Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B13X06		
Policy Title	Stereotactic radiosurgery (SRS) for adults with Parkinson's tremor and Familial Essential Tremor		
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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 **not routinely commission** the use of stereotactic radiosurgery for patients with Parkinson's and Familial Essential Tremor. Prevalence estimates for this patient group vary widely. Essential tremor has a reported prevalence of between 500 and 850 per 100,000 in England and the UK respectively[i,ii]. The prevalence of Parkinson's is estimated to range between 100 and 300 per 100,000.[iii,iv,v, vi] These conditions are therefore estimated to affect between 330,000 and 630,000 people in	

		England[vii].
	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 This policy is targeted at only a subset of the prevalent population; those who are resistant to drugs or where drug side effects are intolerable. It is estimated that fewer than 10 patients would be eligible for SRS in England each year under the proposed policy.[viii]
	K1.3 What age group is the treatment indicated for?	K1.3 This policy would apply only to adults (aged 18 and over).
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 These conditions mainly affect patients above the age of 60 with the highest prevalence amongst patients aged 75 and above. Men are estimated to be c.30%-50% more likely to suffer from Parkinson's or severe tremor.[ix,x] It is estimated that only 4-8% of patients with Parkinson's are younger than 50.[xi]
	K1.5 What is the current annual activity for the target population covered under the new policy?	K1.5 No patients currently receive SRS for Parkinson's or Familial Essential Tremor[xii]. If pharmacotherapy is ineffective then these patients currently receive no further therapies but will continue to be followed up by their neurology team[xiii].
	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 Both Parkinson's and Familial Essential Tremor are expected to grow in line with an ageing population[xiv]. These conditions could therefore affect[xv]: • ~ c. 338k – 648k in 2016/17 (year 1) • ~ c. 344k – 660k in 2017/18 (year 2) • ~ c. 365k – 699k 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 Zero; SRS is not currently undertaken for these conditions and there is no evidence to suggest this will change.
	K1.8 How is the population currently distributed geographically?	K1.8 Based in the evidence reviewed, no significant geographic differences in disease prevalence have been identified.

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 SRS is not currently commissioned for movement disorders[xvi]. This is expected to continue given the policy proposes not to routinely commission.
	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 As prevalence is strongly linked to age, an ageing population is likely to go hand in hand with higher prevalence rates of severe tremor and Parkinson's[xvii].
	K 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	K2.3 No evidence of such changes were identified.
	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 Not net change in activity is expected.
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 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 Future activity would remain to be zero, as in K1.7.
	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 accompanying excel sheet	K3.3 These fewer than 10 patients would be expected to continue receiving either no treatment or medicinal management.

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. K4.2 What are the current treatment access criteria? K4.3 What are the current treatment stopping points?	K4.1 SRS for Parkinson's Disease and Familial Essential Tremor is not currently routinely commissioned. Deep Brain Stimulation and thalamotomy are routinely commissioned for the above indications and are the ideal surgical interventions. Patients with these conditions attend their GP where drug therapy may be commenced and they will be referred to the local neurology department for ongoing management. If pharmacotherapy is ineffective, the neurology team refer to a neurosciences MDT where consideration of surgery takes place. K4.2 Patients considered for treatment must have an identified cause or diagnosis of uncontrollable movements that is not incorporated in other relevant policies. Patients will have failed medical therapy and the uncontrolled movements should be severe enough to be disabling, impacting on activities of daily living and having an adverse effect on quality of life. Patients will be seen and considered by a functional neurosurgery multidisciplinary team to consider the surgical options as well as the radiosurgical option. Patients will need to be fit enough to undergo general anaesthetic and not be using anti-coagulant medications. K4.3 Drug therapy stopped if ineffective. Currently, if patient is not suitable for DBS or thalamotomy there is no further treatment option available.
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. K5.2 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.	K 5.1 - K5.2 There is no best alternative to SRS. These patients have failed medical management and are not candidates for DBS or thalamotomy as above. These patients will currently receive no further therapies but will continue to be followed up by their neurology team.

K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy K6.2 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.	K6.1 The current pathway identified in K4.1 would remain. K6.2 N/A
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Daycase/Outpatient o Mental Health Provider: Inpatient /Outpatient o Community setting o Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.1 This treatment is typically an inpatient procedure under general anaesthetic. A 1 or 2 night stay would be expected.[xviii] 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? K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.1 Given this is an inpatient procedure; this would be recorded in SUS central data collections. K8.2 Activity will be identified using a combination of ICD-10[xix] and OPCS codes[xx].

K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 N/A
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 N/A
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 N/A
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 N/A
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 N/A
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 N/A
	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 N/A
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 services currently provided in Tier 3 or Tier 4 centres only for other indications.

