National Coverage Determination Billing Guide for The Paradise® Ultrasound Renal Denervation System

Effective Date October 28, 2025

Attention All Hospitals and Healthcare Providers,

On October 28, 2025, the Centers for Medicare and Medicare Services (CMS) posted the final decision memo for Renal Denervation (RDN) for Uncontrolled Hypertension (HTN).[1] This NCD establishes coverage, under specific criteria including coverage with evidence development (CED), for FDA-approved indications of the Paradise® System.

Patient Criteria

- Uncontrolled Hypertension SBP ≥ 140 mmHg and DBP > 90 despite active clinical management by a clinician with primary responsibility for HTN management
- Diagnosis confirmed via ambulatory BP monitoring or serial home BP readings
- On stable, maximally tolerated GDMT (+ lifestyle changes),w/ assessment of adherence, for ≥ 6 weeks
- Secondary hypertension evaluated and treated if appropriate. Must be screened for primary aldosteronism, obstructive sleep apnea, and drug or alcohol induced HTN
- No RDN contraindications, consistent with the FDA labeling of the device used
- Coordination managed by primary clinician ≥ 6 months with ≥ 3 encounters, of which 2 can be virtual
- No prior RDN procedure

Physician Criteria

- **Referring Physicians** must have longitudinal responsibility for managing the patient's HTN
- **Treating Physicians** must have interventional and endovascular skills to perform effective RDN treatments. Additionally, they must be able to manage potential complications in case of emergency management
- If **Treating Physicians** do not have prior endovascular training or renovascular expertise, they must complete at least 10 supervised cases of diagnostic / therapeutic renovascular procedures, half as primary operator. Additionally, they must complete at least 5 proctored RDN cases w/ each device used in their practice
- If **Treating Physicians** have prior endovascular training and active endovascular experience, they must complete at least 5 proctored RDN cases w/ each device used in their practice

Facility Criteria

- Facilities performing RDN must have a hypertension program with contributions from a hypertension clinician with longitudinal patient management responsibility, a hypertension navigator, and access to relevant medical specialties (e.g., internal medicine, endocrinology, sleep medicine, cardiology, and nephrology) as appropriate
- Preprocedural imaging capabilities
- An appropriate interventional cardiology or radiology suite

Coverage w/ Evidence Development (CED)

- The RDN device and related items and services are furnished in the context of a CMS-approved Coverage with Evidence Development (CED) study.

Recor Medical®

CED Criteria and Billing/Coding Requirements

RDN Devices and related items and services furnished by this NCD require following CMS-approved CED study protocols. To meet the criteria of the CED study protocol CMS publishes specific RDN claims processing instructions. Please check with your coding department on appropriate coding requirements. The following codes may apply to RDN claims covered under this NCD.

	Physician Claims	Facility Claims	
		Outpatient	Inpatient
Procedure	CPT® 0338T or 0339T		X051329
	Modifier -Q0: Investigational clinical service provided in a clinical research study that is in an approved clinical research study		
Diagnosis	Applicable Primary Diagnosis Code (e.g. . I10, I11.0, I11.9, I12.9, I13.0, I13.10, etc.)		
	Secondary Diagnosis Code: Z00.6 Encounter for examination for normal comparison and control in clinical research program		
Condition Code	N/A	Condition Code 30: Qualified Clinical Trial	
NCT[2]	"CT07231757" reported on Item 19 on CMS-1500 forms	NCT# "07231757" reported with Value Code D4	

SEE THE NEXT PAGES FOR SAMPLE INSTITUTIONAL AND PHYSICIAN CLAIM FORMS

FAQs

What is the implementation date?

The implementation date is the point when Medicare Administrative Contractor (MAC) systems must be ready to process the new coverage rules. It comes after the effective date because contractors need time to update software, apply edits, and train staff. Before this date, claims might not flow normally, some could be held or processed manually, and payment delays or denials are possible. If a claim meets NCD criteria but is denied, providers should appeal and reference the NCD. Once systems are live, contractors can reprocess claims and pay them retroactively to the effective date.

Will participation in this CED impact a patient's ability to participate in the GPS Study?

No. Patients who are part of this CED could also be enrolled in the GPS Study

If my patient is enrolled in GPS, which NCT# should go onto the claim, the CED Study NCT or the GPS NCT?

The CED Study NCT# is a requirement for payment under the NCD. All Medicare claims need this number to be processed appropriately.

Will Prior Authorization be required for these patients?

For Medicare Fee-for-Service, there is no prior authorization required. However, for Medicare Advantage patients, it is likely that prior authorization is required and that the appropriate patient criteria are met in the clinical documentation provided. Additionally, the NCT number of the CED will likely be requested in the prior authorization request.

