The State of Reimbursement for Renal Denervation in the United States

As renal denervation is adopted across the United States for patients with uncontrolled or resistant hypertension, the dubious state of reimbursement presents a barrier to both health systems and patients seeking the procedure.

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Hypertension (HTN) remains a highly prevalent and highly morbid diagnosis in the United States, affecting close to 120 million adults. Nearly half of these individuals meet criteria for refractory or uncontrolled HTN, which over time has lasting effects on multiple organ systems, leading to increased health care burden and cost.[1] Renal denervation (RDN), a catheter-based procedure for treating HTN, has the potential to improve individual patient health as well as population-level morbidity and mortality. Conceptually, RDN uses one of several different treatment modalities to target and destroy the sympathetic nerves surrounding the renal arteries, leading to reduction in blood pressure.[2] These reductions in blood pressure have been associated with lower rates of stroke, myocardial infarction, and all-cause mortality.[3-14]

Despite encouraging clinical data, growing familiarity among interventional cardiologists, and multiple catheter options on the market, RDN has been adopted slowly across the country. This is due in part to the uncertain financial landscape associated with the procedure. The state of reimbursement for RDN currently hangs in a delicate balance, with important implications for the eventual accessibility of the procedure.

FDA APPROVAL

In November of 2023, the United States FDA approved RDN for patients with uncontrolled HTN. There are two systems approved for use: the Symplicity Spyral system (Medtronic) and the Paradise system (Recor Medical).[15,16] These two systems differ in the modality used to deliver heat energy, using radiofrequency and ultrasound, respectively, for destruction of nerve tissue.[4,6,17] Of note, the FDA's instructions for use for both devices are the same, stating, "[RDN] is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure."[15,16] This broad language allows for maximal flexibility in utilizing this paradigm-shifting technology to treat hundreds of millions of Americans.

CPT CODE ASSIGNMENT

The FDA is primarily focused on the clinical efficacy and safety of emerging technologies in their considerations for approval. They do not participate in any decisions on payment structures. Payment for emerging technologies is complex and there are multiple participating entities, starting with the American Medical Association (AMA), which assigns Current Procedural Technology (CPT) billing codes to categorize clinician work in relative value units (RVUs) (Table 1). RVUs are considered but not directly linked to payment. At present, RDN is associated with temporary category III CPT codes 0338T (unilateral) and 0339T (bilateral). Category III codes are assigned to track the use of emerging and experimental technologies before assignment of a permanent category I CPT code. The current RDN CPT codes map to a Centers for Medicare & Medicaid Services (CMS) level 2 endovascu-

TABLE 1. ACTIONS BY GOVERNMENT ORGANIZATIONS, MEDICAL SOCIETIES, AND PRIVATE PAYORS THAT INFLUENCE REIMBURSEMENT FOR RDN

	Government	Medical Societies	Private Payors
Past	FDA device approval	AMA category III CPT code; SCAI and NKF guidelines	Limited coverage of emerging technologies
Present	CMS NTAP (inpatient) and TPT (outpatient) payments	SCAI operator guidelines	Limited coverage of emerging technologies
Future	CMS NCD	AMA category I CPT code; AMA Relative Value Scale Update Committee to assign relative value units	Coverage influenced by NCD and CPT code

Note: There are many stakeholders involved in the processes by which RDN reimbursement is determined. These include government organizations such as the FDA and CMS; medical societies such as AMA, SCAI, and NKF; and private payors.
Abbreviations: AMA, American Medical Association; CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; NCD, National Coverage Determination; NFK; National Kidney Foundation; NTAP, New Technology Add-On Payment; RDN, renal denervation; SCAI, Society for Cardiovascular Angiography and Interventions; TPT, transitional pass-through.

lar procedure Ambulatory Payment Classification (APC) code that reimburses an average unadjusted rate of around $5,500. This is meager in comparison to the direct costs of the consumable product (catheter) and the capital investment (generator) required to perform RDN with both devices. At present, additional Healthcare Common Procedure Coding System (HCPCS) codes have been designated by CMS to delineate radiofrequency (C1735) versus ultrasound (C1736) modalities for performing renal denervation. These codes can be utilized for payers to process claims related to the procedures and are a departure from the device-agnostic language used in the CPT coding for RDN.

CPT categorization affects payment most notably for patients under private payors, many of which do not reimburse for category III procedures, leaving the cost burden on the institution and ultimately the patient (Table 1). Furthermore, RVUs are not assigned to temporary category III CPT codes, as these codes do not identify the effort required to provide the service and are not valued by the Relative Value Scale Update Committee (RUC). The AMA is anticipated to convene a panel to review RDN in the coming year for consideration of conversion to a permanent category I CPT code. Although it would not be effective immediately, this category reassignment—reserved for proven, efficacious devices with real-world experience—would facilitate higher reimbursement for the procedure and open eligibility for patients covered under private payors. It should also be noted that the HCPCS code, as described previously, that delineates the modality of energy utilized for RDN can change when the CPT code for this procedure changes to category I.

