

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B14X08		
Policy Title	Robotic Assisted Surgery for Bladder 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 bladder cancer. Specifically, robotic assisted cystectomy procedures treat muscle-invasive bladder cancer.</p> <p>In the UK more than 46,500 people were still alive at the end of 2006, up to ten years after being diagnosed with bladder cancer (National Cancer Intelligence Network, 2010).</p> <p>Urinary bladder cancer is the second most frequently occurring malignancy of the urinary tract, after prostate cancer. It is the seventh commonest cancer in the U.K with 10,399 new cases diagnosed in 2011. Bladder cancer is the fourth common</p>

		<p>cancer in men and the thirteenth in women (CRUK 2016).</p> <p>Bladder cancer prevalence:</p> <p>These figures relate to bladder 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> <ul style="list-style-type: none"> • 16/17: 12,970 • 17/18: 12,808 • 20/21: 12,159 <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</p>
		<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 bladder cancer. The number of procedure spells currently undertaken is 1,462 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 Bladder cancer is rare under the age of 50, with the peak age standardised rate (ASR) occurring in men aged 75-79 and in women over the age of 85 in the U.K. (Public Health England).</p> <p>A1.5 1,462 spells (see A2.4).</p>

	<p>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> <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</p>	<p>A1.6 In the U.K. there has been a progressive decline in bladder cancer incidence rates since a peak in the early 1990's, with overall ASR falling from 18.4 per 100 000 in 1993 to 11.5 in 2008, although this decline is far more pronounced in men than women. This trend in the U.K. corresponds to declining incidence and mortality rates in the European Union (EU) since the early 1990's and in USA since the 1970's (Bosetti 2011, Ferlay 2008, Zhang 2011).</p> <p>A1.7 It should be noted that over two-thirds of bladder cancer patients actually receive radiotherapy as primary treatment. The number of surgical interventions for bladder cancer has remained flat in recent years despite overall demographic growth. If these trends continue, the estimated activity for the eligible population described in A1.5 is 1,462 per year (average of last 4 years).</p> <p>Of these, in the do nothing scenario, the proportion of robotic procedures is expected to increase by 1% point per year in line with recent years. This is based on the number of centres offering robotic cystectomy procedures remaining the same, i.e., that the policy is not implemented.</p> <p>A1.8 The distribution of bladder cancer is difficult to assess with certainty given the known issues in disease classification and</p>
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	geographically?	recording. However, it does impact more males than females and older people (ONS).
A2 Future Patient Population & Demography	<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 / 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>A2.1 The policy moves to a non-routine commissioning position. It should be noted that the policy, in and of itself, doesn't alter the number of surgical procedures that need to be delivered, it only impacts on the way in which the surgery is delivered.</p> <p>A2.2 Not applicable – this is a non-routine commissioning position that doesn't alter the number of surgeries undertaken.</p> <p>A2.3 See A1.6 and A1.8. Overall, incidence of this disease is falling, therefore the only likely drivers of demand for treatment relates to demographic change. For these reasons, growth has been set to zero.</p> <p>A2.4 There is no change in the number of bladder cancer surgeries associated with this policy, however as robotic procedures are decommissioned, the number of open procedures will increase. <i>It should be noted that the activity model assumes that only 50% of activity will be decommissioned in year 1.</i></p>

		<p><u>Total number of bladder cancer procedures (spells):</u> 2016/17: 1,462 2017/18: 1,462 2020/21: 1,462</p> <p><u>Total number of bladder cancer robotic procedures (spells):</u> 2016/17: 37 2017/18: 0 2020/21: 0</p> <p><u>Total number of bladder cancer non-robotic procedures (spells):</u> 2016/17: 1,425 2017/18: 1,462 2020/21: 1,462</p> <p>It should be noted that, using current data reporting via SUS, that the level of robotic activity for bladder cancer is reported as being 61 spells, This is less than is recorded within the BAUS dataset, however analysis of this dataset indicates that around 1-2% of activity is delivered robotically. For the purposes of the activity and financial model, SUS reporting has been used.</p>
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</p>	<p>A3.1 Current year activity is 1,444 procedures of which 61 were robotic.</p> <p>A3.2 See A2.4.</p>

	<p>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>A3.3 The comparative activity is non-robotic cystectomy procedures (i.e., open and laparoscopic techniques). See A2.4.</p>
<p>A4 Existing Patient Pathway</p>	<p>A4.1 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>A4.1 – A4.3 The clinical pathway for bladder cancer does vary depending on a range of factors, notably the stage at which it is diagnosed. Early stage bladder cancer is non-muscle invasive, this is usually treated principally with a surgical technique called Transurethral resection of a bladder tumour (TURBT), which is followed by a dose of chemotherapy directly into the bladder (called intravesical chemotherapy). TURBT procedures are not undertaken using robotic techniques.</p> <p>Where bladder cancer has invaded the muscle, the primary intervention is a radical cystectomy (surgical) procedure. A small number of partial cystectomy procedures are undertaken, however this type of operation is usually only possible if the patient has an adenocarcinoma of the bladder, which is not a common type.</p> <p>Some invasive bladder cancers can be, and are, treated with radiotherapy which has been shown to offer similar curative benefits as surgery.</p>

	<p>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p>	
<p>A5 Comparator (next best alternative treatment) Patient Pathway</p>	<p>A5.1 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>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>A5.1 The 'next best' alternative routinely commissioned treatment is non-robotic cystectomy &/OR radiotherapy. This may be delivered using open or laparoscopic techniques. The open technique remains the standard approach across most of England</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</p>	<p>A6.1 The pathway would not change from that set out within A4.1.</p>

	<p>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. 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>A6.2 Not applicable.</p>
<p>A7 Treatment Setting</p>	<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,</p>	<p>A7.1 The treatment is carried out in the inpatient setting.</p> <p>A7.2 Not applicable.</p>

	<p>if so what? <i>e.g. service capacity</i></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>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>A8.1 The underlying procedure would be recorded in SUS.</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>A9.1 Not applicable.</p> <p>A9.2 Not applicable.</p> <p>A9.3 Not applicable.</p> <p>A9.4 Not applicable.</p>

	<p>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</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>A9.5 Not applicable.</p> <p>A9.6 Not applicable.</p> <p>A9.7 Not applicable.</p>
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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 bladder cancer.

<p>B2 Geography & Access</p>	<p>B2.1 Where do current referrals come from?</p> <p>B2.2 Will the new policy change / restrict / expand the sources of referral?</p> <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>B2.1 Referrals will be made via the existing pathway and MDT arrangements.</p> <p>B2.2 No. The policy will not alter the referral process for bladder cancer.</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. A small number of centres do currently deliver robotic cystectomy procedures; the impact of the policy proposition will in-effect be the decommissioning of this activity.</p>
<p>B3 Implementation</p>	<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>B3.1 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 Are there new clinical dependency / adjacency requirements that 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>B3.4 No. There are no new dependencies associated with this policy.</p> <p>B3.5 No. There are no changes to the support services that need to put into place.</p> <p>B3.6 No. 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>
B4 Collaborative	B4.1 Is this service currently subject to or	B4.1 These services are not part of national collaborative commissioning or

Commissioning	planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	devolution arrangements.
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Section C - Finance Impact

Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	<p>C1.1 Is this treatment paid under a national prices*, and if so which?</p> <p>C1.2 Is this treatment excluded from national prices?</p> <p>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?</p> <p>C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is</p>	<p>C1.1 The underlying procedure would be within tariff. The activity groups as follows: LB39* Cystectomy with Urinary Diversion and Reconstruction (79.1%) LB67* Complex Open Bladder Procedures (20.5%) Other (0.4%)</p> <p>C1.2 Partly. National prices apply for the main procedure, but robotic consumables are excluded from the national tariff.</p> <p>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.</p> <p>C1.4 Not applicable.</p>

	<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 £9,419.</p> <p>C2.2 The cost per patient in future years is £9,419 This compares to a current cost per patient of £9,495.</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 and the per patient saving is therefore the same as the cost of the consumable. Total saving over 10 years is £2.4m.</p> <p>C3.2 Not applicable.</p>
C4 Overall	C4.1 Indicate whether	C4.1 Cost neutral. However, there will be

<p>cost impact of this policy to the NHS as a whole</p>	<p>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>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 mitigated, if so how?</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>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>