Renal denervation

Clinical Policy ID: CCP.1283

Recent review date: 1/2024

Next review date: 5/2025

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

AmeriHealth Caritas Florida has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Florida's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Florida when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Florida's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Florida's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Florida will update its clinical policies as necessary. AmeriHealth Caritas Florida's clinical policies are not guarantees of payment.

Coverage policy

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

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

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

Background

Hypertension is largely viewed as a major modifiable risk factor associated with mortality. The sympathetic nervous system is activated in stressful or emergency situations and often referred to as the fight-or-flight response. The kidneys play a major role in the response by increasing secretion of renin to activate a chemical chain reaction that changes the hemodynamic system of the body and provides the protective physiological

response needed for a person to react. The systemic effects include arterial blood vessel constriction, increased heart rate, dilated pupils, and elevation of blood pressure (Sarathy, 2021).

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

Renal denervation, also referred to as endovascular renal sympathetic ablation, is a minimally invasive percutaneous procedure that applies radiofrequency or focused ultrasound via a catheter inserted through the femoral artery to selectively engage the sympathetic nerve fibers surrounding the renal artery. The desired result is to interrupt the influence of the sympathetic reflexes on the kidney and systemic hemodynamics and provide a simple solution to the complex issue of hypertension (Persu, 2020).

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

Renal denervation devices are available under investigational device exemption use only. In August 2023, the U.S. Food and Drug Administration Circulatory System Devices Panel found the benefits of the Paradise™ Ultrasound Renal Denervation System (ReCor Medical Inc., Palo Alto, California) outweighed the risks in patients with uncontrolled hypertension. However, the Panel found the risks of radiofrequency renal denervation using the SYMPLICITY™ Renal Denervation System (Medtronic, Inc, Santa Rosa, California) outweighed the benefits (Newmarker, 2023). As of this writing, no renal denervation device has received pre-market approval for clinical use in the United States (U.S. Food and Drug Administration (2023a, 2023b).

Findings

The European Society of Cardiology Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions issued consensus recommendations for renal denervation based on high-quality studies showing blood pressure lowering over 24 hours using both radiofrequency and ultrasound renal denervation for participants with mild-to-moderate, severe, and resistant hypertension. The effect was sustained for up to three years without any significant long-term increase in renal artery stenosis or deterioration of renal function. Renal denervation may be an adjunct treatment option for patients either with uncontrolled resistant hypertension or intolerance to long-term antihypertensive medications (Barbato, 2023).

The National Institute for Health and Care Excellence (2023) recommended that percutaneous transluminal renal sympathetic denervation for resistant hypertension be used only with special arrangements for clinical governance, consent, and audit or research. The Institute cited both the uncertainties about long-term benefit and complications and the unique safety and efficacy profiles of the available renal denervation systems.

Two systematic reviews/meta-analyses (Fadl Elmula, 2015; Shafi, 2016) and a cost-effectiveness analysis (Geisler, 2012) evaluated renal denervation for treatment-resistant hypertension. Two systematic reviews examined the role of renal denervation for treatment of Type 2 diabetes mellitus and obstructive sleep apnea (Pan, 2015; Shantha, 2015).

There is insufficient evidence to support the clinical use of catheter-based renal denervation for any indication. The evidence comprises observational data from multiple small case series and limited comparative clinical trials using the SYMPLICITY™ Renal Denervation System (Medtronic, Inc, Santa Rosa, California). The SYMPLICITY trials enrolled patients with severe treatment-resistant hypertension who were receiving a stable antihypertensive regimen of at least three drugs including a diuretic, and had adequate renal function:

- SYMPLICITY HTN-1 was the first in-human, proof-of-concept and safety study of 45 participants (Krum, 2014).
- SYMPLICITY HTN-2 was a multi-site, randomized controlled trial of 106 participants (Esler, 2014).
- SYMPLICITY HTN-3 was a multi-site, randomized controlled trial of 535 participants with sham controls (Bakris, 2014; Bhatt, 2014).

The evidence from these trials suggests that renal denervation in patients with treatment-resistant hypertension is safe, may be cost-effective, and lowers systolic blood pressure in the short term and medium term, but the results are highly variable. Long-term safety data beyond three years follow-up are lacking. Reduction in systolic blood pressure after renal denervation was greater in observational studies than randomized studies, and in studies that used office blood pressure measurement rather than ambulatory blood pressure measurement as an efficacy endpoint. Of note, while SYMPLICITY HTN-3, the most rigorously designed trial, met its primary safety endpoint with a major adverse event rate of only 1.4%, it failed to meet its primary and secondary efficacy endpoints; no statistically significant difference was shown in blood pressure measurement between the renal denervation treatment and sham control arms.

Results of the SYMPLICITY studies cannot be extrapolated to less severe or secondary forms of hypertension or to other catheter-based systems. Several factors may influence the findings, such as ethnicity, age, renal status, other comorbidities, and technical proficiency; efforts to address the design of future studies have been reported (Lobo, 2015; White, 2014).

A growing body of evidence from non-randomized smaller studies suggests a potentially important role for renal denervation in the management of other disease states characterized by overactivation of sympathetic nerves. Further research using randomized, appropriately controlled, blinded designs, and large-scale registries is needed to identify optimal candidates for renal denervation, refine the technology, define procedural success and clinical efficacy of renal denervation in reducing blood pressure, and improve important clinical outcomes (e.g., risk of stroke, myocardial infarction, heart failure, and death).

