Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B13X04		
Policy Title	Stereotactic radiosurgery/radiotherapy for ependymoma, haemangioblastoma, pilocytic astrocytoma and trigeminal schwannoma		
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Section K - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1. 1 This policy proposes to **routinely commission** stereotactic radiosurgery (SRS) or stereotactic radiotherapy (SRT) for patients with the following rare intracranial tumours: • **Ependymomas:** In the UK, approximately 9,700 people are diagnosed with tumours of the central nervous system each year. Around 2-5% of these are ependymomas, which would equate to between 180-450 cases per year in the UK, or 150-380 cases per year in England.[i] • **Haemangioblastomas:** Haemangioblastomas account for	

		around 2% of all brain tumours. This would roughly equate to around 190 new cases of haemangioblastoma per year in the UK, or 160 new cases in England.[ii] • **Pilocytic Astrocytoma:** The incidence of pilocytic astrocytomas is 0.37 per 100,000 persons per year[iii]. This equates to approximately 200 cases per year in England. The cystic form of pilocytic astrocytoma is found in more than 75% of patients. • **Trigeminal Schwannoma:** Trigeminal schwannomas (TS) are rare and there is limited information around the prevalence. Evidence from a number of case series suggest they account for between 1% and 8% of all intracranial schwannomas. In a large case series of 111 patients (seen over 30 years)[iv], TS accounted for 0.3% of the 37,000 intracranial tumours and 5.8% of intracranial neuromas undergoing surgery during that period. This would equate to approximately 65 cases per year across the UK, 55 in England.[v] Across all indications, the number of new cases in England in 2014/15 may therefore be in the region of **565 to 795.**
	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 Patients eligible for SRS/SRT would be those with the conditions as specified in K1.1 and who fail or are ineligible for surgery as a first line treatment. Given the variety of determining factors it is hard to get a robust estimate of the numbers of individuals likely to be eligible for SRS/SRT for the treatment of other tumours. Clinicians estimate that approximately 140 patients per year across all four indications might be considered for SRS/SRT for recurrent or residual disease.[vi] There is uncertainty around the number of patients who would go on to receive SRS/T; however the best estimate is in the region of **90 patients per year**.[vii]

	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is intended for all ages (children and adults).
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 The age distribution across the different conditions might be as follows[viii]: • **Ependymomas:** Although they can occur at any age, the posterior fossa tumours tend to present more commonly in the paediatric age group (mean age at diagnosis is 6 years of age), with a smaller second peak for supratentorial tumours around the 3rd decade[ix]. • **Haemangioblastomas:** These usually develop in middle age. • **Pilocytic Astrocytoma:** It is most commonly found in children and young adults but can occur in adults. • **Trigeminal Schwannoma:** Patients usually present in middle age, typically the 3rd to 4th decades.[x]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 The five management options for this patient group are: [xi] • Surgical removal (the primary option for most tumours); • Stereotactic radiosurgery (SRS) or (SRT), the subject of this policy; • Fractionated radiotherapy; • Proton beam therapy (where commissioned and in line with policies); or • No intervention. Treatment options will take into consideration the precise anatomical position of the lesion, its size (dictating the perceived risk of

			alternative intervention with microsurgery), the presentation (clinical symptoms and signs of brain stem dysfunction necessitates surgical removal, complete or partial), and the risk of microsurgery.[xii] SRS/SRT would be considered in the patient pathway only after primary surgical resection has been performed, or the tumour has been deemed inoperable.[xiii] If SRS/SRT is not a safe or feasible option, patients may either be considered for surgery or to have conventional fractionated radiotherapy.[xiv] The **c. 90 eligible patients** for SRS/SRT each year, as identified in K1.2, are expected to be currently receiving one of:[xv] • SRS/SRT; • Fractioned radiotherapy; or • No treatment. The activity across each of the management options above is unknown, however it is expected that fractionated radiotherapy would be most frequently used.[xvi] These management options are assumed to hold across each of the indications in K1.1; however it is acknowledged that for those with haemangioblastomas, there is some uncertainty around what they may receive.[xvii]
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 The number of new cases of these rare intracranial tumours, as identified in K1.1, would be expected to increase in line with demographic growth.[xviii] In future years this could be in the region of:[xix] • ~ 575 to 805 in 2016/17 (year 1) • ~ 575 to 810 in 2017/18 (year 2) • ~ 590 to 830 in 2020/21 (year 5)

