (p < 0.001 for both comparisons of the change from baseline), for a difference of -1.96 mm Hg (95% CI: -4.97 to 1.06; p = 0.98 for superiority with a margin of 2 mm Hg). There were significant differences in safety between the 2 groups. The authors concluded that this blinded trial did not show a reduction of SBP in patients with resistant hypertension 6 months after RDN as compared with a sham control.

Bakris et al (2014) noted that prior studies of catheter-based RDN have not systematically performed ambulatory blood pressure monitoring (ABPM) to assess the efficacy of the procedure. SYMPLICITY HTN-3 (Renal Denervation in Patients With Uncontrolled Hypertension) was a prospective, blinded, randomized, sham-controlled trial. The current analysis of the effect of RDN or a sham procedure on ABPM measurements 6 months post-randomization. Patients with resistant hypertension were randomized 2:1 to renal denervation or sham control. Patients were on a stable anti-hypertensive regimen including maximally tolerated doses of at least 3 drugs including a diuretic before randomization. The powered secondary efficacy end-point was a change in mean 24-h ambulatory SBP. Non-dipper to dipper (nighttime BP 10% to 20% below daytime BP) conversion was calculated at 6 months. The 24-hour ambulatory SBP decreased -6.8 ± 15.1 mm Hg in the denervation group and -4.8 ± 17.3 mm Hg in the sham group: difference of -2.0 mm Hg (95% CI: -5.0 to 1.1; p = 0.98 with a 2 mm Hg superiority margin). The daytime ambulatory SBP change difference between groups was -1.1 (95% CI: -4.3 to 2.052). The nocturnal ambulatory SBP change difference between groups was -3.3 (95% CI: -6.7 to 0.1; p = 0.06). The percentage of non-dippers converted to dippers was 21.2% in the RDN group and 15.0% in the sham group (95% CI: -3.8% to 0.30). Change in 24-hour heart rate was -1.4 ± 7.4 in the RDN group and -1.3 ± 7.3 in the sham group; (95% CI: -0.52 to 0.0). The authors concluded that this trial did not demonstrate a benefit of RDN on reduction in ambulatory blood pressure either the 24-hour or day and night periods compared with sham.

On January 9, 2014, Medtronic, Inc. announced that its U.S. pivotal trial in RDN for TRH, SYMPLICITY HTN-3, failed to meet its primary efficacy end-point. Medtronic intends to formulate a panel of independent advisors made up of physicians and researchers who will be asked to make recommendations about the future of the global hypertension clinical trial program as well as provide advice on continued physician and patient access to the Symplicity technology in countries with regulatory approvals. Pending this panel review, the company intends to: (http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1889335&highlight)

Suspend enrollment in the 3 countries where renal denervation hypertension trials are being conducted for approvals (SYMPLICITY HTN-4 in the U.S., HTN-Japan and HTN-India).

Begin informing clinical trial sites and investigators, global regulatory bodies, and customers of these findings.

Continue to ensure patient access to the Symplicity technology at the discretion of their physicians in markets where approval is approved.
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Ukena et al (2012) stated that sympathetic activity plays an important role in the pathogenesis of ventricular tachya.

Catheter-based RDN is a novel treatment option for patients with resistant hypertension, proved to reduce local an body sympathetic activity. Two patients with chronic heart failure (CHF) (non-obstructive hypertrophic and dilated cardiomyopathy, New York Heart Association [NYHA] III) suffering from therapy-resistant electrical storm underwe therapeutic RDN. In both patients, RDN was conducted with agreement of the local ethics committee and after obt informed consent. The patient with hypertrophic cardiomyopathy had recurrent monomorphic ventricular tachycard describe despite extensive anti-arrhythmic therapy, following repeated endocardial and epicardial electrophysiological ablati attempts to destroy an arrhythmogenic intra-mural focus in the left ventricle. The second patient, with dilated non-i cardiomyopathy, suffered from recurrent episodes of polymorphic VT and ventricular fibrillation. The patient decline ablation of these tachycardias. In both patients, RDN was performed without procedure-related complications. For RDN, ventricular tachyarrhythmias were significantly reduced in both patients. Blood pressure and clinical status re stable during the procedure and follow-up in these patients with CHF. The authors concluded that these findings s that RDN is feasible even in cardiac unstable patients. Moreover, they stated that randomized controlled trials (RC urgently needed to study the effects of RD in patients with electrical storm and CHF.

