Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B01X15		
Policy Title	The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option in the management of patients with Spinal arteriovenous malformations, meningiomas and schwannomas		
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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?	A1. 1 This policy proposes to routinely commission SABR as a treatment option for patients with Spinal meningiomas and schwannomas
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 It is estimated that approximately 40 patients per year would receive SABR to spinal tumours. These tumours are usually treated surgically, but this can be difficult in surgically inaccessible sites or those near critical structures.

	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 Meningiomas are tumours arising from the meninges, the membranous layers surrounding the central nervous system. Most are benign, and many are asymptomatic. They can however cause seizures and focal neurological symptoms. Schwannomas are tumours of the nerve sheath and usually benign but can produce symptoms from nerve compression.
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.540 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 spinal tumours will be in line with demographic changes. Not anticipating growth.
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	A1.7 It should be noted that the majority of patients within this cohort received surgery. The activity is described in A1.5 as 40 spells.

	A1.8 How is the population currently distributed geographically?	A1.8 The distribution of these tumours is difficult to assess with certainty given the known issues in disease classification and recording.
A2 Future Patient Population & Demography	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?	A2.1The policy moves to a 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 but does now include the additional option of spinal SABR
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	A2.2 Growth is anticipated to be in line with demographic changes
	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.	A2.3 Overall this is a less common disease and therefore the only likely drivers of demand for treatment relates to demographic change. For these reasons, growth has been set to zero.
	A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the	A2.4 There is no change in the total number of interventions associated with this policy but it is estimated that up to 40patients per year will receive SABR instead of surgery or

	treatment per year in year 2, 5 and 10?	conventional radiotherapy. *Total Number of Spinal tumour spells* *2016/17 40* *2017/18 40* *2018/19 40* *Total Number of Surgeries* *2016/17 17* *2017/18 17* *2018/19 17* *Total Number of Radiotherapy Episodes* *2016/17 18* *2017/18 18* *2018/19 18* IFR SABR = 5 in 2015/16 It should be noted that recording of radiotherapy and chemotherapy activity on SUS is very limited.
A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet. 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.	A3.1 Current activity is described in A1.5 A3.2 As described in A2.4 there is expected to be a shift in activity from spinal surgery to SABR. This is estimated to be in the region of 40 spells per year

	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.	A3.3 The activity under the "Do Nothing" is described in A1.7
A4 Existing Patient Pathway	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. A4.2. What are the current treatment access criteria? A4.3 What are the current treatment stopping points?	A4.1 – A4.3 All patients being considered for SABR must have undergone prior assessment by the local brain & CNS tumours multi-disciplinary team (MDT), who should take into consideration the patients comorbidities, likely outcome of treatment and life expectancy. Conventionally fractionated RT versus SABR should be specifically discussed as an option in the neurosciences MDT A4.3 Patients who have previously tried and failed SRS; OR Operable tumours; OR Stable tumours without progressive symptoms or progressive growth as assessed by serial imaging; OR Larger or diffuse lesions more effectively treated with conventional fractionated external beam radiotherapy.
A5 Comparator (next best alternative treatment) Patient	A5.1 If there is a 'next best' alternative routinely commissioned	A5.1The 'next best' alternative routinely commissioned treatment is surgery or conventional

Pathway	treatment what is the current patient pathway? Describe or include a figure to outline associated activity. 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.	radiotherapy. Then discussion in an SRS/T MDTM with spinal neurosurgeons and neuro-oncologists present. Treatment should take place in a commissioned tier1 / 2 SRS/T centre with appropriate equipment and expertise to deliver both SABR and SRS/T and be delivered by a neuro-oncologist (or neurosurgeon) who is a member of the SRS/T MDT and the spinal cord tumours MDT A5.2 Not applicable
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. A6.2 Where there are different stopping points on the pathway	A6.1 The pathway would not change from that set out within A4.1. A6.2 Not applicable.

	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.	
A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.1 The treatment is carried out in an out-patient setting. A7.2 Changes from in-patient surgery to out-patient radiotherapy in some cases
A8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will	A8.1 The underlying procedure would be recorded in SUS.

	activity related to the new patient pathway be recorded?	
	A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.2 SABR coding but local prices
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	A9.1 Not applicable
	A9.2 If this treatment is a drug, what pharmacy monitoring is required?	A9.2 Not applicable
	A9.3 What analytical information /monitoring/ reporting is required?	A9.3 Not applicable
	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.4 Not applicable
	A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 Not applicable

	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 Not applicable
	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*	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. SRS/T will be delivered in 17-23 centres.
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 This is a new service and will need to be established as part of an existing SRS/SRT and SABR service only
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 spinal tumours.

	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.
B3 Implementation	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?	B3.1 Centres will need a lead in time to a) establish centres in England b) pre-assessment QA
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 Not applicable
	B3.3 Is there a change in provider staffing required?	B3.3 Not applicable
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 No. There are no new dependencies associated with this policy.
	B3.5 Are there changes in the support services that need to be in place?	B3.5 No. There are no changes to the support services that need to put into place.

	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 No. There are no changes to provider/inter-provider governance arrangements.
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 No change is expected.
	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	C1.1 Is this treatment	C1.1 SABR is not covered by a

	paid under a national prices*, and if so which?	national tariff
	C1.2 Is this treatment excluded from national prices?	C1.2 N/A
	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 Yes – the local price is based on the national radiotherapy tariffs.
	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?	C1.4 The local price for 15-16 is £4,144 based on 4 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.
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 N/A
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 No.
C2 Average Cost per Patient	C2.1 What is the revenue cost per	C2.1 £4,609

	patient in year 1? C2.2 What is the revenue cost per patient in future years (including follow up)?	 C2.2 £4,609
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. C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	C3.1 Cost Saving of £20k per year as SABR is less expensive than spinal surgery.
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs). C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole. C4.3 Where this has not been identified, set out the reasons why this cannot be measured. C4.4 Are there likely to be any costs or savings for non NHS	C4.1 Cost Neutral – alternative treatment commissioned by NHS England. C4.2 Cost Saving –see C3 C4.4 No

	commissioners / public sector funders?	
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*	C
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy? C6.2 Can these be mitigated, if so how? C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.1 There are not expected to be any material financial risks associated with this policy C6.2 Not applicable C6.3 Not applicable
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature* C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	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. C7.2 No risks have been identified as evidence of cost effectiveness was not identified.

C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	C8.1 Not applicable.
	C8.2 If so, confirm the source of funds to meet these costs.	C8.2 Not applicable.