In 2018, we added one new Cochrane review that found low- to moderate-quality evidence from randomized controlled trials did not support a clear benefit of renal denervation for treatment-resistant hypertension and lacked long-term outcomes (Coppolino, 2017). The U.S. Food and Drug Administration has still not approved renal denervation for commercial use in the United States. No policy changes are warranted.

In 2019, we added one guideline from the American Heart Association (Carey, 2018). In the United States, renal denervation continues to be available under research protocols only. No policy changes are warranted. The policy ID was changed from CP# 09.03.04 to CCP.1283.

In 2020, we added four systematic reviews and meta-analyses confirming previous policy findings that renal denervation could safely reduce blood pressure compared with sham control, but incomplete medication adherence was common (Agasthi, 2019; Cheng, 2019; Liu, 2019; Lobo, 2019). Clinical studies to evaluate the safety and effectiveness of these devices are progressing (U.S. Food and Drug Administration, 2018). Such studies will employ randomization, sham controls, careful attention to medication adherence (on and off antihypertensive medications), careful ambulatory blood pressure measurement to evaluate efficacy, and careful attention to patient preferences to address the limitations that occurred in previous research. No policy changes are warranted.

In 2021, we added two registry studies (Lee, 2019; Rodriguez-Leor, 2020) and one longitudinal study (Naduvathumuriyil, 2020) that suggest renal denervation is safe and effective for patients with treatment-resistant hypertension with a clinically significant antihypertensive effect. In all instances, the authors called for randomized controlled trials to determine the specific context within which renal denervation should be considered a therapeutic option in antihypertensive care. To that end, Böhm (2020) published study design

details of two ongoing randomized, sham-controlled clinical trials that enrolled subjects with uncontrolled hypertension in the absence (SPYRAL HTN-OFF MED Pivotal; clinicaltrials.gov identifier NCT02439749) or presence (SPYRAL HTN-ON MED Expansion; clinicaltrials.gov identifier NCT02439775) of antihypertensive medications. Both studies are sponsored by Medtronic, Inc. (Santa Rosa, California) with an estimated completion date of March 2023.

In 2023, we added a new guideline by Hypertension Canada (Hiremath, 2020) that does not recommend renal denervation for the routine treatment of hypertension, because the device has not been approved for use in Canada. The guideline recommends investigating the device in the context of controlled clinical studies. No policy changes are warranted.

In 2024, we updated the references and added two guidelines, two analyses, and new clinical trial data assessing the safety and efficacy of the Paradise Ultrasound Renal Denervation System. As of this writing, Paradise has not received regulatory approval for clinical use. No policy changes are warranted.

Three clinical trials examined the Paradise system — the RADIANCE-HTN SOLO and TRIO Study (ClinicalTrials.gov identifier NCT02649426), the RADIANCE II Study (ClinicalTrials.gov identifier NCT03614260), and the REQUIRE Study (ClinicalTrials.gov identifier NCT02918305). All three studies are multinational, blinded, randomized, sham-controlled trials of adults age 18 to 75 years with uncontrolled hypertension in the absence (SOLO and RADIANCE II) or presence (TRIO and REQUIRE) of antihypertensive medications. All trials were funded by the manufacturer.

In the RADIANCE trials, ultrasound renal denervation safely and significantly reduced daytime ambulatory systolic blood pressure at two months (the primary efficacy endpoint) compared to a sham procedure in all three cohorts (Azizi, 2018, 2021, 2023). At six months, the effect was maintained with reduced antihypertensive prescriptions (Azizi, 2019, 2022).

In a pooled individual patient data analysis of all three RADIANCE trial cohorts (n = 506), at two months following the procedures, the magnitude of the decrease of daytime ambulatory systolic blood pressure was 8.5 mm Hg across the renal denervation groups and 2.9 mm Hg across the sham groups. The mean difference between groups was -5.9 (95% confidence interval -8.1 to -3.8 mm Hg, $P < .001$) in favor of renal denervation. Reductions were consistent across the three trial cohorts. Renal denervation produced greater reductions in blood pressure, even when the sham groups received additional antihypertensive medications. A greater proportion of patients in the renal denervation group had blood pressure controlled at a target threshold of daytime ambulatory blood pressure less than 135/85 mm Hg (24.2% vs. 12.3%, $P < .001$). Studies with long-term follow-up are in progress (Kirtane, 2023).

The REQUIRE study took place in Japan and South Korea. Adults with resistant hypertension (seated office blood pressure ≥ 150/90 mm Hg and 24-hour ambulatory systolic blood pressure ≥ 140 mm Hg) with suitable renal artery anatomy were randomized to ultrasound renal denervation (n = 72) or a sham procedure (n = 71). The primary endpoint was change from baseline in 24-hour ambulatory systolic blood pressure at three months. There were no significant differences between group in the primary efficacy endpoint, home and office systolic blood pressure, or medication load. No procedure- or device-related major adverse events were observed. The authors cited study design issues to explain an unexpected blood pressure reduction in the sham control group (Kario, 2022).

Another systematic review and meta-analysis included six studies (n = 989) of different renal denervation systems and trial populations with resistant hypertension. The authors found renal denervation did not significantly reduce 24-hour ambulatory blood pressure and office blood pressure compared with sham/placebo. The authors reported low certainty in the findings, and the potential mechanisms affecting sympathetic output and potentially underlying these results require further study (Ahmed, 2023).

References

On October 19, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “renal denervation,” “ablation,” “sympathectomy,” and “treatment resistant hypertension.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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

1/2018: Policy references updated.

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

1/2020: Policy references updated.

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

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