

Clinical Commissioning Policy: Stereotactic Radiosurgery (SRS) for adults with Parkinson's Tremor and Familial Essential Tremor

Reference: NHS England: 16007/P



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Medical	Operations and Information	Specialised Commissioning
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Finance		

Publications Gateway Reference: 05527s

Document Purpose	Policy
Document Name	Clinical Commissioning Policy 16007/P
Author	Specialised Commissioning Team
Publication Date	13 July 2016
Target Audience	CCG Clinical Leaders, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, NHS Trust CEs
Additional Circulation List	
Description	Not Routinely Commissioned - NHS England will not routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	This document is part of a suite of policies with Gateway Reference 05527s.
Superseded Docs (if applicable)	N/A
Action Required	N/A
Timing / Deadlines (if applicable)	N/A
Contact Details for further information	england.specialisedcommissioning@nhs.net

Document Status

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Clinical Commissioning Policy: Stereotactic Radiosurgery (SRS) for adults with Parkinson's Tremor and Familial Essential Tremor

First published: July 2016

**Prepared by NHS England Specialised Services Clinical Reference Group for
Central Nervous System (CNS) Tumours**

Published by NHS England, in electronic format only.

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Policy Statement

NHS England will not routinely commission stereotactic radiosurgery (SRS) for adults with Parkinson's tremor and Familial Essential Tremor in accordance with the criteria outlined in this document. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About Parkinson's tremor and familial essential tremor

Parkinson's disease and familial essential tremor (FET) are types of 'movement disorder'. They can severely affect patients being able to do everyday things – like eating, shopping, and brushing teeth.

About current treatments

Medicines can be used to control unwanted movements – but sometimes they do not work. Also, side effects can stop the medicines being used. This means that further treatments need to be considered.

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- 'Lesional surgery' was used in the past. This destroys small areas of brain tissue which cause the uncontrolled movements.
- 'Deep brain stimulation' or DBS has mostly replaced lesional surgery. DBS can be adjusted in response to a patient's symptoms.

About the new treatment

Stereotactic radio surgery (SRS) is another way the area of the brain causing the uncontrolled movements can be destroyed.

What we have decided

NHS England has carefully reviewed the evidence to treat drug resistant movement disorders with SRS. We have concluded that there is not enough evidence to make the treatment available at this time.

1 Introduction

This document describes the evidence that this been considered by NHS England in formulating a proposal to not routinely commission stereotactic radiosurgery (SRS) for Parkinson's tremor and familial essential tremor.

The basic principle of stereotactic radiosurgery (SRS) is the elimination of a functional disorder, or destruction of abnormal tissues, by administration of a strong and highly focused dose of radiation. The procedure allows radiation to be limited to the targeted area and thus helps spare the surrounding tissues as much as possible.

SRS is routinely used in the treatment of a number of different brain and central nervous system pathologies as defined by a number of clinical commissioning pathways. Here, we consider the use of SRS as the final treatment option for patients with drug resistant tremor associated with Parkinson's disease and familial essential tremor (FET).

2 Definitions

For the purpose of this policy the term SRS is used to mean treatment given as a single fraction. SRS is a highly conformal radiotherapy treatment to a precisely delineated target volume, delivered using stereotactic localisation techniques. A multidisciplinary team of neurosurgeons, neuro-oncologists and neuro-radiologists are involved in SRS case selection, treatment planning and delivery.

Parkinson's disease is a chronic disease of the brain which may occur when the brain does not produce enough dopamine, a chemical it needs to perform certain functions. This affects the brain's ability to control movement and other muscle functions and is characterised by gradually worsening tremor, muscle rigidity and difficulties with starting and stopping movements. The condition is usually treated with drugs. Surgery can be considered in people who have responded poorly to drugs, who have severe side-effects from medication, or who have severe fluctuations in response to drugs (on-off syndrome).

Essential tremor is a progressive neurological condition that causes a trembling of the hands, head, voice, legs, or trunk. It is not caused by loss of dopamine. Essential tremor has familial tendency, people with familial essential tremor (FET) may get it earlier in life than those with non-familial or sporadic essential tremor. Severe tremor can be disabling because it affects fine-movement coordination. Tremor can be treated by rehabilitation and drug therapy, and early appropriate treatment may minimise functional disability. Anti-tremor drugs reduce the amplitude but not the frequency of tremor, and this does not always translate into functional improvement. Due to the side-effect profile of anti-tremor medications, there are some cases where the dose required to effectively control the tremor causes unacceptable side effects, worsening the patient's quality of life. Lesional surgery, which often involves ablation of the thalamic nucleus, is reserved for patients with severe disabling tremor and functional disability that interferes with activities of daily living, and for tremor that is refractory to the highest tolerated doses of medication. Surgery of this nature is currently routinely commissioned and has a significant evidence base. Due to the degenerative nature of Parkinson's disease, the anticipated benefits acquired by undergoing SRS can relapse, in contrast to essential tremor where SRS outcomes remain permanent.

