

Integrated Impact Assessment Report for Clinical Commissioning Policies		
Policy Reference Number	1913	
Policy Title	Stereotactic Ablative Body Radiotherapy (SABR) for Hepatocellular Carcinoma (HCC)	
Proposal	<u>for routine commission</u> (ref A3.1)	
Integrated Impact Assessment – Index		
Section A – Activity	Section B - Service	Section C – Finance
A1 Activity	B1 Service Organisation	C1 Tariff
A2 Existing Patient Pathway	B2 Geography & Access	C2 Average Cost per Patient
A3 Comparator (next best alternative treatment) Patient Pathway	B3 Collaborative Commissioning	C3 Overall Cost Impact of this Policy to NHS England
A4 New Patient Pathway		C4 Overall cost impact of this policy to the NHS as a whole
A5 Treatment Setting		C5 Funding
A6 Coding		C6 Financial Risks Associated with Implementing this Policy
		C7 Cost Profile

About this Impact Assessment: instructions for completion and explanatory notes
<ul style="list-style-type: none"> Each section is divided into themes with each theme setting out a number of questions. All figures should be provided up to 5 years only. The cost per patient methodology is impact against Year 0 rather than incrementally against the previous year. All questions are answered by selecting a drop-down option or including free text. Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.

- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.
- A bespoke financial model should be developed unless agreed otherwise. This will be worked up against a checklist of inputs/considerations. This will include the approach to regional allocations which will also be outlined in the Commissioning Plan.

Section A - Activity Impact

A1 Activity

To be completed by the Clinical Policy Team

A1.1 Provide the number of patients eligible for the treatment. If different, also provide the number of patients accessing treatment.

Include OPCS codes where applicable.

150

Source: Policy Working Group

This policy replaces an existing not for routine commissioning policy. Patients have been able to access treatment previously under the SABR Commissioning through Evaluation (CtE) programme. 91 patients were treated under the CtE programme through 7 designated centres.

A2 Existing Patient Pathway (complete where additional information outside the policy proposition is likely to be beneficial)

To be completed by the Clinical Policy Team

A2.1 **Existing pathway:** Describe the relevant currently routinely commissioned:

- Treatment or intervention
- Patient pathway
- Eligibility and/or uptake estimates.

Current treatments for people with HCC include:

- Surgery;
- Transarterial chemoembolisation (TACE);
- Radiofrequency ablation (RFA); or
- Systemic chemotherapy.

This policy is specifically for people who are unsuitable for any of the treatments listed above or as an alternative treatment option for some people currently being treatment with either RFA or systemic chemotherapy, delaying or avoiding the use of the treatments.

	<i>Source: Policy Proposition</i>
<p>A2.2 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? 	<ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 100% e) 100%
<p>A3 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option) <i>To be completed by the Clinical Policy Team</i></p>	
<p>A3.1 Next best comparator: Is there another 'next best' alternative treatment which is a relevant comparator? <i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> • <i>Treatment or intervention</i> • <i>Patient pathway</i> • <i>Actual or estimated eligibility and uptake</i> 	Not applicable – see section A2.
<p>A3.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> f) Be clinically assessed for treatment g) Be considered to meet an exclusion criteria following assessment h) Choose to initiate treatment i) Comply with treatment 	Not applicable – see section A2.

j) Complete treatment?	
A4 New Patient Pathway <i>To be completed by the Clinical Policy Team</i>	
<p>A4.1 Specify the nature and duration of the proposed new treatment or intervention. For example, e.g patients receive a course of treatment over 6 cycles with the drug being administered via IV infusion on days 1 and 3 of each cycle.</p> <p>Include OPCS codes where applicable.</p>	<p><u>Time limited</u></p> <p>It is expected that prescription doses of 40-50 Gray (Gy) in 5 fractions of SABR should be delivered in the treatment of HCC.</p> <p><i>Source: Policy Proposition.</i></p>
A5 Treatment Setting <i>To be completed by the Clinical Policy Team</i>	
A5.1 How is this treatment delivered to the patient?	<p>SABR is delivered in an outpatient setting and includes:</p> <ul style="list-style-type: none"> • Appointment 1: Oncologist / Consent • Appointment 2: Pre-treatment preparations and planning • Appointment 3: Pre-treatment planning checks • Treatment: delivered over 5 fractions.
A5.2 What is the current number of contracted providers for the eligible population by region?	<p>As part of the CtE programme, 7 centres offered SABR treatment including for this indication. However, a total of 25 centres offer SABR treatment across England.</p>