	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 come from neurosciences MDT to the SRS MDT at Tier 3 or Tier 4 centres. Currently, these referrals for SRS treatments are for other indications, not movement disorders.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No anticipated change
	L2.3 Is the new policy likely to improve equity of access?	L2.3 No anticipated change
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 No anticipated change
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 No lead time to implementation.
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No
	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	L3.6 No

	arrangements / prime contractor) L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers? L3.8 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)	 L3.7 No L3.8 N/A
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? M1.2 Is this treatment excluded from national	M1.1 Currently, there is no national tariff for SRS for Parkinson's and essential tremors. However, SRS for other indications is charged via the national tariff (HRG codes *AA09 - Intracranial Procedures Except Trauma with Other Diagnoses*).These are: • AA09A: Intracranial Procedures Except Trauma with Other Diagnoses – category 4 with CC: c. £3,650[xxi] - £9,850[xxii] • AA09B: Intracranial Procedures Except Trauma with Other Diagnoses – category 4 without CC: c. £1,790[xxiii] - £5,990.[xxiv] The current weighted average tariff for SRS for other indications is expected to hold also for Parkinson's and essential tremor. This is expected to be c. £7,311[xxv]. M1.2 SRS for other indications is not excluded from national prices and

	prices?	does not use any excluded devices.
	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 N/A
	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 N/A
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 N/A
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 N/A
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 The revenue cost per patient per year would be nil as the decision is to not routinely commission. For reference, the unit cost of the treatment per patient per year is expected to have been as follows:[xxvi] 1. Specialist MDT appointment: £163[xxvii] 2. SRS MDT: £163[xxviii] 3. SRS procedure: The average cost of a procedure is £7,311 as described in M1.1. 4. Follow-up shortly after treatment: £88[xxix] 5. 6-monthly follow up: £176 (2 × £88) Total revenue costs per patient could therefore be: c. £7,900 in year 1.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Costs per patient in future years are not expected to change.
M3 Overall Cost Impact of	M3.1 Indicate whether this is cost saving,	M3.1 A not routinely commissioned position is expected to be cost neutral

this Policy to NHS England	neutral, or cost pressure to NHS England? M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	to NHS England. M3.2 N/A
	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs) M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole? M4.3 Where this has not been identified, set out the reasons why this cannot be measured? M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.1 This is expected to be cost neutral to other parts of the NHS. M4.2 This is expected to be cost neutral to the NHS as a whole. M4.3 N/A M4.4 N/A
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? M6.2 Can these be mitigated, if so how? M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios.	M6.1 No material risks have been identified. M6.2 N/A M6.3 N/A
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 There is no evidence available pertaining to the cost-effectiveness of SRS for movement disorders.

	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 No evidence available
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs*, *periodical costs* M8.2 If so, confirm the source of funds to meet these costs.	M8.1 No. M8.2 N/A

[i] Commissioning Policy And Referral Guidelines For The Deep Brain Stimulation For The Treatment Of Patients With Dystonia And Tremors (Excluding Parkinson's Disease), NHS Commissioning Board (2013)
[ii] The Neurological Alliance (2013) "a brief review of the numbers of people in the UK with a neurological condition
[iii] Parkinson's prevalence in the United Kingdom, Parkinson's UK (2009)
[iv] The Neurological Alliance (2013) "a brief review of the numbers of people in the UK with a neurological condition.
[v] Baumann (2012) "Epidemiology, diagnosis and differential diagnosis in Parkinson's disease tremor", Parkinsonism & related disorders.
[vi] NICE Clinical Knowledge Summaries: Parkinson's Disease
[vii] This is based on ONS population estimates for 2014.
[viii] Based on discussions with the policy working group.
[ix] Parkinson's prevalence in the United Kingdom, Parkinson's UK (2009)
[x] NICE Clinical Knowledge Summaries: Parkinson's Disease
[xi] NICE Clinical Knowledge Summaries: Parkinson's Disease
[xii] Based on discussions with the policy working group
[xiii] Based on discussions with the policy working group
[xiv] Based on conversations with the policy working group
[xv] The patient group identified in K1.1 has been grown in line with ONS population growth estimates for the over 60s.
[xvi] Based on conversations with the policy working group, and triangulated with IFR data.
[xvii] Based on information from the policy working group
[xviii] Based on conversation with the policy working group
[xix] G20X: Parkinson's, G250: Essential tremor, G252: Other specified forms of tremor.
[xx] 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.

[xxi] 2014/15 National Tariff, Combined day case / ordinary elective spell tariff, an average MFF of 10% is applied.
[xxii] 2014/15 National Tariff, Non-elective spell tariff, an average MFF of 10% is applied.
[xxiii] 2014/15 National Tariff, Combined day case / ordinary elective spell tariff, an average MFF of 10% is applied
[xxiv] 2014/15 National Tariff, Non-elective spell tariff, an average MFF of 10% is applied.
[xxv] Based on data received from NHS England Finance Lead
[xxvi] 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.
[xxvii] General Surgery Outpatient First-attendance, multi professional
[xxviii] General Surgery Outpatient First-attendance, multi professional
[xxix] General Surgery Outpatient Follow-up attendance, single-professional