	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	K1.7 As discussed in K1.5, it is uncertain how the c. 90 eligible patients are currently treated across SRS/SRT, fractionated radiotherapy or no treatment. It is expected that these c. 90 patients would increase over time in line with demographic growth,[xx] and is estimated to be[xxi]: • ~ 91 in 2016/17 (year 1) • ~ 92 in 2017/18 (year 2) • ~ 94 in 2020/21 (year 5)
	K1.8 How is the population currently distributed geographically?	K1.8 Across England, no specific geographical differences have been identified within this review.
K2 Future Patient Population & Demography	K2.1 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?	K2.1 The new policy proposes to move to a **routinely commissioned** position for SRS/SRT for the target population as defined in K1.2.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	K2.2 Over time there may be a growth in numbers if surgical practice begins to incorporate SRS/SRT treatment for such tumours, in an endeavour to move away from high risk radical excision to a more conservative approach combining two treatment modalities in order to reduce morbidity and achieve a better outcome for the patient.
	K 2.3 Are there likely to be changes in geography/demography of the patient	K2.3 None identified.

	population and would this impact on activity/outcomes? If yes, provide details.	
	K2.4 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?	K2.4 It is estimated that under the policy, all c. 90 patients would now receive SRS/SRT. As discussed in K1.5, there is uncertainty around how many patients currently receive SRS/SRT, compared to other treatment options. As such, the following scenarios for **net increase** have been considered[xxii]: • **All activity** (c. 90 additional patients). This assumes that no patients receive SRS/SRT in the 'do-nothing'; • **50% of activity** (c. 45 additional patients) receive SRS/SRT; or • **10% of activity** (c. 9 additional patients) receives SRS/SRT. This would lead to a range in the **net increase in SRS/SRT** activity of[xxiii]: • ~ 9 to 91 in 2016/17 (year 1) • ~ 9 to 92 in 2017/18 (year 2) • ~ 9 to 94 in 2020/21 (year 5) The majority of these patients would, however, be receiving treatment in the 'do-nothing' case as identified in K1.5. It is expected that the net increase in SRS/SRT activity above would be associated with a corresponding **net decrease** in patients receiving either fractionated radiotherapy or no intervention. It is assumed that where SRS/SRT was not being received, c. 90% would likely receive fractionated radiotherapy and c.10% no treatment.[xxiv] Therefore the net decrease in fractionated radiotherapy activity could be in the region of:

		• ~ 8 to 82 in 2016/17 (year 1) • ~ 8 to 83 in 2017/18 (year 2) • ~ 8 to 84 in 2020/21 (year 5) And a reduction in those patients receiving 'no intervention' of: • ~ 1 to 9 in 2016/17 (year 1) • ~ 1 to 9 in 2017/18 (year 2) • ~ 1 to 9 in 2020/21 (year 5)
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	K3.1 Current annual activity is identified in K1.5.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	K3.2 Based on K1.7 and K2.4, the total activity under the policy for the target patient group identified in K1.2 is expected to be: For SRS/SRT: • ~ 91 in 2016/17 (year 1) • ~ 92 in 2017/18 (year 2) • ~ 94 in 2020/21 (year 5) It is further expected that **no patients** would now receive either fractionated radiotherapy or no treatment.
	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in	K3.3 In a do nothing scenario, it is assumed that current activity will continue to be steady state. Please refer to K1.5 for the do-nothing.

	accompanying excel sheet.	
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	K4.1 Surgical resection (microsurgery) is the standard first line treatment for all of these tumour types. There is no currently routinely commissioned pathway for patients who would meet the inclusion criteria for SRS/SRT. Some are likely to already be undergoing SRS/SRT, others are likely to be undergoing higher risk surgery, some are likely to have no treatment and the remainder to be having fractionated radiotherapy. This will vary depending on historical clinical practice and the individual patient circumstances.
	K4.2. What are the current treatment access criteria?	K4.2 Not applicable. There are currently no standard treatment access criteria for alternative treatments.
	K4.3 What are the current treatment stopping points?	K4.3 As above, there are currently no standard stopping points for alternative treatments.
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 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.	K5.1 There is no 'next best' alternative routinely commissioned treatment.
	K5.2 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	K5.2 Not applicable.