<p>A5.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p>TBC – There is no impact on the delivery of this treatment as a result of this policy. However, capacity requirements will require consideration. This is because this policy expands access beyond the CtE recruitment numbers to enable all eligible patients within this cohort to access treatment.</p>																				
<p>A6 Coding</p>																					
<p>A6.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Aggregate Contract Monitoring</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level drugs dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level devices dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Clinical Database**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other**</td> <td><input type="checkbox"/></td> </tr> </table> <p>**Radiotherapy Treatment Dataset (RTDS)</p>	Aggregate Contract Monitoring	<input checked="" type="checkbox"/>	Patient level contract monitoring	<input checked="" type="checkbox"/>	Patient level drugs dataset	<input type="checkbox"/>	Patient level devices dataset	<input type="checkbox"/>	Devices supply chain reconciliation dataset	<input type="checkbox"/>	Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>	Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>	National Return**	<input checked="" type="checkbox"/>	Clinical Database**	<input type="checkbox"/>	Other**	<input type="checkbox"/>
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<p>A6.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p>Aggregate Contract Monitoring.</p>																				

A6.3 Identification Rules for Devices: How are device costs captured?	<u>Not applicable</u>
A6.4 Identification Rules for Activity: How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)	<u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u> NCBPS01R Radiotherapy
<p style="text-align: center;">Section B - Service Impact <i>To be completed by the Lead Commissioner</i></p>	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Radiotherapy services are currently accessed through tertiary centres. As part of the CtE programme, 7 centres offered SABR treatment including for this indication. However, a total of 25 centres offer SABR treatment across England. <i>Source: SABR Commissioning through Evaluation Programme</i>
B1.2 Will the proposition change the way the commissioned service is organised?	<u>TBC</u> If the policy is approved, it is anticipated that in the first-year treatment will be provided by the CtE participating centres. However, it is anticipated that treatment provision will be expanded over the coming years, in line with the commitments for radiotherapy outlined in the Long Term Plan.

B2 Geography & Access	
B2.1 How is the service currently accessed (e.g., self referral, referral from GP, secondary care, other)	Secondary care and/or tertiary care.
B2.2 What impact will the new policy have on the sources of referral?	<p><u>Increase</u></p> <p>This policy expands access beyond the CtE recruitment numbers to enable all eligible patients within this cohort to access treatment.</p>
B2.3 Is the new policy likely to improve equity ¹ of access?	<p><u>Increase</u></p> <p>See section B2.2.</p>
B2.4 Is the new policy likely to improve equality ¹ of access and/or outcomes?	<p><u>Increase</u></p> <p>This policy has been developed in line with the results of a CtE programme and an evidence review. This policy expands access beyond the CtE recruitment numbers to enable all eligible patients within this cohort to access treatment.</p>
B3 Commissioning Responsibility	

¹ <https://www.england.nhs.uk/wp-content/uploads/2016/02/nhse-specific-duties-equality-act.pdf>

B3.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. new service (NHS England responsibility), future CCG lead, devolved commissioning arrangements, STPs)

No change - NHSE

Section C - Finance Impact

To be completed by the Finance Lead with the exception of C1.2

C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?
Only specify for the relevant section of the patient pathway

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
	Excluded from tariff – pass through	<input type="checkbox"/>
	Excluded from tariff – other	<input type="checkbox"/>
Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
	Excluded from tariff (excluding HCTED programme) – pass through	<input type="checkbox"/>
	Excluded from tariff (excluding HCTED) – other	<input type="checkbox"/>
	Via HCTED model	<input type="checkbox"/>
Activity	Paid entirely by National Tariffs	<input checked="" type="checkbox"/>
	Paid entirely by Local Tariffs	<input type="checkbox"/>
	Partially paid by National Tariffs	<input type="checkbox"/>
	Partially paid by Local Tariffs	<input type="checkbox"/>

	<table border="1"> <tr> <td data-bbox="1084 97 1243 156"></td> <td data-bbox="1243 97 2042 156">Part/fully paid under a Block arrangement</td> <td data-bbox="2042 97 2145 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 156 1243 215"></td> <td data-bbox="1243 156 2042 215">Part/fully paid under Pass-Through arrangements</td> <td data-bbox="2042 156 2145 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 215 1243 274"></td> <td data-bbox="1243 215 2042 274">Part/fully paid under Other arrangements</td> <td data-bbox="2042 215 2145 274"><input type="checkbox"/></td> </tr> </table>		Part/fully paid under a Block arrangement	<input type="checkbox"/>		Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>		Part/fully paid under Other arrangements	<input type="checkbox"/>
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	Part/fully paid under Other arrangements	<input type="checkbox"/>								
<p>C1.2 Drug Costs <i>(to be completed by the Clinical Policy Team)</i></p> <p>Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption.</p> <p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>Not applicable.</p>									
<p>C1.3 Device Costs <i>(to be completed by LC)</i></p> <p>Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>Not applicable.</p>									
<p>C1.4 Activity Costs covered by National Tariffs <i>(to be completed by Finance)</i></p> <p>List key HRG codes and descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %). Include details of first and follow up outpatients appointment etc.</p>	<p>Planning code:</p> <p>Between 1 and 3 x HRG SC41Z Preparation for Intensity Modulated Radiation Therapy, with Technical Support @ £1,317</p> <p>Treatment code:</p> <p>Either 3, 5 or 8 x HRG SC31Z Deliver a Fraction of Adaptive Radiotherapy on a Megavoltage Machine @ £151</p>									