In addition to the AMA, other medical societies such as the Society for Cardiovascular Angiography and Interventions, the American Heart Association, and the National Kidney Foundation influence the uptake of new technologies by publishing guidelines about their appropriate clinical application. While guidelines exist, there are currently no formal recommendations from these societies for use of RDN in the clinical management of HTN (Table 1), and this could affect the pace of coverage from private payors.

CONSIDERATIONS FOR EMERGING TECHNOLOGIES

While awaiting more permanent payment structures, devices such as RDN catheters may be granted several financial incentives that offer a reprieve for breakthrough technologies to encourage scaling. For outpatient procedures, a transitional pass-through (TPT) payment provides incremental reimbursement from CMS in addition to the APC payment to cover the cost of the device.[18,19] The TPT payment is determined on a case-by-case basis, taking into account the amount a hospital charges for a device, the hospital's specific cost-to-charge ratio, and the device offset or device-related portion of the relevant HCPCS procedure code. For RDN, a TPT payment for both Medtronic and Recor RDN systems was granted by CMS, effective January 1, 2025, covering around $15,000 to $20,000.[20] The payment from CMS to a hospital for outpatient RDN procedures is the total of the APC plus TPT payment. It should be noted that TPT payments are temporary, meant for breakthrough technologies, so they last for only 3 years.

CMS also assigns the APC codes, with levels 1 to 4 correlating to increasing complexity and likewise correlating to higher reimbursement. These codes are permanent but may be updated annually, reflecting changes in technology, procedures, and costs over time. The APC code for RDN is currently a level 2 endovascular procedure code, the same as percutaneous transluminal coronary angioplasty without stent, for example.[21] Level 3 includes percutaneous coronary angioplasty with drug-eluting stent placement. Level 4 often includes multiple procedural steps, such as percutaneous coronary atherectomy with angioplasty and drug-eluting stent placement.[21] If RDN remains at level 2, it is likely to remain unprofitable for hospitals, particularly as the temporary incremental TPT payments expire after 3 years.

For inpatient procedures, a similar payment is made to the hospital by CMS in cases of new technologies, as determined by diagnostic-related group (DRG) code. This is called a New Technology Add-On Payment (NTAP).[22] Starting on January 1, 2025, CMS assessed an NTAP through the Medicare Hospital Inpatient Prospective Payment System for both approved RDN devices, between $10,000 to $15,000 to cover device costs.[22] Similar to TPT payments, the NTAP is determined on a case-by-case basis to cover incremental costs of a device when added to the DRG payment. While temporary payments are beneficial as RDN awaits CPT code conversion, these payments remain inadequate, making early adoption of the procedure into a hospital's offerings an ongoing challenge. Institutions considering business models for RDN in this current state must take lessons from previous new technologies, such as transcatheter aortic valve replacement or left atrial appendage occlusion devices.

NEXT STEPS

While the FDA has deemed RDN safe and efficacious, they did not define clinical eligibility for the procedure. This information is expected within this next year as a National Coverage Determination (NCD) from CMS. In this process, a committee will assign clinical criteria for patients to be eligible for coverage for RDN. These criteria are independent of the initial FDA approval indications for RDN devices and will take into account the patients reflected in the studied population, among other factors. While this decision will apply directly to patients with Medicare and Medicaid coverage, private payors often follow the lead of CMS. Thus, the coverage of RDN for patients nationwide will be driven in part by this decision.[23,24] Although it is possible for Medicare Administrative Contractors to make local coverage determinations while awaiting the national determination, additional reimbursement via this mechanism has not come to fruition.

Between the anticipated NCD from CMS and CPT code conversion by the AMA, this coming year has the potential to affect the scalability of RDN across the nation (Table 1). Lastly, for operators to receive credit for their procedures, we await the AMA convening a RUC to develop RVUs associated with RDN. Until that point, even if the NCD and CPT code are favorable for the financial solvency of an institution offering RDN, there would remain no standard RVU accrual for proceduralists performing RDN.

CONCLUSION

RDN has the potential to improve health outcomes for millions of Americans by decreasing the rates of uncontrolled HTN and highly morbid sequelae such as myocardial infarction, stroke, and death.[1-14] However, for RDN to positively impact patients, it must be economically feasible for health systems to develop high-quality RDN programs. In the coming year, we await AMA and CMS decisions as they assess CPT code, NCD, and RVU assignment for the procedure, which will vastly change the financial viability and landscape of how this procedure is embraced nationally.[17-24] ■

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