NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

HTG10527 Renal sympathetic denervation for resistant hypertension (provisional title)

Draft scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are for renal sympathetic denervation for resistant hypertension. The assessment type will be determined by the NICE Prioritisation Board and will be confirmed in the final scope. The topic will follow either the NICE technology appraisal and highly specialised technologies guidance: the manual if the assessment type is via the National HealthTech Access Programme, otherwise it will follow the NICE HealthTech programme manual if it is routine HealthTech Guidance.

This guidance will update and replace NICE's HealthTech guidance HTG662 on percutaneous transluminal renal sympathetic denervation and HTG741 on alcohol-mediated renal sympathetic denervation.

2. The condition

Hypertension, also known as high blood pressure, is a common condition in which the force of blood pushing through the arteries is consistently high. Hypertension is one of the most important, treatable causes of premature morbidity and mortality in the world. It is a major risk factor for cardiovascular disease and chronic kidney disease. In 2025, it was reported that high blood pressure affected around 16 million adults in the UK, with up to half of them not receiving effective treatment, and a further 5 million adults have undiagnosed high blood pressure (British Heart Foundation, 2025). Most people with hypertension are asymptomatic, but it can cause symptoms such as headache, blurred vision and nosebleeds.

In most cases, high blood pressure doesn't have an identifiable cause. This is called primary hypertension, and usually develops due to factors like lifestyle, genetics and age. In some cases, high blood pressure is linked to an underlying health condition. This is called secondary hypertension, which is less common and is caused by conditions affecting the kidneys, arteries, heart or endocrine system.

Treatment options initially include lifestyle changes and medications to lower blood pressure. If left untreated, hypertension is a major risk factor for stroke, myocardial infarction, heart failure, chronic kidney disease, cognitive decline and premature death. In some people, poor blood pressure control may result from measurement inaccuracies, lifestyle factors, suboptimal treatment, multi-drug intolerance to multiple antihypertensive medicines or undiagnosed secondary hypertension. However, a proportion will have high blood pressure despite taking optimal tolerated therapy which is called resistant hypertension.

The British and Irish Hypertension Society estimates that 5-10% of patients treated for hypertension have true resistant hypertension. People with resistant hypertension have the highest risk of cardiovascular complications (Schiffrin, 2023). One study found that among 200,000 patients with newly diagnosed hypertension, those with resistant hypertension had a 47% higher risk of death, myocardial infarction, heart failure, stroke or chronic kidney disease over 3.8 years (Irvin, 2014).

3. Current practice

In the NHS, the referral, diagnosis and treatment of resistant hypertension follow the:

- Hypertension in adults: diagnosis and management (2019) NICE guideline 136. Last updated: 18 Mar 2022
- Hypertension in adults (2013) NICE quality standard 28 Last updated: 01 September 2015
- Alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension (2025) NICE HealthTech guidance 741

- Percutaneous transluminal renal sympathetic denervation for resistant hypertension (2023) NICE HealthTech guidance 662
- Faconti, L et al (2024) Investigation and management of resistant hypertension: British and Irish Hypertension Society position statement Journal of Human Hypertension
- Lewis, P et al (2024) Adult hypertension referral pathway and therapeutic management: British and Irish Hypertension Society position statement Journal of Human Hypertension
- Lobo MD et al. (2019) Joint UK societies' 2019 consensus statement on renal denervation Heart 105(19): 1456-63
- McEvoy et al (2024) ESC Guidelines for the management of elevated blood pressure and hypertension, European Heart Journal, Volume 45, Issue 38, 7 October 2024, Pages 3912–4018
- Mancia G et al. (2023) ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension Journal of hypertension 2023; 41:1874–2071

3.1 Diagnosis

NICE guideline on hypertension (NG136) recommends diagnosis of hypertension following measurements of blood pressure in a clinic by a healthcare professional. For readings between 140/90 mmHg and 180/120 mmHg, the diagnosis must be confirmed using either a 24-hour ambulatory Blood Pressure Monitoring (ABPM) device or a home blood pressure monitor (HBPM). However, if the clinic reading is 180/120 mmHg or higher with signs of end organ damage, a same-day specialist review may be required. A confirmed diagnosis of hypertension is made in people with:

- clinic blood pressure of 140/90 mmHg or higher **and**
- ABPM daytime average or HBPM average of 135/85 mmHg or higher.

Investigations for target organ damage should be done followed by formal assessment of cardiovascular risk, while waiting for confirmation of a diagnosis of hypertension.

Following a diagnosis of hypertension, it can be classified into 3 stages based on the blood pressure readings with stage 3 being the most severe.