Surgical care of drug-resistant Parkinson's disease and FET may be deep brain stimulation and thalamotomy. SRS represents a different tool by which to make a lesion in the area of the brain responsible for the uncontrolled movements.

3 Aims and Objectives

The policy aims to define NHS England's commissioning position on stereotactic radiosurgery for the treatment of patients with movement disorders associated with Parkinson's disease and familial essential tremor.

The objective is to ensure evidence based commissioning in the use of stereotactic radiosurgery for the treatment of adults with Parkinson's tremor and familial essential tremor.

4 Epidemiology and Needs Assessment

Parkinson's disease affects 0.5% of the population aged 65-74 and 1-2% of the population over 75 (NICE Clinical Knowledge Summaries: Parkinson's Disease). Of this patient cohort, 90-99% of patients will respond to medications, leaving a small group of patients suitable for brain surgery. Deep brain stimulation will remain the preferred choice of brain surgery for these patients.

Estimations of the incidence and prevalence of tremor vary widely as a mild degree of tremor is a common finding affecting between 2-4% of the population. More unusual is to have a tremor severe enough to interfere with activities of daily living, necessitating surgical intervention. One functional neurosurgery practice estimates that tremor surgery (deep brain stimulation) is being offered to one patient in 400,000 - 500,000. The majority of interventions for tremor will continue to be deep brain stimulation, due to the flexibility that this device offers, or alternatively thalamotomy. The remaining patients suitable to receive stereotactic radiosurgery is estimated at less than 10 patients per year nationwide.

5 Evidence Base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of SRS for drug-resistant Parkinson's tremor and familial essential tremor.

We conclude there is low level evidence (level 3) to support the use of stereotactic radiosurgery in the treatment for movement disorders. In conclusion there is insufficient evidence for efficacy, safety, impact on quality of life and cost effectiveness.

To date there has been no randomised trial comparing stereotactic radiosurgery with any other treatment modality such as deep brain stimulating and/or radiofrequency ablation. Stereotactic radiosurgery has been reserved for patients with intractable tremor, where more invasive surgical therapies are contraindicated.

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Two recent prospective studies (level 3) have reported a significant improvement in activities of daily living (ADL). Witjas et al. (2015) reported a 72.2% improvement (0-100%) in ADL and Ohye et al. (2012) reported 81.1% patients rating a tremor score as 'excellent' or 'good' post stereotactic radiosurgery. The largest case series (level 3) within the last five years by Kooshkabadhi et al. (2013) (n=88) showed at least 81% improvement in at least one of the three tremor scores.

These two prospective studies have also evaluated the size of the thalamic lesion pre and post radiation with brain MRI scans, with an overall expected lesion response in the majority of patients. However, authors have noted the thalamic site can fluctuate and warrants further investigation. Witjas et al. (2015), described one patient (n=50) with an extensive thalamic response that spontaneously resolved.

The results of these three cases series are consistent with a recent systematic review by Campbell et al., 2015 (level -2). The review evaluated 29 papers of which were primarily case reports and patient case series. Sixteen studies evaluated tremor scores pre and post stereotactic radiosurgery, patient numbers in the studies varied from 172 to 8. All studies except one study showed an improvement in tremor score, range of improvement from 50-100%. Overall the systematic review concluded approximately 80% of patients with intractable tremor had some clinical benefit following the procedure. The review identified the largest case series, conducted by Young et al. 2010 (n=172) which showed an improvement in both drawing and writing scores ($P < 0.001$), at 6 month follow-up.

The three recent cases series (Witjas et al. (2015), Ohye et al. (2012) and Kooshkabadhi (2013)) describe at least one patient developing transient contralateral weakness following SRS therapy, which resolved spontaneously. No other significant side effects were reported. In the systematic review (Campbell et al., 2015) complication rate reported varied between 0% -16%, predominately motor symptoms. In the review, one group reported a thalamic haemorrhage at treatment site, although the patient was on anticoagulant treatment. In addition three groups in the review reported patient deaths attributed to the therapy. One patient developed aspiration pneumonia secondary to dysphagia, one died of radiation necrosis (bilateral lesions), one died of haemorrhagic stroke at site of lesion 7.5 years after procedure. One

group described a correlation between lesion size and dose in Gy. The authors concluded on the basis of the systematic review unilateral gamma knife thalamotomy using doses from 130-150 Gy is well tolerated and safe. However to date there has not been a long term follow-up study and requires further investigation.

We found no specific evidence relating to the model of care post-SRS that may impact on the long term duration of response, for example input from other specialities such as occupational health, physiotherapy.

6 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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