

**Integrated Impact Assessment Report for Clinical Commissioning Policies**

<b>Policy Reference Number</b>	A09X02		
<b>Policy Title</b>	Renal denervation for resistant hypertension		
<b>Accountable Commissioner</b>	Sue Sawyer	<b>Clinical Lead</b>	Jim McLenachan
<b>Finance Lead</b>	Robert Cornall/Jonathan Storey	<b>Analytical Lead</b>	Ceri Townley
<b>Section K - Activity Impact</b>			
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	<p>K1. 1 This policy proposes to <b>not routinely commission renal denervation</b> for patients with resistant hypertension.</p> <p><b>Hypertension</b> is a chronic medical condition in which the blood pressure in the arteries is persistently raised. The prevalence of hypertension in those aged 16 years or older is 31.5% in men and 29% in women.<sup>1</sup> There are therefore</p>	

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	<p>K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?</p>	<p>estimated to be around 12.9m adults with hypertension in England.<sup>ii</sup></p> <p>K1.2 The population <b>eligible for treatment</b> is a subset of the prevalent population; those with <b>resistant hypertension</b> that meet the criteria for renal denervation. This is defined as when an individual cannot control their blood pressure (and have a clinic systolic blood pressure of more than 160 mm Hg) despite the use of at least three antihypertensive agents.<sup>iii</sup> Around 10-20% of those with hypertension, may have resistant hypertension.<sup>iv</sup> There may therefore be between c. 1.3 and 2.6m adults with resistant hypertension.</p> <p>Patients could be selected for renal denervation if they:<sup>v</sup></p> <ul style="list-style-type: none"><li>• are on three or more medications and can prove that they have deployed step 4 therapies<sup>vi</sup> on the NICE (GC127) guideline.<sup>vii</sup></li><li>• have a suitable renal artery anatomy<sup>viii</sup></li><li>• do not have secondary hypertension or white coat hypertension</li></ul> <p>It is difficult to estimate the exact number of patients who could be considered for renal denervation and only a small fraction of those with resistant hypertension might be suitable for treatment.</p> <p>Past estimates (2013/14) have indicated a potential 360-400 patients that might be suitable for renal denervation procedures in England.<sup>ix</sup></p>
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K1.3 What age group is the treatment indicated for?

K1.3 The procedure is indicated for adults (aged 18 and older).<sup>x</sup>

K1.4 Describe the age distribution of the patient population taking up treatment?

K1.4 Based on international studies, the mean age of patients with resistant hypertension is estimated at c. 70, with 1 in 4 patients older than 80.<sup>xi</sup> Out of those receiving the renal denervation procedure in England, around half were aged between 65 and 80.<sup>xii</sup>

K1.5 What is the current activity associated with currently routinely commissioned care for this group?

K1.5 In 2014/15 there were 34 **renal denervation** procedures recorded in the Hospital Episode Statistics (HES).<sup>xiii</sup>

Patients with resistant hypertension are typically treated with **antihypertension drugs**:<sup>xiv</sup>

- Conventional therapies (for all patients<sup>xv</sup>):
  - Diuretics
  - ACE inhibitors or angiotensin II receptor blockers
  - Calcium antagonists
- Step four treatments (for all patients<sup>xvi</sup>):
  - Beta blockers
  - Alpha blockers
  - Spirnonolactone
- Other treatments<sup>xvii</sup>

Patients that receive renal denervation may **remain on current antihypertension drugs** after the procedure.<sup>xviii</sup>

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	<p>K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?</p>	<p>K1.6 The prevalence of hypertension in the population of adults has remained relatively constant over the last 10 years.<sup>xix</sup> No change in the prevalence rate has been anticipated. The prevalent population identified in K1.1 (the <b>hypertensive population</b>) is estimated to grow in line with population growth, and to be in the region of:<sup>xx</sup></p> <ul style="list-style-type: none"><li>• 13.08m in 2016/17 (year 1)</li><li>• 13.17m in 2017/18 (year 2)</li><li>• 13.44m in 2020/21 (year 5)</li></ul> <p>The number of <b>patients with resistant hypertension</b> and potentially eligible for treatment is expected to grow in a similar manner, and therefore is estimated to be:<sup>xxi</sup></p> <ul style="list-style-type: none"><li>• 1.31m to 2.62m in 2016/17 (year 1)</li><li>• 1.32m to 2.63m in 2017/18 (year 2)</li><li>• 1.34m to 2.69m in 2020/21 (year 5)</li></ul>
	<p>K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years</p>	<p>K1.7 Under a do nothing scenario (i.e. assuming the policy is not implemented and activity grows with demographic growth), the activity for renal denervation is estimated to remain relatively constant at the current state of around 35 procedures a year. For the target population (those with resistant hypertension meeting the criteria set out in K1.2), the use of medical therapy is also not expected to change.</p>
	<p>K1.8 How is the population currently distributed</p>	<p>K1.8 The geographical distribution of high blood pressure</p>

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	geographically?	may be explained by social inequalities. People that live in deprived areas are 30% more likely to have high blood pressure than the least deprived. <sup>xxii</sup>
K2 Future Patient Population & Demography	<p>K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?</p> <p>K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)</p> <p>K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details</p> <p>K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?</p>	<p>K2.1 This policy is to <b>not routinely commission</b> renal denervation for the population with resistant hypertension.</p> <p>K2.2 Based on an international study, the factors that affect the prevalence of hypertension may include environmental factors such as:<sup>xxiii</sup></p> <ul style="list-style-type: none"> <li>• lack of exercise</li> <li>• raised low density lipoprotein cholesterol</li> <li>• smoking</li> </ul> <p>K2.3 None identified.</p> <p>K2.4 The policy proposes that <b>renal denervation</b> is not routinely commissioned. Based on this, there could be a decrease of up to c. 35 patients accessing the treatment. There could be c. 35 fewer patients accessing the treatment each year as compared to the do nothing position.</p> <p>A 75% full year effect is anticipated in year 1 (2016/17), and so it is estimated that activity in that year would be around</p>

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<p>K3 Activity</p>	<p>K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet</p> <p>K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet</p> <p>K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet</p>	<p>9.</p> <p>K3.1 Current annual activity is identified in K1.5.</p> <p>K3.2 Renal denervation activity is expected to be very low in future years (as set out in K2.4) given a non-routinely commissioned position. However, patients would be expected to continue with the pharmacological treatments listed in K1.5.</p> <p>K3.3 This is set out in K1.7.</p>
<p>K4 Existing Patient Pathway</p>	<p>K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity</p> <p>K4.2. What are the current treatment access criteria?</p>	<p>K4.1 According to NICE guidelines, people with resistant hypertension should be considered for further diuretic therapy</p> <p>K4.2 Access criteria is based on insufficient reduction of blood pressure levels after being treated with three or more antihypertensive medications. Specific diuretic treatments depend on factors such as blood potassium levels,</p>

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	<p>K4.3 What are the current treatment stopping points?</p>	<p>K4.3 Lack of response, intolerance or contraindication to the treatment.</p>
<p>K5 Comparator (next best alternative treatment) Patient Pathway</p>	<p>K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>K5.1 If further diuretic therapy is not tolerated, is contraindicated or ineffective, an alpha- or beta- blocker can also be considered.</p> <p>K5.2 Lack of response, intolerance or contraindication to the treatment. There is a prevalence rate for resistant hypertension of c. 10-20% of the general hypertension population.</p>
<p>K6 New Patient Pathway</p>	<p>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy</p> <p>K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each</p>	<p>K6.1-6.2 Not applicable as position is to not routinely commission.</p>

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	stopping point.	
K7 Treatment Setting	<p>K7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> <li>○ Acute Trust: Inpatient/Daycase/Outpatient</li> <li>○ Mental Health Provider: Inpatient /Outpatient</li> <li>○ Community setting</li> <li>○ Homecare delivery</li> </ul> <p>K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what?</p> <p><i>e.g. service capacity</i></p>	<p>K7.1 Inpatient/daycase. A typical patient may not require an overnight stay.<sup>xxiv xxv</sup></p> <p>K7.2 Not applicable as the position is to not routinely commission.</p>
K8 Coding	<p>K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>K8.1 Activity for renal denervation may be recorded in the SUS dataset.</p> <p>K8.2 New activity may be identified through the OPCS and ICD-10 codes.<sup>xxvi</sup></p>
K9 Monitoring	<p>K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule.</p>	<p>K9.1 No change anticipated as position is to not routinely commission.</p>



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K9.2 If this treatment is a drug, what pharmacy monitoring is required?

K9.2-9.7 Not applicable as position is to not routinely commission.

K9.3 What analytical information /monitoring/ reporting is required?

K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?

K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?

K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?

K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*

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Section L - Service Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	<p>L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)</p> <p>L1.2 How will the proposed policy change the way the commissioned service is organised?</p>	<p>L1.1 Specialists in hypertension that are based in tertiary centres.</p> <p>L1.2 No change anticipated as the service is not currently routinely commissioned -- any reductions in activity would not be at a scale sufficient to impact organisation.</p>
L2 Geography & Access	<p>L2.1 Where do current referrals come from?</p> <p>L2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>L2.3 Is the new policy likely to improve equity of access</p> <p>L2.4 Is the new policy likely to improve equality of access / outcomes?</p>	<p>L2.1 GPs, cardiologists.</p> <p>L2.2 No change anticipated.</p> <p>L2.3-2.4 No change anticipated as interim policy position was to not routinely commission.</p>
L3 Implementation	<p>L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p>	<p>L3.1-3.6 Not applicable as position is to not routinely commission.</p>

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	<p>L3.2 Is there a change in provider physical infrastructure required?</p> <p>L3.3 Is there a change in provider staffing required?</p> <p>L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p> <p>L3.5 Are there changes in the support services that need to be in place?</p> <p>L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy,</p>	<p>L3.7 No change anticipated.</p> <p>L3.8 Publication and notification of new policy.</p>
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	competitive selection process to secure revised provider configuration)	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 Not applicable.
<b>Section M - Finance Impact</b>		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 The procedure falls under national tariff with the associated HRG code RC14Z. <sup>xxvii</sup> This code is associated with a tariff of c. £2,000, after applying the 10% market forces factor. <sup>xxviii</sup>
	M1.2 Is this treatment excluded from national prices	M1.2 Partially. The treatment is under tariff, but the device is excluded.
	M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	M1.3 The percutaneous renal denervation system used in the procedure is listed as an excluded device. <sup>xxix xxx</sup> The percutaneous renal denervation system is comprised of a single use disposable catheter and a reusable radiofrequency generator. <sup>xxxi</sup> The catheter may cost around £3,500 to £5,000 depending on the brand used, <sup>xxxii</sup> while the generator controlling the device may cost around

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	<p>M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes</p> <p>M1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p>	<p>£10,000.<sup>xxxiii</sup></p> <p>Please see M2.1 for the cost per patient.</p> <p>M1.4 Not applicable.</p> <p>M1.5 VAT would be payable on excluded devices and it has been included in the cost calculations.<sup>xxxiv</sup></p> <p>M1.6 Not applicable.</p>
<p>M2 Average Cost per Patient</p>	<p>M2.1 What is the revenue cost per patient in year 1?</p>	<p>M2.1 The revenue cost would be nil as the position is to not routinely commission.</p> <p>For reference, the total direct surgical cost of renal denervation is estimated at c. £5,500 to £7,000.<sup>xxxv</sup> This is</p>

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	<p>M2.2 What is the revenue cost per patient in future years (including follow up)?</p>	<p>comprised of:</p> <ul style="list-style-type: none"> <li>• the cost of the catheter, which ranges from c. £3,500 to £5,000 (including VAT)</li> <li>• the tariff cost for the procedure of c. £2,000<sup>xxxvi</sup></li> </ul> <p>There would also be pre and post-operative care. This may include:<sup>xxxvii</sup></p> <ol style="list-style-type: none"> <li>1. Pre-operative assessment by the MDT at a cost of c. £169 per patient.<sup>xxxviii</sup></li> <li>2. Pre-procedural imaging of the renal artery – CT or MRI scan at a cost of c. £85 to £329 per patient.<sup>xxxix</sup></li> <li>3. An outpatient review with their hypertension specialist 4-6 weeks following discharge and pre admission. This costs c. £271.<sup>xl</sup></li> <li>4. Post-procedural monitoring of blood pressure. The cost of which is based on a local price arrangement for between providers and commission groups.</li> </ol> <p>The pre and post-operative care is estimated to be £525 to £770.</p> <p>M2.2 In the years following the procedure patients are monitored with regular measurement of their blood pressure, as consistent with their long term medical management.<sup>xli</sup></p>
<p>M3 Overall Cost Impact of this Policy to NHS England</p>	<p>M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England</p>	<p>M3.1 Cost neutral or cost saving. Under a policy not to routinely commission, renal denervation would not be funded by NHS England. This could be cost saving to NHS England to the extent that any existing activity is passed through to NHS England (however it is the view of the policy working group that the costs for renal denervation are most</p>

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	M3.2 Where this has not been identified, set out the reasons why this cannot be measured	likely being borne locally by CCGs/trusts).  M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	<p>M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)</p> <p>M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole</p> <p>M4.3 Where this has not been identified, set out the reasons why this cannot be measured</p> <p>M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>M4. Cost neutral or cost saving. Under existing policy, CCGs and Trusts may save costs in relation to renal denervation of up to c. £209k to £269k in 2017/18 (c. £155 to £201k in 2016/17 assuming only 75% of a full year effect) as the treatment is not routinely commissioned.</p> <p>M4.2 Cost neutral or cost saving. Under existing policy, the NHS may save costs in relation to renal denervation of up to c.£209k to £269k in 2017/18 (c. £155k to £201k in 2016/17 assuming only 75% of a full year effect) as the treatment is not routinely commissioned.</p> <p>M4.3 Not applicable.</p> <p>M4.4 Not applicable.</p>
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified <i>e.g. decommissioning less clinically or cost-effective services</i>	M5.1 Not applicable.

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<p>M6 Financial Risks Associated with Implementing this Policy</p>	<p>M6.1 What are the material financial risks to implementing this policy?</p> <p>M6.2 Can these be mitigated, if so how?</p> <p>M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p>M6.1 No material financial risks have been identified.</p> <p>M6.2 Not applicable.</p> <p>M6.3 The range of cost savings set out in M3 and M4 is based on variations in the unit costs.</p> <p>The cost of pre and post-operative assessments and the surgical cost (for the device) may vary.</p> <p>The high scenario is based on a cost per patient of c. £7,000 for the procedure and c. £770 for pre and post operative costs.</p> <p>The low scenario is based on a cost per patient of c. £5,500 for the procedure and c. £525 for pre and post operative costs.</p>
<p>M7 Value for Money</p>	<p>M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p>M7.1 There is only one paper in the literature search that provided evidence for the cost effectiveness of renal denervation in the context of resistant hypertension. Gladwell et al., 2014 concluded that RDN resulted in a greater health benefit to the patient compared to standard of care pharmacological intervention alone, extending QALYs from 12.16 to 12.77. This added health benefit came at a cost of £4805 per QALY.</p> <p>M7.2 Gladwell et al., 2014 published their findings in the same year as the publication of SYMPLICITY HTN-3 trial results but were not able to include these results in their economic model. Given the reported lack of clinical</p>



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		effectiveness in SYMPLICITY HTN-3 (Bhatt et al., 2014, Bakris et al., 2015), the cost effectiveness of this treatment likely to impact the cost-effectiveness analysis. An updated model including results from this blinded RCT is needed before the cost effectiveness of RDN for RH can be accurately ascertained.
M8 Cost Profile	<p>M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p> <p>M8.2 If so, confirm the source of funds to meet these costs</p>	<p>M8.1 None identified.</p> <p>M8.2 Not applicable.</p>

<sup>i</sup> Department of Health: Health Survey for England - 2010, Trend tables. [Online] Available at <http://www.hscic.gov.uk/pubs/hse10trends> [Accessed 13 Jan. 2016]

<sup>ii</sup> This accounts for the different population sizes between females and males (there were 21.8m female adults and 20.8m male adults in 2014 – ONS (2012) population projections). This applies the prevalence rates to ONS (2012) population projections for the adult population for both males and females in 2014/15 (for the population of those aged 18 and above).

<sup>iii</sup> Please refer to the policy proposition.

<sup>iv</sup> BMJ (2012). Resistant Hypertension. [Online] Available at <http://dx.doi.org/10.1136/bmj.e7473>. Published date: 20 November 2012 [Accessed Jan. 13 2016]

<sup>v</sup> The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2011).[Online] Available at : <http://www.bhsoc.org/docs/joint-uk-societies-summary-on-renal-denervation.pdf> [Accessed Dec. 12 2015]

<sup>vi</sup> Step 4 treatments include further diuretic therapy with low-dose spironolactone and higher-dose thiazide-like diuretic treatment.

<sup>vii</sup> NICE Guideline (2011). Hypertension in adults: diagnosis and management. [Online] Available at: <https://www.nice.org.uk/guidance/cg127/resources/hypertension-in-adults-diagnosis-and-management-35109454941637> [Accessed Jan 13 2016]

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<sup>viii</sup> This requires a main renal artery of >20mm in length and >4mm in diameter without significant stenosis.

<sup>ix</sup> Based on around 30 procedures in 12 centres in 2013/14, or approximately 360 in total (up to 400 procedures). Source: NHS Commissioning Board. (2012). Clinical commissioning policy: Renal denervation for resistant hypertension. NHSCB/A9b/2. [Online] Available at: [https://www.engage.england.nhs.uk/consultation/ssc-area-a/supporting\\_documents/a9b2policy.pdf](https://www.engage.england.nhs.uk/consultation/ssc-area-a/supporting_documents/a9b2policy.pdf) [Accessed 13 Jan. 16]

<sup>x</sup> Please refer to the policy proposition.

<sup>xi</sup> Gijón-Conde, T., Graciani, A. and Banegas, J. (2014). Resistant Hypertension: Demography and Clinical Characteristics in 6292 Patients in a Primary Health Care Setting. *Revista Española de Cardiología (English Edition)*, 67(4), pp.270-276. [Online] accessed at: <http://www.revespcardiol.org/en/resistant-hypertension-demography-and-clinical/articulo/90283824/> [Accessed 13. Jan 16]

<sup>xii</sup> 17 of the 34 episodes in 2014/15 were aged between 65 and 80. The Health and Social Care Information Centre, Hospital Episode Statistics for England. Admitted Patient Care statistics, 2014-15.

<sup>xiii</sup> Based on HES data, in 2014/15 there were 34 finished consultant episodes and 32 admissions for the procedure - Percutaneous transluminal radiofrequency denervation of renal artery. The Health and Social Care Information Centre, Hospital Episode Statistics for England. Admitted Patient Care statistics, 2014-15. This is identified using the OPCS code - L43.6 – and is listed as the recommended OPCS code for renal denervation (NICE Guidance - nice.org.uk/guidance/ipg418)

<sup>xiv</sup> The NICE CG127 Hypertension Guideline indicates that patients with hypertension are at step 4 of the clinical pathway. [Online] Available at: <https://www.nice.org.uk/Guidance/CG127> [Accessed 13. Jan 16]

<sup>xv</sup> Based on discussions with the policy working group.

<sup>xvi</sup> Based on discussions with the policy working group.

<sup>xvii</sup> Moxonidine, Minoxidil, Hydralazine, Methyldopa, Oral Nitrate and Clonidine. Based on the policy working group.

<sup>xviii</sup> 'Renal denervation will not allow you to stop taking drugs to lower your blood pressure: you will almost certainly need to continue taking your current drug treatment after the procedure' The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2011).

<sup>xix</sup> Health & Social care information (2011), Hypertension. Chapter 3 – volume 1. [Online] Available at: <http://www.hscic.gov.uk/catalogue/PUB09300/HSE2011-Ch3-Hypertension.pdf> [Accessed 16. Jan 2016]

<sup>xx</sup> The demographic specific growth rate is estimated using the cohorts from the ONS (2012) population projections to calculate a growth rate of the population of adults in England over the period 2015 to 2025.

<sup>xxi</sup> The demographic specific growth rate is estimated using the cohorts from the ONS (2012) population projections to calculate a growth rate of the population of adults in England over the period 2015 to 2025.

<sup>xxii</sup> Public Health England (2014). Tackling high blood pressure: From evidence into action. [Online] Available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/404881/Tackling\\_high\\_blood\\_pressure\\_-\\_FINAL.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404881/Tackling_high_blood_pressure_-_FINAL.pdf) [Accessed 16. Jan 2016]

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- xxiii Poulter, N. (1991). Management of multiple risk factors for coronary heart disease in patients with hypertension. American Heart Journal, 121(1), pp.246-249. [Online] available at: <http://www.ncbi.nlm.nih.gov/pubmed/2262939> [Accessed 16. Jan 2016]
- xxiv Information for patients from the Departments of Renal (Kidney) Medicine and Interventional Radiology. Renal Denervation (Percutaneous Transluminal Radiofrequency sympathetic Denervation, PTRSD). East Kent Hospitals University, NHS.
- xxv Patients may be treated as day cases or may be kept in hospital for one night; this is dependent on the local arrangements The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2011).
- xxvi OPCS - L436 Percutaneous transluminal radiofrequency denervation of renal artery – and the ICD 10 codes relating to hypertension.
- xxvii The OPCS code – L43.6 Percutaneous transluminal radiofrequency denervation of renal artery – aligns with the HRG code – RC14 in the OPCS code to group document. (HRG201415 Payment Code to Group). Based on the 2014/15 elective/day case tariff.
- xxviii A MFF uplift of 10% has been applied to the weighted average tariff £1,847 (weighted in HES 2014/15 data). In 2015/16, an efficiency factor of -3.5% and inflation rate of 1.9% are applied to all costs paid via tariff.
- xxix This is the device used in the procedure. The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2012).
- xxx The device may be categorised as 'Radiofrequency, cryotherapy and microwave ablation probes and catheters' on the 2014/15 'PbR Excluded Devices and Procedures' sheet.
- xxxi The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2012).
- xxxii Healthcare Improvement Scotland (2013). Renal denervation topic referral form. [Online] Available at: [http://www.healthcareimprovementscotland.org/our\\_work/technologies\\_and\\_medicines/shtg/shtg\\_work\\_programme/renal\\_denervation.aspx](http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg/shtg_work_programme/renal_denervation.aspx) [Accessed 16. Jan 2016]
- xxxiii Healthcare Improvement Scotland (2013). Renal denervation topic referral form. [Online] Available at: [http://www.healthcareimprovementscotland.org/our\\_work/technologies\\_and\\_medicines/shtg/shtg\\_work\\_programme/renal\\_denervation.aspx](http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg/shtg_work_programme/renal_denervation.aspx) [Accessed 16. Jan 2016]
- xxxiv Based on discussions with NHS pharmacists and finance leads. Section 3.2, When can goods being provided on prescription be zero-rated for VAT purposes? [Online] Available at: <https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products> [Accessed January 18 2016].
- xxxv This does not include the capital cost of the generator. It is assumed that patients do not exceed the ordinary elective long stay trim point days of 5.
- xxxvi The procedure involves haemodynamic and oxygen saturation monitoring, an angiography to allow access to the femoral artery, and the insertion and removal of the catheter into the renal artery (with 4-6 treatments recommended per patient). The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2012).
- xxxvii This is the patient pathway as described in the 'Information for patients from the Departments of Renal (Kidney) Medicine and Interventional Radiology' document produced by Renal Denervation (Percutaneous Transluminal Radiofrequency sympathetic Denervation, PTRSD) East Kent Hospitals University (NHS).

## DRAFT FOR PUBLIC CONSULTATION ONLY

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<sup>xxxviii</sup> An MFF uplift of 10% has been applied to the tariff for a multi professional first attendance in vascular surgery of £154 based on 2014/15 tariff.

<sup>xxxix</sup> The lower bound cost refers to the HRG tariff – RA08 Computerised Tomography Scan, one area, no contrast - £77 and the upper bound refers to the HRG tariff – RA07Z Magnetic Resonance Imaging Scan, requiring extensive patient repositioning and/or more than one contrast agent - £299. An MFF uplift of 10% has been applied to both tariffs and from £2015/16.

<sup>xl</sup> An MFF uplift of 10% has been applied to the tariff for a first attendance (single professional) in vascular surgery of £154 and a follow up attendance in vascular surgery of £92 based on 2014/15 tariff.

<sup>xli</sup> The Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension (2011).