

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B14X12		
Policy Title	Robotic Assisted Surgery for Kidney Cancer		
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Section A - Activity Impact			
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)	
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	<p>A1. 1 This policy proposes to not routinely commission RAS to treat people diagnosed with kidney cancer.</p> <p>In the UK around 26,500 people were still alive at the end of 2006, up to ten years after being diagnosed with kidney cancer (National Cancer Intelligence Network).</p> <p>Kidney cancer prevalence:</p> <p>These figures relate to kidney cancer prevalence - the number of people expected to be living with the condition who may require health services. This could include patients who have been treated, require follow up, or are watch and wait for clinical management. The figures are based on patients diagnosed up to 2010, and statistically modelled in PHE/Macmillan Cancer Prevalence Project (http://www.ncin.org.uk/about_ncin/releases)</p>	

	<p>A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?</p> <p>A1.3 What age group is the treatment indicated for?</p> <p>A1.4 Describe the age distribution of the patient population taking up treatment?</p> <p>A1.5 What is the current activity associated with currently routinely commissioned care for this group?</p> <p>A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?</p>	<ul style="list-style-type: none"> • 16/17:9,407 • 17/18:8,616 • 20/21:5,450 <p>A1.2 The policy pertains to a surgical technique, and as such doesn't alter the number of surgical procedures actually delivered to treat kidney cancer. The number of procedure spells currently undertaken is 4,992 p.a. (see A2.4).</p> <p>A1.3 The treatment is indicated for adults (over 18 years), in accordance with the NHS Prescribed Services Manual.</p> <p>A1.4 There is a 1.5:1 predominance in men over women, with peak incidence occurring between 60 and 70 years of age (Public Health England, 2015).</p> <p>A1.5 4,992 spells (see A2.4).</p> <p>A1.6 Robotic surgery, and indeed all forms of surgery, is not an ongoing treatment. As such, incidence is the more reliable predictor of activity growth over time.</p> <p>The rate of new diagnoses (incidence) of kidney cancer has risen significantly in England since 2011 and in 2013 there were 8,562 new diagnoses in England (Public Health England, 2015).</p>
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	<p>A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?</p> <p>A1.8 How is the population currently distributed geographically?</p>	<p>A1.7 The number of surgical interventions for kidney cancer is estimated to have increase by an average of 5.2% in recent years. If these trends continue, the estimated activity for the eligible population described in K1.5 is estimated to be in the region of:</p> <ul style="list-style-type: none"> • 2016/17: 5,251 • 2017/18: 5,523 • 2020/21: 6,426 <p>Of these, in the do nothing scenario, the proportion of robotic procedures is expected to increase by 0.5% point per year in line with recent years.. This is based on the number of centres offering robotic nephrectomy procedures remaining the same, i.e., that the policy is not implemented.</p> <p>A1.8 Cases of kidney cancer are unevenly distributed throughout England, with higher incidence and prevalence being observed in the North as compared to the South. However, kidney cancer is the eighth most common cancer in the UK, as such will impact all areas of England. It should be noted that kidney cancer is also more common in males than females.</p>
<p>A2 Future Patient Population & Demography</p>	<p>A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold /</p>	<p>A2.1 The policy moves to a non-routine commissioning position.</p>

	<p>add an additional line / stage of treatment / other?</p> <p>A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).</p> <p>A 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>A2.4 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>A2.2 Not applicable – this is a non-routine commissioning position.</p> <p>A2.3 See K1.6 and K1.8. Overall, incidence of this disease is increasing.</p> <p>A2.4 There is no change in the number of kidney cancer surgeries associated with this policy, however as robotic procedures are decommissioned, the number of open procedures will increase. It should be noted that the activity model assumes that only 50% of activity will be decommissioned in year 1.</p> <p>Total number of kidney cancer procedures (spells):</p> <ul style="list-style-type: none"> • 2016/17: 5,251 • 2017/18: 5,523 • 2020/21: 6,426 <p>Total number of kidney cancer robotic procedures (spells):</p> <ul style="list-style-type: none"> • 2016/17: 45
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A3 Activity	<p>A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.</p> <p>A3.2 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>A3.3 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>A3.1 Current year activity is c5,000 procedures of which 59 were robotic.</p> <p>A3.2 Not applicable, the policy doesn't alter the number of surgical interventions for kidney cancer.</p> <p>A3.3 The comparative activity is non-robotic nephrectomy and partial nephrectomy procedures (i.e., open and laparoscopic techniques).</p>
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely	A4.1 – A4.3 The current mainstay treatment for kidney cancer, diagnosed at any stage, is surgery. Unlike many other

