

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B01X29		
Policy Title	The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for patients with Renal 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	<p>A1.1 What is the prevalence of the disease/condition?</p> <p>A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?</p>	<p>A1.1 This policy proposes not to routinely commission SABR as a treatment option for patents with renal cancer.</p> <p>A1.2 The condition, usually described as renal carcinoma or renal cancer, is the most frequent malignant disorder of the kidney in adults, but is uncommon, accounting for only about 3% of cancers in the United Kingdom; its annual incidence is about 13 per 100,000. It is estimated that this treatment pertains to approximately 100 patients that are currently treated using surgery, or</p>

		chemotherapy.
A1.3 What age group is the treatment indicated for?	A1.3 The treatment is indicated for adults (over 18 years), in accordance with the NHS Prescribed Services Manual	
A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 Renal carcinoma is the most frequent malignant disorder of the kidney in adults	
A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 100 Spells see (A2.4)	
A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 The incidence is apparently rising, but this probably reflects the incidental detection of radiological abnormalities in the kidney when patients are scanned for other reasons. This has led to annual increases in the detection of renal cancers of about three percent, with the incidence of small renal tumours increasing at a faster rate. Lesions detected in this way may have a more favourable prognosis than those which present with symptoms.	
		2017/18 106 spells 2020/21 115 spells 2025/26 134 Spells

	<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>A1.8 The distribution of these cancers is difficult to assess with certainty given the known issues in disease classification and recording.</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 / 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>A2.1 The policy moves to a non-routinely commissioning position. It should be noted that the policy does not in itself alter the number of patients requiring treatment using existing treatment options.</p> <p>A2.2 Not applicable – this is a non-routine commissioning position that doesn't alter the number of alternative treatments being delivered.</p> <p>A2.3 Overall this is a less common cancer disease but annual increases in the detection of renal cancers of about three percent, with the incidence of small renal tumours increasing at a faster rate.</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>A2.4 A 3% increase in the number of interventions associated with this policy has been included.</p> <p><i>Total Number of Renal cancer spells</i></p> <table data-bbox="890 481 1101 604"> <tr><td>2016/17</td><td>100</td></tr> <tr><td>2017/18</td><td>106</td></tr> <tr><td>2018/19</td><td>134</td></tr> </table> <p><i>Total Number of Surgeries</i></p> <table data-bbox="890 705 1093 828"> <tr><td>2016/17</td><td>50</td></tr> <tr><td>2017/18</td><td>53</td></tr> <tr><td>2018/19</td><td>67</td></tr> </table> <p><i>Total Number of Chemotherapy spells</i></p> <table data-bbox="890 963 1085 1086"> <tr><td>2016/17</td><td>50</td></tr> <tr><td>2017/18</td><td>53</td></tr> <tr><td>2018/19</td><td>67</td></tr> </table> <p>It should be noted that recording of radiotherapy and chemotherapy activity on SUS is very limited.</p>	2016/17	100	2017/18	106	2018/19	134	2016/17	50	2017/18	53	2018/19	67	2016/17	50	2017/18	53	2018/19	67
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<p>A3 Activity</p>	<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>A3.1 Current year activity relates to 100 episodes</p> <p>A3.2 See A2.4</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 surgery and chemotherapy 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>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p>	<p>A4.1 – A4.3 Initial treatment is most commonly a radical or partial nephrectomy. Where the tumour is confined to the renal parenchyma, the five-year survival rate is 60% to 70%, but it is much lower when metastasis has occurred. Small tumours may be treated non-invasively with cryotherapy and radio-frequency ablation, both of which are the subject of guidance from the National Institute for Health and Care Excellence.[1][2][3] Renal cancer is relatively resistant to radiation therapy and chemotherapy, but sunitinib, temsirolimus, bevacizumab and other forms of immunotherapy can have some effect.</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</p>	<p>A5.1 The 'next best' alternative routinely commissioned treatment is surgery or chemotherapy</p>

	<p>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>A5.2 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. expected number dropping out due to side effects of drug, or</p>	<p>A6.1 The pathway would not change from that set out within A4.1.</p> <p>A6.2 Not applicable</p>

	<p>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>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10</p>	<p>A8.1 The underlying procedure would be recorded in SUS.</p> <p>A8.2 Not applicable</p>

	codes/procedure codes)	
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>A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</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 Not applicable</p>

	A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i>	A9.7 Not applicable
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 SABR is delivered for non-small cell lung cancer and clinical trials by 17 centres in England, or CtE in 17 centres (slightly different set) in England
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 No change and this indication will remain as part of the SABR CtE programme
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Tertiary centres by existing pathways 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 renal cancer.
	B2.3 Is the new policy likely to improve equity of access?	B2.3 Moving to a consistent commissioning position across England will improve equity of access.
	B2.4 Is the new policy likely to improve	B2.4 The policy will have no impact on equality of access or outcomes.

	equality of access / outcomes?	
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 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>B3.1 Some centres are already delivering this treatment as part of the SABR CtE programme and this will continue</p> <p>B3.2 Not applicable</p> <p>B3.3 Not applicable</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 be put into place.</p> <p>B3.6 No. There are no changes to provider/inter-provider governance arrangements.</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>B3.7 No change is expected.</p> <p>B3.8 The policy will be secured through the usual commissioning/decommissioning</p>
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 These services are not part of national collaborative commissioning or devolution 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	<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>C1.1 SABR is not covered by a national tariff</p> <p>C1.2/A</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 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>C1.3 Yes – the local price is based on the national radiotherapy tariffs.</p> <p>C1.4 The local price for 15-16 is £4,856 based on 5 SABR fractions. The price has been tested as part of the SABR CtE. For modelling, the price has been uplifted by 1.1% to 16-17 rates and by 10% to reflect average MFF.</p> <p>C1.5 N/A</p> <p>C1.6 No – policy is for Not Routine Commissioning</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 £7,389</p> <p>C2.2 £7,389</p>
C3 Overall Cost	C3.1 Indicate whether	C3.1 Small cost pressure of £11.8k

Impact of this Policy to NHS England	<p>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>	per annum as SABR is marginally cheaper than chemotherapy and current baseline assumes 5 SABR via IFR.
C4 Overall cost impact of this policy to the NHS as a whole	<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 – alternative treatment commissioned by NHS England.</p> <p>C4.2 Cost Pressure –see C3</p> <p>C4.4 No</p>
C5 Funding	C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. e.g. <i>decommissioning less</i>	C5.1 N/A – cost pressure is negligible as policy is for Not Routine Commissioning.

	<i>clinically or cost-effective services</i>	
C6 Financial Risks Associated with Implementing this Policy	<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>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p>C6.1 There are not expected to be any material financial risks associated with this policy</p> <p>C6.2 Not applicable</p> <p>C6.3 Not applicable</p>
C7 Value for Money	<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>
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i>	C8.1 Not applicable.

	C8.2 If so, confirm the source of funds to meet these costs.	C8.2 Not applicable.
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For public consultation