Tsioufis (2013) reported that a small study presented at ACC 2013 has shown that RDN, besides reducing resista hypertension, produces a favorable effect on atrial and ventricular arrhythmias. In the study, the researchers treate patients with resistant hypertension who underwent ABPM and Holter monitoring at baseline and 1 month after RD procedure, the investigators used the EnligHTN ablation catheter (St Jude Medical). Patients with grade II and ab Lown-Wolf classification were considered to have complex ventricular arrhythmias while the presence of greater th to 3 consecutive premature supraventricular contractions was defined as paroxysmal atrial fibrillation. These rese found that after 1 month, office and 24-hour BP was significantly reduced by 38/14.1 mmHg, p < 0.001/0.003 and 1 mmHg, p < 0.001/0.001, respectively. Office heart rate was reduced by 7 beats per minute (bpm), (p = 0.046), am heart rate by 5.5 bpm, and average 24-hour heart rate by 6.7 bpm (p = 0.022). The researchers also found that co ventricular arrhythmias were present in 5 out of the 14 patients (1 with non-sustained VT and 4 with ventricular cou baseline but persisted only in 2 of them 1 month after RDN (2 patients with ventricular couplets). The number of pr ventricular contractions was significantly decreased after RDN (from 2.23/hour to 0.39/hour, p = 0.019). Episodes paroxysmal atrial fibrillation were detected in 5 of 14 subjects at baseline and in 2 of those patients 1 month after R total number of premature supraventricular contractions was also significantly decreased after RDN from 1.62/hour 0.72/hour (p = 0.039), the authors found. There was no relationship between the observed difference in premature supraventricular and ventricular contractions after RDN and the drop in office and 24-hour BP.

Hoffman et al (2013) presented a case of ventricular storm (VS) in a patient with acute ST-elevation myocardial inf (STEMI). After initial successful thrombus extraction and percutaneous coronary intervention (PCI) of the proximal anterior descending (LAD) coronary artery, a 63-year old male patient showed recurrent monomorphic VT and ven fibrillation (VF) episodes refractory to anti-arrhythmic drug therapy. After initial successful VT ablation, fast VT and episodes remained an evident problem despite maximum anti-arrhythmic drug therapy. Due to an increasing insta was performed. Implantable cardioverter defibrillator interrogation and 24-hour Holter monitoring excluded recurre of VT or VF at a 6-month follow-up after discharge. The authors concluded that this case high-lighted that RDN wa and safely performed in a hemodynamically unstable patient with VS after STEMI and adjunct catheter ablation. T that RDN may open a new avenue for an adjunctive interventional bailout treatment of such highly challenging pati

Remo et al (2014) reported the largest case series to-date using RDN as adjunctive therapy for refractory VT in pa underlying cardiomyopathy. A total of 4 patients with cardiomyopathy (2 non-ischemic, 2 ischemic) with recurrent V maximized anti-arrhythmic therapy and prior endocardial (n = 2) or endocardial/epicardial (n = 2) ablation underwe repeat VT ablation. Renal denervation was performed spirally along each main renal artery with either a non-irriga 50°C for 60 seconds) or an open irrigated ablation catheter (10 to 12 W for 30 to 60 seconds). Renal arteriography performed before and after RDN. Renal denervation was well-tolerated acutely and demonstrated no clinically sign
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Complications during follow-up of 8.8 ± 2.6 months (range of 5.0 to 11.0 months). No hemodynamic deterioration or worsening of renal function was observed. The number of VT episodes was decreased from 11.0 ± 4.2 (5.0 to 14.0 per month before ablation to 0.3 ± 0.1 (0.2 to 0.4) per month after ablation. All VT episodes occurred in the first 4 months after ablation (2.6 ± 1.5 months). The responses to RDN were similar for ischemic and non-ischemic patients. The conclusion was that this case series provided promising preliminary data on the safety and effectiveness of RDN as an adjunctive therapy in the treatment of patients with cardiomyopathy and VT resistant to standard interventions.

There is an ongoing clinical trial, “RESCUE-VT” (RENal Sympathetic Denervation to sUpRess Ventricular Tachy Arrhythmias) but this study has suspended participant recruitment (Last verified August 2014). (http://clinicaltrials.gov/show/NCT01342005

Shantha and Pancholy (2014) noted that recent evidence associates sympathetic tone with severity of obstructive sleep apnea (OSA). Renal sympathetic denervation, by decreasing sympathetic tone, has the potential to decrease OSA. Small observational studies that assessed this hypothesis lacked precision. In a meta-analysis, these investigator attempted to pool available data from studies that have assessed the effect of RDN on OSA severity in patients with obstructive sleep apnea (OSA). Medline, Embase, Cochrane central, Ovid, Cinahl, web of science, and conference abstracts were searched for eligible citations by 2 independent reviewers using key words "renal denervation", "hypertension", and "obstructive sleep apnea". From a total of 2,863 identified citations, using meta-analysis of observational studies in epidemiology method, 5 studies were assessed eligible and included in the meta-analysis. All 5 studies followed an observational study design, involving 49 patients with OSA and hypertension, and reported an apnea-hypopnea index (AHI) 6 months post-RDN; 4 were "be before" studies and 1 compared continuous positive airway pressure with RDN. In the pooled analysis, involving 49 patients, RDN was associated with a significant reduction in mean AHI [weighted mean difference -9.61 (95 % CI: -15.43 to -3.79)] 6 months post-RDN. One study also reported improvement in oxygen desaturation index and Epworth sleep scale score 6 months post-RDN. The authors concluded that RDN is associated with significant improvement in OSA severity. Moreover, they stated that these findings need validation in RCTs that evaluate the effect of RDN in patients with OSA, which can potentially broaden the clinical applicability of RDN.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:

Radiofrequency ablation of the renal sympathetic nerve:

No specific code

0338T - 0339T

ICD-9 codes not covered for indications listed in the CPB (not all inclusive):

401.0 - 401.9 Essential hypertension

The above policy is based on the following references:

