

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B01X26		
Policy Title	The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for patients with Hepatocellular carcinoma or Cholangiocarcinoma		
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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 Hepatocellular carcinoma and Cholangiocarcinoma</p> <p>A1.2 Primary tumours in the liver are much less common than ones which have metastasised there from elsewhere. The commonest primary liver tumour is hepatocellular carcinoma, which often develops from liver cells affected by chronic liver disease such as cirrhosis or hepatitis. Cholangiocarcinoma is less common, and arises from the cells</p>

	lining the bile ducts. It is estimated that this treatment pertains to approximately 100 patients that are currently treated using surgery, or 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 HCC and cholangiocarcinoma are rare and estimated to be around 1900 patients per annum in England.
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 It is anticipated that the number of patients presenting with HCC or cholangiocarcinoma will be in line with demographic changes. Not anticipating growth. It should be noted that the majority of patients within this cohort received either chemotherapy or surgery. The activity is described in A1.5 as 100 spells.
A1.7 What is the associated projected growth in activity (prior to applying the new	

	<p>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>A2.4 What is the resulting expected net</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 and 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 interventions associated</p>

	<p>increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?</p>	<p>with this policy</p> <p><i>Total Number of HCC / Cholangiocarcinoma spells</i></p> <p>2016/17 100 2017/18 100 2018/19 100</p> <p><i>Total Number of Surgeries</i></p> <p>2016/17 47 2017/18 47 2018/19 47</p> <p><i>Total Number of Chemotherapy spells</i></p> <p>2016/17 48 2017/18 48 2018/19 48</p> <p>It should be noted that recording of radiotherapy and chemotherapy activity on SUS is very limited.</p>
<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 The clinical pathway for Liver cancer does vary depending on a range of factors, notably the stage at which it is diagnosed. It is treated principally with surgery of chemotherapy.</p> <p>Patients with hepatocellular carcinoma (HCC) whose tumour is suitable for treatment such as hepatic resection, transarterial chemoembolization (TACE) or liver transplantation</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>A5.1 The 'next best' alternative routinely commissioned treatment is surgery or chemotherapy.</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 number who don't continue to treatment after having test to determine likely success). If possible please indicate likely</p>	<p>A6.1 The pathway would not change from that set out within A4.1.</p> <p>A6.2 Not applicable.</p>

	outcome for patient at each stopping point.	
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 codes/procedure codes)</p>	<p>A8.1 The underlying procedure would be recorded in SUS.</p> <p>A8.2 Not applicable</p>
A9 Monitoring	A9.1 Do any new or revised requirements	A9.1 Not applicable

	<p>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>A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to</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> <p>A9.7 Not applicable</p>
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	treatment? If so, please outline. <i>See also linked question in M1 below</i>	
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 liver 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 equality of access / outcomes?	B2.4 The policy will have no impact on equality of access or outcomes.

<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>B3.4 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>B3.1 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 No change is expected.</p>
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	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)	B3.8 The policy will be secured through the usual commissioning/decommissioning
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>C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that</p>	<p>C1.1 SABR is not covered by a national tariff</p> <p>C1.2 N/A</p> <p>C1.3 Yes – the local price is based on the national radiotherapy tariffs.</p>

	<p>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>C1.4 The local price for 15-16 is £6,992 based on 8 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 £5,638</p> <p>C2.2 £5,638</p>
C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.	C3.1 Cost Saving of £16.3k per year from reducing IFRs.

	C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	
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 Saving –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. <i>e.g. decommissioning less clinically or cost-effective services</i>	
C6 Financial Risks Associated with	C6.1 What are the material financial risks	C6.1 There are not expected to be any material financial risks

<p>Implementing this Policy</p>	<p>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>associated with this policy</p> <p>C6.2 Not applicable</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>