If the payer has provided an approval number, please append it to the claim for smooth processing.

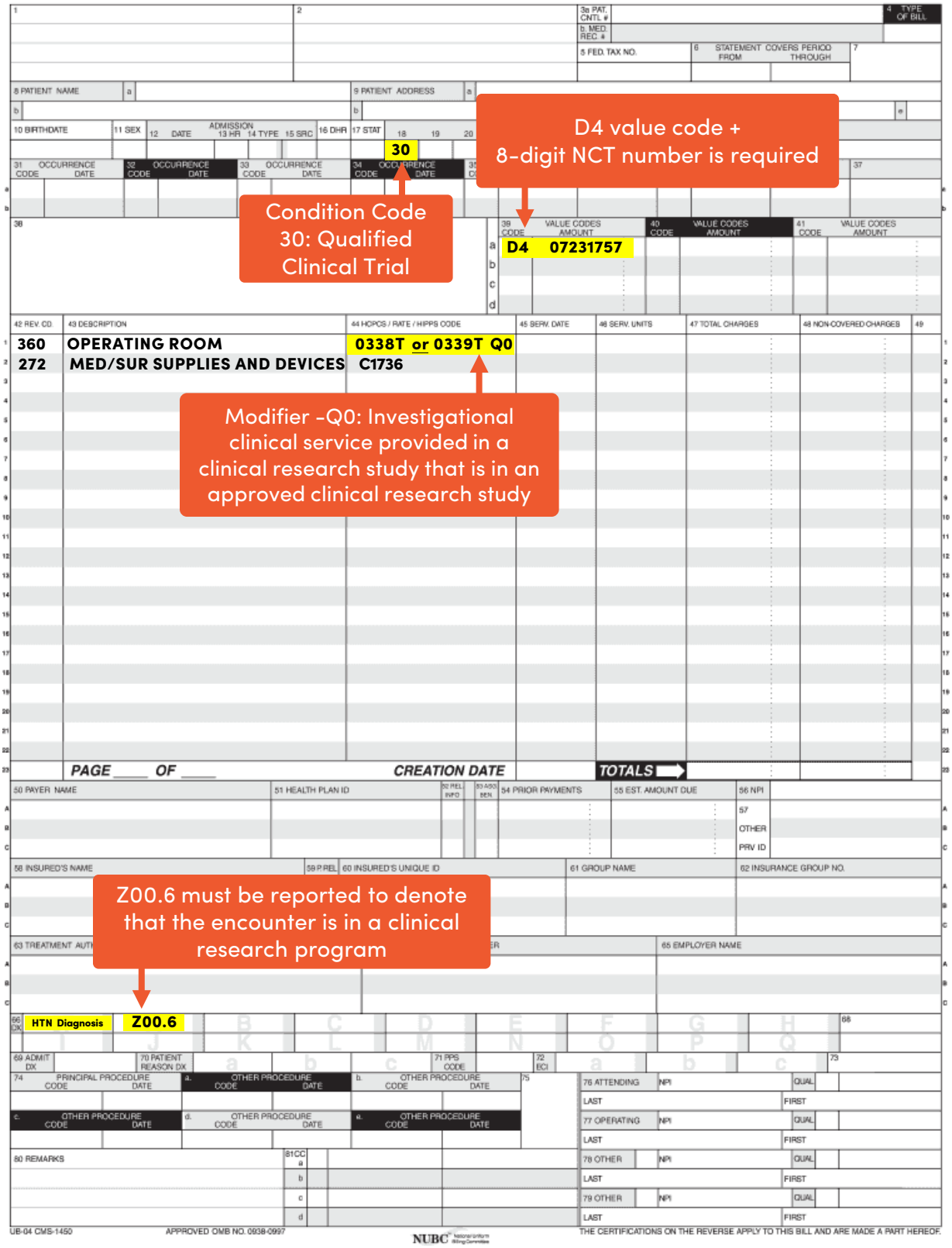
Do these billing requirements apply to non-Medicare procedures?

No. These specific billing requirements (Secondary Diagnosis Code Z00.6, Condition Code 30, -Q0 modifier, and the NCT# 07231757) apply only to Medicare-covered procedures. Non-Medicare procedures should follow the appropriate billing guidelines for their respective payer.

For additional reimbursement support contact Recor Medical at reimbursement@recormedical.com

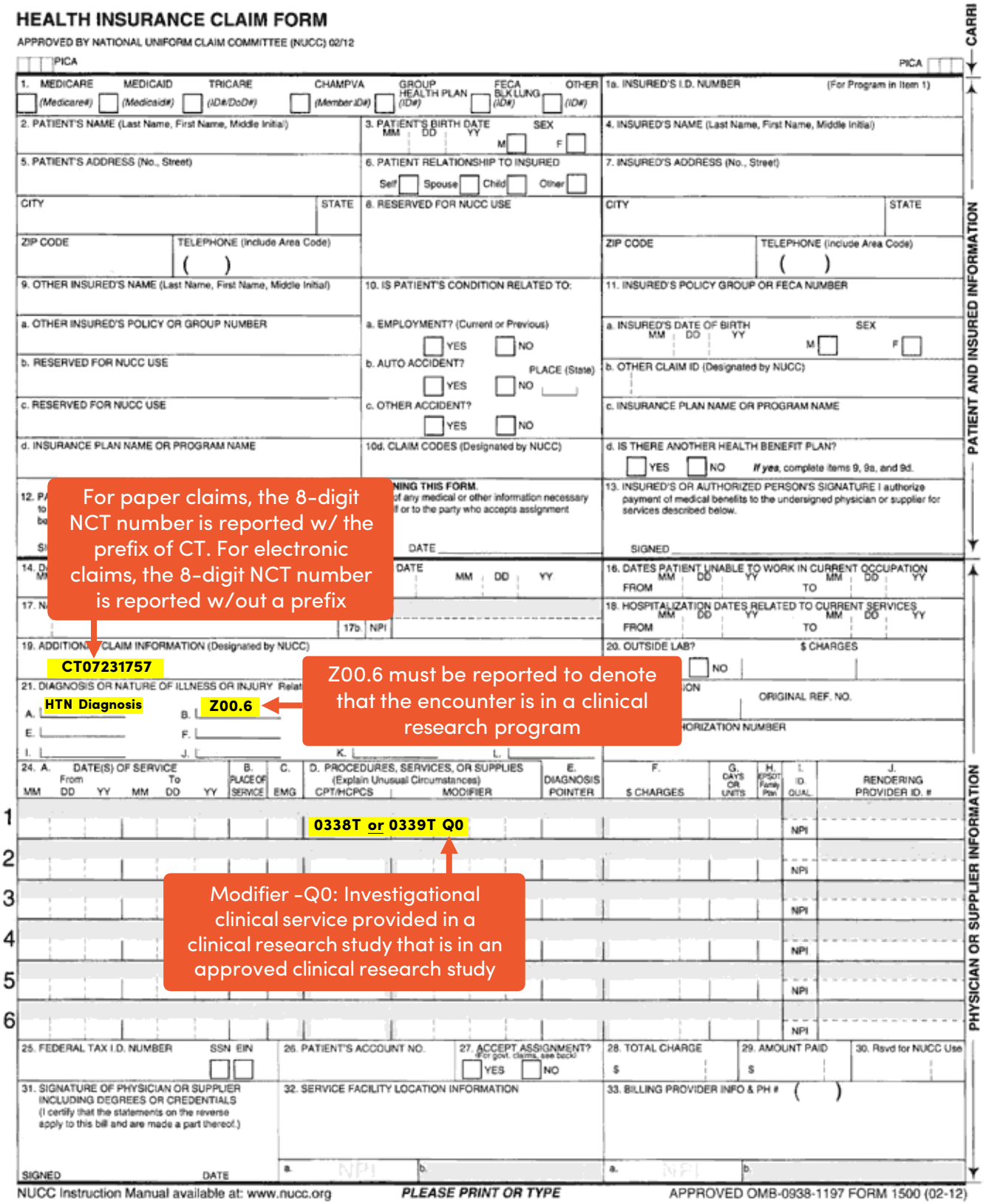
Recor Medical®

Sample Institutional Claim Form



CPT copyright 2024 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association . No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use

Sample Physician Claim Form



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

12. PA... NING THIS FORM. ...of any medical or other information necessary ...lf or to the party who accepts assignment

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED DATE SIGNED

14. D... DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. N... 17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

CT07231757

20. OUTSIDE LAB? NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relat...

HTN Diagnosis

Z00.6

ORIGINAL REF. NO.

...HORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1				0338T or 0339T Q0						NPI	
2										NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRI...

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

For paper claims, the 8-digit NCT number is reported w/ the prefix of CT. For electronic claims, the 8-digit NCT number is reported w/out a prefix

Z00.6 must be reported to denote that the encounter is in a clinical research program

Modifier -Q0: Investigational clinical service provided in a clinical research study that is in an approved clinical research study

CPT copyright 2024 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association . No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use

Recor Medical®

References

1. Centers for Medicare & Medicaid Services. NCA Tracking Sheet – Renal Denervation for Uncontrolled Hypertension. Available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=318 . Accessed October 28, 2025.
2. ClinicalTrials.gov. The RADIANCE CED Study (NCT07231757). Available at: https://clinicaltrials.gov/study/NCT07231757?term=NCT07231757&rank=1. Accessed November 17, 2025.