3.2 Treatment

NICE guideline on hypertension (NG136) first recommends lifestyle advice on diet, exercise, weight and intake of substances such as alcohol. If lifestyle adjustments are not enough to bring blood pressure down persistently below 140/90 mmHg, antihypertensive medications are offered in a stepwise manner. Steps 1 to 3 include an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin-receptor blocker (ARB), plus a calcium channel blocker (CCB) and a thiazide-like diuretic considering age, ethnicity, stage of hypertension and associated co-morbidities.

A review of medications and discussion on adherence is recommended to ensure intake at the optimal tolerated dose before considering each next step treatment for hypertension. If hypertension is not controlled in adults taking the optimal tolerated doses of anti-hypertensive medications, a diagnosis of resistant hypertension is made. A diagnosis of resistant hypertension begins with the exclusion of evident treatment resistance, which most commonly results from poor medication adherence, the white coat effect (transient elevation in blood pressure observed in a clinical setting), or incorrect blood pressure measurement techniques.

Step 4 recommends considering the addition of a 4th antihypertensive drug such as low dose spironolactone or alpha-blocker or beta-blocker, depending on blood potassium level, or seeking specialist advice when hypertension remains resistant. In addition, identification and reversal of lifestyle factors contributing to treatment resistance, accurate diagnosis and appropriate treatment of secondary causes of hypertension and discussion on adherence should be addressed.

4. Unmet need

Treatment options remain limited for people with resistant hypertension and where this is not addressed, they remain at increased risk of cardiac events. Experts have also mentioned that a number of people in the UK may still have uncontrolled blood pressure despite treatment due to intolerance to multiple antihypertensive medications which can limit optimisation and increase their risk of complications.

Percutaneous transluminal renal sympathetic denervation provides a device-based, non-pharmacological intervention that may reduce blood pressure. Importantly, it bypasses issues regarding non-adherence. Given the correlation between blood pressure increases and the risk of cardiac events, this intervention has the potential to reduce cardiac event rates and improve patient quality of life.

It is currently only recommended with special arrangements for clinical governance, consent, and audit or research by NICE HTG662 on percutaneous transluminal renal sympathetic denervation for resistant hypertension or in research setting by HTG741 on alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension. This guidance will look to update the previous assessments, look at the individual technologies used for the procedure and include a cost effectiveness analysis.

5. The technology/technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions. The included technologies will only be assessed within their intended use in terms of target condition and population.

Based on the initial searches a greater level of evidence is expected for at least 2 technologies.

5.1 Purpose of the technologies

Renal sympathetic nerve denervation (RDN) is a therapeutic alternative or adjunct to pharmacological therapy for treatment of hypertension. It is indicated for use in patients with hypertension, alone or in combination with other blood-pressure-lowering therapy. Experts have advised that patients are generally advised to continue antihypertensive medication after renal denervation but that over time some may be able to reduce them. Others may remain on the same regimen but achieve better BP control.

The procedure is minimally invasive and is usually carried out under local anaesthetic with sedation and anticoagulation, by an interventional cardiologist or interventional radiologist. The most commonly used RDN techniques are radio frequency, ultrasound energy, and a chemical method that introduces various compounds and drugs (most often, ethanol).

A catheter is introduced through the femoral artery and advanced into each renal artery under fluoroscopic guidance. The catheter is connected to a generator which delivers radiofrequency or ultrasound energy (depending on the type of system used) from the distal to proximal end of each renal artery. With the chemical method, the catheter slowly delivers microdoses of neurolytic agents into the proximal parts of the nerve fibres. The main aim of the procedure is to burn the sympathetic renal nerves around the renal arteries that help to control blood pressure to cause disruption of their activity with the goal of lowering blood pressure. This is proposed to be due to the role sympathetic signalling between the central nervous system and the kidneys plays in maintenance of high blood pressure (Krum et al, 2009).

Sections 5.2 to 5.5 describe the included technologies. All the included technologies were available to the NHS at the time of writing this scope or were expected to become available during the assessment period.

5.2 IBERIS Multi-electrode Renal Artery RF Ablation Catheter (Biosensors International UK Ltd)

IBERIS Multi-channel Renal Denervation System is a class IIb medical device that includes a generator and a 4Fr compatible catheter with a single use probe. It delivers radiofrequency energy to ablate the nerve surrounding the renal arteries from a monopolar platinum electrode on the distal tip of the catheter. The catheter has a lumen size of less than 4Fr, about 155cm length and is typically introduced via a 6Fr guiding catheter. Ablation is performed up to 8 times for about 120 seconds each.

5.3 Paradise Ultrasound Renal Denervation System (Recor Medical)

The Paradise Ultrasound Renal Denervation System is a class IIb medical device that includes a single-use sterile catheter, cartridge (coolant/fluid management), connection cable (energy transfer) and a generator (touchscreen, sensors, control software). It delivers ultrasound energy to ablate the nerves surrounding the renal arteries. The Paradise catheter consists of a sterile, single-use, multi-lumen 7-Fr catheter with an ultrasound generating cylindrical transducer inside an inflatable balloon (available in 6 sizes to match renal artery sizes of 3-8mm) at the distal end of the catheter. The catheter is designed to deliver a circumferential (360 degree) ultrasound energy with each ablation taking 7 seconds. It includes a cooling balloon which provides protection to the arterial wall and allows targeting of the renal nerve. Ablation is performed 2–3 times along each main renal artery, and once in each treatable accessory artery. It is currently in use in NHS.

5.4 Peregrine System Infusion Catheter (Ablative solutions)

The Peregrine System Infusion Catheter is a class IIb medical device that includes a continuous flush catheter. It delivers small doses of neurolytic agent (such as dehydrated alcohol) to ablate the nerves surrounding the renal arteries. The catheter consists of 3 distal microneedles within 3 guide tubes which are deployed using the control handle. The micro-needles and the guide tubes are radiopaque for fluoroscopic visibility. During placement of the

catheter through the blood vessels, the microneedles remain retracted within the radiopaque guide tubes. This is to allow confirmation of catheter position and placement of the guide tubes using the fluoroscope, prior to delivery of the neurolytic agent. The device is compatible with guide catheters of at least 7-Fr and is intended for vessels 3-7 mm in diameter. Fluids are administered through the proximal injection lumen in the handle, which delivers the fluid through the needles at the distal end of the device.

5.5 Symplicity Spyral renal denervation system (Medtronic)

Symplicity Spyral renal denervation system is a class IIb medical device that includes a G3 radiofrequency generator and spyral multi-electrode catheter for renal denervation. The catheter connects to the generator using an integrated cable attached to the catheter handle. The catheter requires the use of a 0.36 mm guidewire for delivery. In addition, an adult-sized dispersive electrode (also known as a neutral electrode, return electrode pad, or grounding pad) must be placed on the patient and connected to the generator for the therapy to be delivered. The system consists of a 6-Fr 117cm long guide catheter with 4 gold radiopaque electrodes at the spiral distal end for treating renal arteries with diameters ranging from 3 mm to 8 mm. The catheter features 4 gold radiopaque electrodes at the spiral (helical) distal end. The electrodes are deployed into a spiral (helical) shape by partially retracting the guidewire proximal to the spiral section of the catheter. A radiopaque tip marker and straightening tool that assist in the safe insertion and positioning of the catheter using fluoroscopic guidance. The technology can be used repeatedly at multiple sites for about 60s per site if needed. It is currently in use in the NHS.

5.6 The place of technologies in the care pathway

RDN may be considered in some people with resistant hypertension. If renal sympathetic denervation is considered appropriate, the decision is made by a multidisciplinary team including a hypertension specialist, a cardiologist and/or interventional radiologist, and sometimes pharmacists and specialist nurses. Ongoing follow-up is carried out by the hypertension specialist.

This assessment will consider the use of renal sympathetic denervation technologies as an option for the treatment of resistant hypertension despite optimal medical therapy. Experts have also proposed that it may be of benefit for people who are intolerant to multiple antihypertensives. The technology will be used alongside ongoing treatment with antihypertensives.

5.7 Innovative aspects

Renal denervation technologies are potentially transformative innovations, as defined by the Department of Health and Social Care's medical technology innovation classification framework. They introduce a new interventional treatment option into the care pathway which has the potential to provide sustained blood pressure reduction in people with resistant hypertension while minimising reliance on blood pressure medications.

6. Comparator

The comparator for this assessment is standard care for hypertension including lifestyle advice and the use of multiple antihypertensive medications to optimal or tolerated doses. Experts have noted that in clinical practice, some people may be intolerant to use of multiple anti-hypertensives and may not be able to tolerate optimal doses. So, treatment focuses on use of tolerated medications, lower dosage, non-pharmacological options and specialist follow-up.

Medications as detailed in the NICE guideline on hypertension (NG136) will be most relevant to the UK NHS but other comparators may need to be considered in the assessment of clinical evidence if reported in studies.

7. Patient issues and preferences

People with certain treatable secondary causes of hypertension which are often prevalent and undiagnosed such as primary aldosteronism may not be eligible for RDN. All eligible patients should be screened before referral for the procedure as targeted, effective treatment may be available. People who

cannot tolerate or take sufficient dose of BP medication may likely benefit from RDN.

RDN is an invasive procedure, and health professionals have indicated that this is the primary concern for patients. Experts have described the procedure as having a relatively low complication rate, with serious procedural complications considered rare. A remaining need to take pills, and uncertainty about long-term effects are further perceived concerns for patients.

Response to RDN varies among people with resistant hypertension. Experts have estimated that up to 60% of people may respond, while 40% may not and there is currently no reliable way to predict response before treatment. However, factors which could influence response to RDN may include lower baseline BP, high arterial stiffness, and presence of anatomical variants such as accessory arteries. Factors which could influence long-term effectiveness of RDN in controlling BP include age, comorbidities, change in medications and potential regrowth of renal nerves.

Factors such as younger age, male sex, higher office or home BP, need for more antihypertensive medication, cardiovascular comorbidities, medication side effects, and poor drug adherence may influence preference for RDN, highlighting the importance of individualised assessment. Preferences may also be influenced by lifestyle and communication needs. Shared decision making and appropriate education and support from healthcare professionals may help people make informed choices about RDN considering benefit-risk and follow-up monitoring (see the NICE guideline for shared decision making).

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others. Resistant hypertension may have a substantial and long-term adverse effect on a person’s ability to carry out normal day-to-day activities. People with this condition may be classified as having a disability and therefore protected under the Equality Act 2010.

Hypertension affects some groups disproportionately. Hypertension tends to increase with advancing age, affecting over 60% of people aged 60 years and above in the UK. However, people under age 50 are 40% less likely to have controlled blood pressure than older patients. People of younger age with poorly controlled blood pressure have a higher risk of heart attack or stroke (Gill D et al, 2020). Up to about 65 years, men tend to have a higher blood pressure than women. Between 65 to 74 years of age, women tend to have a higher blood pressure.

People from Black ethnic groups have a greater prevalence of hypertension than any other ethnic group and are almost 10% less likely to have controlled blood pressure compared to white groups. They also have a higher risk of stroke and cardiovascular outcomes (Rison et al, 2023).

The burden of high blood pressure is greatest among individuals from low-income households and those living in deprived areas. People from the most deprived areas in England are 30% more likely to have hypertension than those from the least deprived areas (PHE, 2017). Rural populations face access challenges to specialist services. There is geographic variation in access to services capable of performing renal denervation.

Some people may be disproportionally affected by factors such as multiple clinic appointments, transport to specialist centres, time off work for assessments and understanding complex medication regimens. Data from GP records for 47% of patients in England in 2017/18 comparing people with and without learning disability showed that hypertension rates were similar between both groups after adjusting for differences in age. However, younger people with learning disabilities were more likely to have a diagnosis of hypertension than older people with learning disabilities.

9. Decision problem

The key decision question for this assessment is:

- Is offering renal sympathetic denervation for people with resistant hypertension or those intolerant to multiple hypertensive medications a clinically and cost-effective use of NHS resources?

Table 1: Decision problem

Population	Adults with resistant hypertension Adults who are intolerant to anti-hypertensive medication
Interventions	Renal sympathetic denervation using any one of the following technologies with or without ongoing treatment with antihypertensives: • IBERIS multi-electrode renal artery radiofrequency ablation catheter • paradise ultrasound renal denervation system • peregrine system infusion catheter • symplicity spyral renal denervation system
Comparator	• standard of care including use of multiple antihypertensive medications at the optimal tolerated dose
Setting	Specialist secondary care settings or tertiary care
Outcomes and costs (may include but are not limited to)	Intermediate outcomes: • systolic ambulatory and/or office BP • proportion responding to treatment (>5mmHg reduction in blood pressure) • change in use of antihypertensive medications • rate of reintervention • renal function measured by estimated Glomerular Filtration Rate (eGFR) and serum creatinine Clinical outcomes: • adverse events associated with procedure • end-organ damage • cardiovascular events including hypertensive crisis, stroke, myocardial infarction, heart failure, renal failure and mortality • hospitalisations Patient-reported outcomes: • health-related quality of life • patient satisfaction and tolerance to procedure Costs and resource use: • implementation and ongoing costs associated with the technology such as device components, catheter laboratory time, training, staff costs and post-procedure monitoring.

	• healthcare costs such as hospitalisations for cardiovascular events • cost of antihypertensive medications • resource use such as number of blood pressure appointments, specialist reviews, investigations to monitor response
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

10. Other issues for consideration

10.1 Definition of resistant hypertension

There is a variation in the definition of resistant hypertension across guidelines and the evidence base. Also, thresholds for adequate blood pressure control differ. It will therefore need to be considered how generalisable the evidence base is where different or broader definitions of resistant hypertension have been used. The NG136 definition of hypertension would likely be most relevant to clinical practice and the population any NICE recommendation on renal denervation would apply to.

10.2 Factors influencing clinical effectiveness and generalisability of evidence

The following factors have been identified that may influence the magnitude and consistency of blood pressure reduction observed following renal denervation.

- Baseline blood pressure: Experts have noted that baseline BP at the time of treatment is likely to influence magnitude of blood pressure reduction. People with higher baseline BP may experience larger reductions and this should be considered when interpreting effect sizes across the evidence base.

- Treatment response: There is a variation in the response to RDN. Some people may experience clinically meaningful blood pressure reductions while others may show limited or no response. This variability in response rates across studies may reflect differences in patient demographics, baseline BP, BP measurement methods or factors related to the procedure. There is currently no method to predict response prior to treatment. BP targets used to define response vary across guidelines, patient groups and studies.
- Versions of devices: Overtime, devices have evolved and generalisability of evidence on older versions of the technologies will need to be considered during the assessment.
- Learning curve: There is likely to be a learning curve associated with the procedure, and outcomes may be influenced by operator experience. Experts have noted they expect the learning curve to be relatively short.

10.3 Potential implementation issues

10.4 Centre and patient selection

RDN is usually carried out by a multidisciplinary team including interventionalists, hypertension expert with focus on management of hypertension and assessment of secondary hypertension, clinical cardiologist, and nephrologist. Patient selection is also done by the team following evaluation to check if the technology and/or procedure is suitable for the person. A centre for RDN should have an appropriate multidisciplinary team, onsite or remote hypertension outpatient clinic, inpatient ward, radiology division, clinical and hormonal laboratory, catheterisation laboratory, coronary care or intensive care unit, and access to an emergent vascular surgery facility to facilitate the programme. Experts estimate that there are around 18 to 20 centres across the UK that currently perform renal denervation, although a national survey by the British and Irish Hypertension Society is underway to establish more up-to-date information.

10.5 Workforce capacity and training

Clinician interest and confidence in using technologies may affect use and outcomes. Both interventional cardiologists and interventional radiologists could appropriately deliver renal denervation, provided they have suitable training and maintain procedural experience. Implementation of renal sympathetic denervation may require more standardised training programmes due to involvement of complex renal artery and nerve anatomy to help mitigate variability in outcomes and ensure a safe and effective procedure across different settings.

10.6 Data collection and registries

There is currently no national registry for RDN in the UK. Experts have noted that there are existing technology-specific registries, such as the Global Symplicity Registry and Global Paradise™ System (GPS) registry, which collect real-world outcomes data and may provide real-world evidence relevant to this assessment.

10.7 Care pathway and commissioning

In 2016, NHS England developed a commissioning policy for this procedure which highlighted a lack of evidence to support routine commissioning outside of a clinical trial setting (NHS England, 2016). Experts have mentioned an absence of reimbursement process, high catheter device costs and limited catheter laboratory as barriers to NHS adoption. This means trusts are unable to recover per-case costs and have limited financial incentive to establish services. Device costs are substantial and lack of reimbursement may stall uptake. Funding would need to cover both the procedure and the cost of specialist catheter device. Initial rollout may need to concentrate in hospitals that already have the required expertise and equipment which could serve as regional hubs for patient referral through clear pathways.

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Appendix A: Questions for the scoping consultation

- Are there any other clinical guidelines for renal sympathetic denervation that are followed in the NHS and that NICE should be aware of?
- Are the populations outlined in the draft scope appropriate?
    - Is it appropriate to include people who are intolerant to multiple antihypertensives?
    - Are there any subgroups for whom you would expect the clinical and cost effectiveness of the intervention to differ?
- Are the suggested technologies suitable for inclusion in this assessment?
- Is the care pathway appropriately described?
- Are the suggested comparators appropriate for this assessment?
- Are all the outcomes and costs suitable for inclusion in the assessment?
- NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people who share a protected characteristic and those who do not. Are there any potential equality issues that have not been covered in the draft scope?
- Are there any other issues that should be included in the scope?
- Are there any audits or registries relevant to this topic?
- Please let us know if we have missed any important organisations from the stakeholder list in Appendix C, and which organisations we should include that have a particular focus on relevant equality issues.