Paradise® Ultrasound RDN System Clinical Checklist

Effective Date October 28, 2025

This form is intended to be used by the treating physician as a guide to help gather information in connection with an HTN diagnosis. The documentation referenced below may be submitted to the insurance company or kept in the patient's medical records prior to procedure being performed. The clinical information highlighted in this checklist is derived from CMS' National Coverage Determination (NCD) for Renal Denervation for Uncontrolled Hypertension. See the full policy including physician and facility criteria here: LINK

This checklist is intended for informational purposes only and does not replace independent clinical judgment. Clinical decision-making should be based on the clinician's professional assessment of each patient's individual circumstances, in accordance with applicable standards of care and institutional policies. Meeting all patient criteria does not guarantee reimbursement.

Please note: The coverage criteria referenced herein apply only to Medicare Fee-for-Service (FFS) and Medicare Advantage beneficiaries. Coverage criteria for other payers may differ. It is the responsibility of the clinician to verify applicable clinical and coverage requirements with each payer's policy.

For questions on the Paradise Ultrasound RDN System Clinical Checklist, please contact the Recor Medical Market Access team at Reimbursement@recormedical.com

HEALTHCARE PROVIDER INSTRUCTIONS

DO NOT INCLUDE THIS INSTRUCTION PAGE IN YOUR SUBMISSION

1. The Physician completes the Paradise Ultrasound RDN System Clinical Checklist, sign and date.
2. If submitting for Prior Authorization the documents below may be submitted to the insurance company

- ☐ Letter of Medical Necessity
- ☐ Paradise Ultrasound RDN System Clinical Checklist
- ☐ 3-6 months of treatment notes
- ☐ Ambulatory blood pressure monitoring or serialized home BP measurements report

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)

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PHYSICIAN USE ONLY

Patient Name: _____ Date of Birth: _____

BLOOD PRESSURE MEASUREMENTS

NCD criteria for uncontrolled HTN are SBP ≥ 140 mm Hg and DBP ≥ 90 mm Hg

SBP: _____ DBP: _____ Date: _____

Has uncontrolled HTN been confirmed with either ambulatory BP monitoring or serial home BP readings?

With: ☐ ABPM ☐ Serial Home BP Date(s): _____

MEDICATION HISTORY

Has patient been on stable maximally tolerated GDMT and lifestyle modifications for at least 6 weeks? ☐ **Yes** ☐ No

Has adherence to the prescribed regimen been assessed? ☐ **Yes** ☐ No

Notes on patient adherence: _____

Medication	Class	Dosage	Notes

SECONDARY HTN EVALUATION

Have secondary causes of HTN been evaluated and treated if appropriate?

Primary Aldosteronism ☐ **Yes** ☐ No

Obstructive Sleep Apnea ☐ **Yes** ☐ No

Drug or Alcohol Induced HTN ☐ **Yes** ☐ No

Other: _____ ☐ **Yes** ☐ No

PRIMARY CLINICIAN / MULTIDISCIPLINARY TEAM MANAGEMENT

Has the primary clinician coordinated management of the patient for at least 6 months? ☐ **Yes** ☐ No

Has the patient had ≥3 visits (no more than 2 virtual) focused on active blood pressure management?

Encounter 1 Date: _____ ☐ Virtual ☐ In-Person

Encounter 2 Date: _____ ☐ Virtual ☐ In-Person

Encounter 3 Date: _____ ☐ Virtual ☐ In-Person

OTHER PATIENT CRITERIA

Does the patient have any contraindications consistent with the FDA labeling of the device used? ☐ Yes ☐ **No**

Has the patient ever had a prior RDN procedure? ☐ Yes ☐ **No**

DIAGNOSIS

Primary Diagnosis

- ☐ I10: Essential (primary) hypertension
- ☐ I11.0: Hypertensive heart disease w/ heart failure
- ☐ I11.9: Hypertensive heart disease w/out heart failure
- ☐ I12.9: Hypertensive chronic kidney disease w/ stage 1 through stage 4 CKD, or unspecified CKD
- ☐ I13.0: Hypertensive heart and CKD w/ HF and stage 1 through stage 4 CKD, or unspecified CKD
- ☐ I13.10: Hypertensive heart and CKD w/out HF, w/ stage 1 through stage 4 CKD, or unspecified CKD
- ☐ Other: _____

Potential Secondary Diagnosis

- ☐ I1A.0 Resistant Hypertension

Healthcare Provider Signature: _____

Healthcare Provider Name (Print): _____ **Date:** _____

Bolded 'Yes/No' responses indicate criteria that align with Medicare National Coverage Determination (NCD) 20.40 for Renal Denervation.