Rx Only. Brief Summary - Prior to use, please reference the Instructions for Use

Indications for Use

The Paradise Ultrasound Renal Denervation System (Paradise System) is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications

The Paradise Catheter is contraindicated in any of the following:

- Renal arteries diameter <3 mm and >8mm
- Renal artery Fibromuscular disease (FMD)
- Stented renal artery
- Renal artery aneurysm
- Renal artery diameter stenosis >30%
- Pregnancy
- Presence of abnormal kidney (or secreting adrenal) tumors
- Iliac/femoral artery stenosis precluding insertion of the catheter

Warnings

- Failure to use the recommended balloon size may result in renal artery stenosis, dissection, perforation, aneurysm, significant vasospasm requiring intervention, ablation of unintended tissues or structures, and/or no ablation of target tissue achieved.
- Energy emission in an unintended location may result in unintended tissue damage.
- Do not move the Paradise Catheter during sonication.
- Do not sonicate in renal artery at locations with visible plaque.
- Do not deliver sonications in an overlapping arterial target zone.

Precautions

- Patients with known allergy to contrast medium may be at increased risk of hypersensitivity reactions.
- Only use specified coolant (Sterile water) for fluid supply. DO NOT USE SALINE.
- Avoid multiple balloon inflations to achieve apposition of the balloon to the renal artery wall; multiple balloon inflations may result in increased vessel trauma.
- The Paradise Catheter is for single use only. Do not resterilize or reuse. Reuse, reprocessing, or resterilization will compromise device integrity which may result in patient injury, illness, or death.
- Do not touch the Paradise Catheter balloon during sonication, as it may result in serious injury.
- The Paradise System may interfere with or adversely affect the operation of cardiac pacemakers or other active implants, unless proper precautions have been taken or managed per the manufacturer's instructions. When in doubt regarding possible hazards, seek qualified advice and/or consult with the manufacturer(s) prior to initiating a procedure. The Paradise Catheter is a Type CF, defibrillation-proof Applied Part.

Potential risks of renal denervation procedure/response to treatment

Ablation or thermal injury to vessel, adjacent tissue or other structures, Acute kidney injury, Angina, Anxiety, Arrhythmia, Atrial tachycardia, Bradycardia, Gastrointestinal complications (diarrhea, nausea, vomiting), Hypotension/ Dizziness and/or Headaches, Hypertension, Hyperhidrosis, Pain (transient abdominal, lower back), Renal failure or renal insufficiency, Renal artery aneurysm or pseudoaneurysm, Renal infarction, Renal artery dissection, or perforation, Renal artery stenosis, Vasospasm, Vasovagal response, Stroke or transient ischemic event

Potential risks of arterial catheterization procedure

Allergic reaction to contrast, Arterio-enteric fistula, Arterio-venous fistula, Bleeding, Cardiopulmonary arrest, Complications related to pain and anti-anxiety medications, Death, Deep vein thrombosis, Edema, Embolism (pulmonary, renal, peripheral vasculature, plaque), Hematuria, Infection, Myocardial infarction, Pain, Vascular access site complications (pseudoaneurysm, pain, swelling, hematoma)

Disclaimer

The information contained in this resource is provided for general educational and informational purposes only and is not intended to constitute legal, financial, or clinical advice. Recor Medical, Inc. does not guarantee reimbursement or payment, nor is this material intended to increase or maximize payment by any payer. Nothing in this document should be viewed as instructions for selecting any particular code, and Recor Medical does not advocate or warrant the appropriateness of the use of any particular code. The ultimate responsibility for coding accuracy, billing, and obtaining reimbursement rests with the healthcare provider or facility. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations. It is important to consult with appropriate professionals, such as your Medicare contractor, the patient's plan, legal counsel, reimbursement specialists, or coding experts, for specific guidance and interpretation of coding, coverage, and payment policies. This information is for FDA approved indications only. Where reimbursement is requested for a use not expressly specified in Recor Medical FDA approved labeling (including but not limited to instructions for use, operator's manual or package insert) consult with your billing advisors or payers for advice on handling such billing issues. Use of this document is completely voluntary by the healthcare provider and is not intended to be a substitute for, or to influence, the independent medical judgment of the physician.

CPT copyright 2024 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association . No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

Recor Medical®

Recor Medical, Inc.
1049 Elwell Ct, Palo Alto, 94303 USA

© 2025 Recor Medical, Inc. All rights reserved.
RECOR MEDICAL and PARADISE
are trademarks of Recor Medical, Inc.