	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.	
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.	K6.1 All patients must first be considered by the local brain & CNS tumours MDT (neuro-oncology, skull-base, pituitary, spinal cord or paediatric), who can decide on the appropriateness of onward referral to an agreed SRS/SRT centre, whether local or not. The service will accept referrals after discussion in the specialist MDT in line with eligibility and referral guidelines. The provider of SRS treatment will discuss all referrals in an SRS MDT prior to accepting the patient for treatment. SRS/SRT would be considered in the patient pathway only after primary surgical resection has been performed, or the tumour has been deemed inoperable, in accordance with the commissioning criteria set out in the policy proposition.
	K6.2 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.	K6.2 Not applicable – there are no stopping criteria for SRS as it is a one-off package of treatment.

K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery	K7.1 This treatment is typically an inpatient procedure. A 1 or 2 night stay would be expected.[xxv]
	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.2 No anticipated change in delivery setting as SRS is currently commissioned for other indications and thus the infrastructure is already in place. No anticipated increase in capacity requirements.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 Given this is an inpatient procedure; this would be recorded in SUS central data collections.
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 Activity could be identified using a combination of ICD-10 and OPCS codes[xxvi].
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 No.
	K9.2 If this treatment is a drug, what	K9.2 Not applicable.

	pharmacy monitoring is required?	
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 No new reporting required - SRS activity should be monitored through routine contract monitoring via SUS.
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 No new reporting required - SRS activity should be monitored through routine contract monitoring via SUS.
	K9.5 Is there linked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 No.
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 No.
	K9.7 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*	K9.7 No.
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions

		made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 SRS is organised in specialist SRS centres.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 – No change anticipated.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 – Current referrals for SRS/SRT come from brain and CNS tumour MDTs, who determine the appropriateness of onward referral.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 - No
	L2.3 Is the new policy likely to improve equity of access?	L2.3 – Yes, through having a consistent commissioning position across the country.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 – Yes, through having a consistent commissioning position across the country.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 – None identified.

	L3.2 Is there a change in provider physical infrastructure required?	L3.2 – None identified.
	L3.3 Is there a change in provider staffing required?	L3.3 – No.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 – No.
	L3.5 Are there changes in the support services that need to be in place?	L3.5 – No.
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 – No.
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 – No.
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g.	L3.8 – Through publication of the commissioning policy and notification to providers.

	publication and notification of new policy, competitive selection process to secure revised provider configuration)	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 – No.
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 Yes. The current weighted average price for SRS/SRT relating to the brain is estimated to be c. £7,311[xxvii]. *Please note that there is currently a national procurement being undertaken for this, and as such it could be expected that the price for this procedure may fall in future years.*[xxviii]
	M1.2 Is this treatment excluded from national prices?	M1.2 No, see M1.1.
	M1.3 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?	M1.3 Please refer to M1.1.

	M1.4 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?	M1.4 Not applicable
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 VAT would be recoverable under certain specific conditions[xxix]. It is assumed here that VAT would not be recoverable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 No.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 The cost per patient in the first year is expected to include the following: [xxx] 1. **Pre-assessment.** In the form of both a specialist MDT and an SRS/SRT MDT appointment. This could cost c. £324.[xxxi] 2. **The procedure**. The average cost of SRS/SRT for the brain is c. £7,311 as described in M1.1. 3. **Follow-up.** Both shortly after treatment and then 6-monthly in the first year. This could cost c. £264.[xxxii] The total cost per patient could therefore be: c. **£7,900** in year 1. For the comparator treatment, fractionated radiotherapy, the pathway is expected to be the same as above, expect step 2, the procedure cost, would be replaced with the cost of 30 fractions of radiotherapy,[xxxiii] at an estimated to cost c. £7,180. [xxxiv] As such, the

		total cost for the comparator treatment is c. **£7,770** in year 1, broadly similar to the cost of SRS/SRT above.[xxxv]
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Patients would be expected to be followed-up either annually or every other year, at an expected cost of c. £88 per attendance, plus the cost of any imaging where applicable.[xxxvi]
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.	M3.1 Based on the scenarios for the net change in activity discussed in K2.4, and the costs per patient in M2.1, this policy is expected to range between being **broadly cost neutral** to a **cost pressure** of c. £80k each year to NHS England, with a mid-cost pressure of c. £40k each year. This cost impact is comprised of the following impacts: 1. Patients who previously received fractionated radiotherapy would now receive SRS/SRT (the cost impact here would be on the difference in the costs identified in M1.1); and 2. Patients who previously received no treatment who now receive SRS/SRT (the cost impact here would be the additional cost of receiving SRS/T).
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured.	M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	M4.1 This is expected to be **cost neutral** to other parts of the NHS.

	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.	M4.2 Based on the cost impacts identified in M3.1 and M4.1, this is expected to range between being **broadly cost neutral** to a **cost pressure** of c. £80k per year to the NHS as a whole, borne by NHS England, with a mid-cost pressure of c. £40k each year.
	M4.3 Where this has not been identified set out the reasons why this cannot be measured.	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 None identified.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. *e.g. decommissioning less clinically or cost-effective services*	M5.1 For consideration at CPAG.
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 No material risks have been identified.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested	M6.3 Please refer to K2.4 for the scenarios considered.

	to generate best case, worst case and most likely total cost scenarios?	
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 We did not identify any studies assessing the cost-effectiveness of SRS or SRT for the indications within this policy proposition.
	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 Not applicable.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	M8.1 No
	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable

[i] See policy proposition

[ii] Cancer research UK – see policy proposition.

[iii] As per policy proposition

[iv] This is based on a study undertaken between 1961 and 1994 at one Russian hospital – see policy proposition.

[v] Applying the proportion from the literature to incidence figures from NHS England's existing commissioning policy and Cancer UK incidence figures

[vi] See policy proposition – based on discussions with the policy working group

[vii] Based on discussions with the policy working group

[viii] Based on discussions with the policy working group - see policy proposition

[ix] Smith A, Smirniotopoulos J, Horkanyne-Szakaly I. From the Radiologic Pathology Archives: Intraventricular Neoplasms: Radiologic-Pathologic Correlation. Radiographics. 2013;33 (1): 21-43

[x] Trigeminal schwannoma, Dr Bruno Di Muzio and A.Prof Frank Gaillard et al. Source: http://radiopaedia.org/articles/trigeminal-schwannoma accessed on 8 February 2016

[xi] Please refer to the policy proposition

[xii] Please refer to the policy proposition

[xiii] Please refer to the policy proposition

[xiv] Please refer to the policy proposition

[xv] Based on discussions with the policy working group

[xvi] Based on discussions with the policy working group

[xvii] Based on discussions with the policy working group

[xviii] Based on discussions with the policy working group

[xix] This applies the prevalence rate to ONS (2012) population projections for England in 2014/15. Please note that figures are rounded to the nearest 5.

[xx] Based on discussions with the policy working group

[xxi] This applies the prevalence rate to ONS (2012) population projections for England in 2014/15.

[xxii] Based on discussions with the policy working group

[xxiii] Based on discussions with the policy working group

[xxiv] Based on discussions with the policy working group

[xxv] Based on conversation with the policy working group

[xxvi] NICE (https://www.nice.org.uk/guidance/ipg85) recommend coding Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife using: X65.4 Delivery of a fraction of external beam radiotherapy NEC, Y91.8 Other specified external beam radiotherapy, Y11.7 Gamma wave destruction of organ NOC.

[xxvii] Based on data received from NHS England Finance Lead. As this is based on local prices, MFF adjustments have already been accounted for.

[xxviii] Based on discussions with the policy working group

[xxix] Please refer to Section 3.2 of VAT Notice 701/557 (https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products)

[xxx] Based on conversations with the policy working group, Source: 2014/15 national tariff where a 10% MFF uplift has been applied. An efficiency factor of 3.5% and inflation of 1.9% have been applied to uplift to 2015/16 prices. These are assumed constant for future years.

[xxxi] General Surgery Outpatient First-attendance, multi professional (x 2)

[xxxii] General Surgery Outpatient Follow-up attendance, single-professional (x 3)

[xxxiii] Based on discussions with the policy working group

[xxxiv] Prices are from the 2014/15 National Tariff. This is based on the patient receiving preparation for radiotherapy (HRG code SC41Z: Preparation for Intensity Modulated Radiation Therapy, with Technical Support, £1,296) and 30 fractions of radiotherapy (HRG code: SC31Z: Deliver a Fraction of Adaptive Radiotherapy on a Megavoltage Machine, £178 per fraction). All figures include a 10% MFF uplift and are uplifted to 2015/16 prices with a -3.5% efficiency factor and 1.9% inflation uplift. (Source: based on discussions with the NHS England Finance Lead).

[xxxv] It is expected that some activity may be charged for fractionated radiotherapy under the HRG codes SC51Z and SC23Z, which could cost c. £2,640 less per patient that if SC41Z and SC31Z were used.

[xxxvi] Based on discussions with the policy working group