	<p>commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p>	<p>forms of cancer, chemotherapy is not usually effective at treating kidney cancer, however radiotherapy may be used.</p> <p>Depending on the stage and/or location of the kidney cancer, the surgical intervention will either remove the whole or part of the kidney. These procedures can be undertaken in three ways: (i) open; (ii) laparoscopic; and (iii) robotic assisted laparoscopic (partial kidney removal only).</p> <p>The number of nephrectomies performed for kidney cancer has risen broadly in line with the rising number of diagnoses. For those diagnosed in 2013 there were 2,474 radical nephrectomies performed in men, and 1,511 in women. There were 743 partial nephrectomies performed in men, and 407 in women. As a percentage of all diagnoses, around half had a radical nephrectomy; this rate has decreased marginally over time as the rate of partial nephrectomies has increased.</p> <p>The database operated by the British Association of Urological Surgeons (BAUS) finds that in 2012 and 2013, the proportion of nephrectomy procedures which were recorded as being robotically-assisted was 4%.</p>
<p>A5 Comparator (next best</p>	<p>A5.1 If there is a 'next best' alternative routinely</p>	<p>A5.1 The 'next best' alternative routinely commissioned treatment is non-robotic nephrectomy or partial nephrectomy.</p>

<p>alternative treatment) Patient Pathway</p>	<p>commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A5.2 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>These may be delivered using open or laparoscopic techniques.</p> <p>A5.2 Not applicable.</p>
<p>A6 New Patient Pathway</p>	<p>A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.</p> <p>A6.2 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.</p>	<p>A6.1 The pathway would not change from that set out within K4.1.</p> <p>A6.2 Not applicable.</p>

	<p>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>	
A7 Treatment Setting	<p>A7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery <p>A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p>	<p>A7.1 The treatment is carried out in the inpatient setting.</p> <p>A7.2 Not applicable.</p>
A8 Coding	<p>A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p>	<p>A8.1 The underlying procedure would be recorded in SUS.</p>

	<p>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>A8.2 Robotic procedures have an additional OPCS code of Y765 Robotic assisted minimal access approach to other body cavity added to the patient episode.</p>
A9 Monitoring	<p>A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>A9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>A9.3 What analytical information /monitoring/ reporting is required?</p> <p>A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?</p> <p>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p>	<p>A9.1 Not applicable.</p> <p>A9.2 Not applicable.</p> <p>A9.3 Not applicable.</p> <p>A9.4 Not applicable.</p> <p>A9.5 Not applicable.</p>

	<p>A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p> <p>A9.7 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</p>	<p>A9.6 Not applicable.</p> <p>A9.7 Not applicable.</p>
Section B - Service Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 Robotic surgery is currently carried out in specialist centres with the robotic equipment.
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 No change. These centres also carry out non-robotic procedures to treat kidney cancer.
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Referrals will be made via the existing pathway and MDT arrangements.
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 No. The policy will not alter the referral process for kidney cancer.

	<p>B2.3 Is the new policy likely to improve equity of access?</p> <p>B2.4 Is the new policy likely to improve equality of access / outcomes?</p>	<p>B2.3 Yes. Moving to a consistent commissioning position across England will improve equity of access.</p> <p>B2.4 The policy will have no impact on equality of access or outcomes. However, in centres where robotic partial nephrectomy has become the accepted approach there will need to be a change to open or laparoscopic surgery. NHS England's intention is to ensure that all patients are offered choice of a nephron sparing surgical procedure, in-line with the Improving Outcomes Guidance.</p>
B3 Implementation	<p>B3.1 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>B3.2 Is there a change in provider physical infrastructure required?</p> <p>B3.3 Is there a change in provider staffing required?</p> <p>B3.4 Are there new clinical dependency / adjacency requirements that</p>	<p>B3.1 As some centres in England are currently delivering this treatment, it is likely that there would need to be time set aside to allow NHS England commissioning hubs to formally decommission this activity. Therefore it is likely that this policy would be implemented, at the latest, from April 2017.</p> <p>B3.2 No change is required to provider physical infrastructure.</p> <p>B3.3 It is not likely that tis policy will require any changes to provider staffing. This is because patients will still require surgical treatment.</p> <p>B3.4 No. There are no new dependencies associated with this policy.</p>

	<p>would need to be in place?</p> <p>B3.5 Are there changes in the support services that need to be in place?</p> <p>B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)</p>	<p>B3.5 No. There are no changes to the support services that need to put into place.</p> <p>B3.6. There are no changes to provider/inter-provider governance arrangements.</p> <p>B3.7 No change is expected.</p> <p>B3.8 The policy will be secured through the usual commissioning/decommissioning processes operated by NHS England and its commissioning hubs.</p>
<p>B4 Collaborative Commissioning</p>	<p>B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead,</p>	<p>B4.1 These services are not part of national collaborative commissioning or devolution arrangements.</p>

	devolved commissioning arrangements)	
Section C - Finance Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	<p>C1.1 The underlying procedure would be within tariff. The activity groups as follows:</p> <ul style="list-style-type: none"> • LB60* Complex Open or Laparoscopic, Kidney or Ureter Procedures (5.6%) • LB61* Major Open Kidney or Ureter Procedures, 19 years and over (36.0%) • LB62* Major Laparoscopic Kidney or Ureter Procedures, 19 years and over (58.4%)
	C1.2 Is this treatment excluded from national prices?	C1.2 Partly. National prices apply for the main procedure, but robotic consumables are excluded from the national tariff.
	C1.3 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?	C1.3 Consumables are excluded from tariff. Because the consumable is a high-cost excluded device, they are reimbursed through a pass-through arrangement. The cost of consumables does vary, however a reasonable average is approximately £1,800 per procedure. This is on-top of the HRG national price for the underlying procedure.
	C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is	C1.4 Not applicable.

	<p>not additionally / double charged through existing routes?</p> <p>C1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p>	<p>C1.5 Not applicable.</p> <p>C1.6 Not applicable.</p>
C2 Average Cost per Patient	<p>C2.1 What is the revenue cost per patient in year 1?</p> <p>C2.2 What is the revenue cost per patient in future years (including follow up)?</p>	<p>C2.1 The cost per patient in year 1 is £4,764.</p> <p>C2.2 The cost per patient in future years is £4,749.</p>
C3 Overall Cost Impact of this Policy to NHS England	<p>C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.</p> <p>C3.2 Where this has not been identified, set out the reasons why this cannot be measured.</p>	<p>C3.1 Cost saving. A proportion of activity is currently delivered using the robotic technique. This will no longer be funded (having never been an explicitly commissioned procedure) and the per patient saving is therefore the same as the cost of the consumable. Total saving over 10 years is £5.1m.</p> <p>C3.2 Not applicable.</p>

<p>C4 Overall cost impact of this policy to the NHS as a whole</p>	<p>C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).</p> <p>C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.</p> <p>C4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>C4.1 Cost neutral. However, there will be an impact on providers if they are unable to recover income against the revenue consequences of the cost of capital of the robot.</p> <p>C4.2 Cost neutral.</p> <p>C4.3 Not applicable.</p> <p>C4.4 Not applicable.</p>
<p>C5 Funding</p>	<p>C5.1 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></p>	<p>C5.1 Not applicable.</p>
<p>C6 Financial Risks Associated with Implementing this Policy</p>	<p>C6.1 What are the material financial risks to implementing this policy?</p> <p>C6.2 Can these be</p>	<p>C6.1 There are not expected to be any material financial risks associated with implementing this policy.</p> <p>C6.2 Not applicable.</p>

	<p>mitigated, if so how?</p> <p>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p>C6.3 Not applicable.</p>
<p>C7 Value for Money</p>	<p>C7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>C7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p>C7.1 This question was asked as part of the evidence review which found that there is extremely limited evidence in relation to cost effectiveness of the procedure.</p> <p>C7.2 No risks have been identified as evidence of cost effectiveness was not identified.</p>
<p>C8 Cost Profile</p>	<p>C8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p> <p>C8.2 If so, confirm the source of funds to meet these costs.</p>	<p>C8.1 Not applicable.</p> <p>C8.2 Not applicable.</p>