<p>C1.5 Activity Costs covered by Local Tariff <i>(to be completed by Finance)</i></p> <p>List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how it has been derived, validated and tested.</p>	<p>Not applicable.</p>
<p>C1.6 Other Activity Costs not covered by National or Local Tariff <i>(to be completed by Finance)</i></p> <p>Include descriptions and estimates of all key costs.</p>	<p>Not applicable.</p>
<p>C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?</p>	<p><u>No</u></p>
<p>C2 Average Cost per Patient</p>	
<p>C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?</p>	<p>Model assumptions:</p> <ul style="list-style-type: none"> • A maximum of three different sites treated with: <ul style="list-style-type: none"> ○ 70% of patients (1,540) with one site treated ○ 20% of patients (440) with two sites treated ○ 10% of patients (220) with three sites treated <p>The average cost of each patient is £2,842</p>
<p>C3 Overall Cost Impact of this Policy to NHS England</p>	

<p>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. Use list prices where drugs and devices are included. Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.</p>	<p><u>Cost pressure</u></p> <table border="1" data-bbox="1093 181 1603 456"> <tr> <td>Year 1</td><td>£426.3k</td></tr> <tr> <td>Year 2</td><td>£429.1k</td></tr> <tr> <td>Year 3</td><td>£434.8k</td></tr> <tr> <td>Year 4</td><td>£437.6k</td></tr> <tr> <td>Year 5</td><td>£437.6k</td></tr> </table> <p>The cost shown above is the gross impact of the SABR treatment only, costed at national tariffs.</p> <p>Outpatient appointment costs are not expected to significantly change from the current pathway and have therefore not been included.</p>	Year 1	£426.3k	Year 2	£429.1k	Year 3	£434.8k	Year 4	£437.6k	Year 5	£437.6k
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<p>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</p>	<p>Not applicable.</p>										
<p>C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?</p>	<p>Not applicable.</p>										
<p>C4 Overall cost impact of this policy to the NHS as a whole</p>											
<p>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</p>	<p>Budget impact for CCGs: <u>No impact on CCGs</u></p> <p>Budget impact for providers: <u>No impact on providers</u></p>										

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u>Cost pressure</u></p> <table border="1"> <tr> <td>Year 1</td> <td>£426.3k</td> </tr> <tr> <td>Year 2</td> <td>£429.1k</td> </tr> <tr> <td>Year 3</td> <td>£434.8k</td> </tr> <tr> <td>Year 4</td> <td>£437.6k</td> </tr> <tr> <td>Year 5</td> <td>£437.6k</td> </tr> </table>	Year 1	£426.3k	Year 2	£429.1k	Year 3	£434.8k	Year 4	£437.6k	Year 5	£437.6k
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C4.3 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<u>No</u>										
C5 Funding											
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG prioritisation reserves.										
C6 Financial Risks Associated with Implementing this Policy											
C6.1 Describe the parameters used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.	The projected number of patients is reasonably robust due to the previous CtE programme, and therefore it has not been viewed as necessary to model a range of scenarios. As the treatment is based on a cost per patient, the overall cost will vary directly in line with the number of patients.										

	For the purpose of this policy, the use of SABR has been calculated as an additional line of treatment, however, it is possible that in some patients the treatment may avoid the use of RFA or systemic cancer treatments.
C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	Not applicable.
C7 Cost Profile	
C7.1 Factors which impact on costs	<u>None.</u>

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing not for routine commissioning

Appendix A – Current Patient Population & Demography / Growth (for Public Health Lead to complete)

		Source	Please specify any further detail
Number of patients who meet the proposed commissioning criteria and who would be treated if the proposal is approved per year.	150	Policy Working Group	
Age group for which the treatment is proposed according to the proposed criteria	Adults	Policy proposition	

Age distribution of the patient population eligible according to the proposed criteria	Not applicable.	Policy proposition	
How is the population currently geographically distributed	Evenly	Policy proposition	
What are the growth assumptions for the disease / condition?	ONS growth only.	Policy proposition	
Is there evidence of current inequalities in access to service or outcomes?	Yes. See Section B2 of Impact assessment.	Impact assessment	
Is there evidence that implementing the policy/service specification will improve current inequities of access or outcomes?	Yes. See Section B2 of Impact assessment.	Impact assessment	