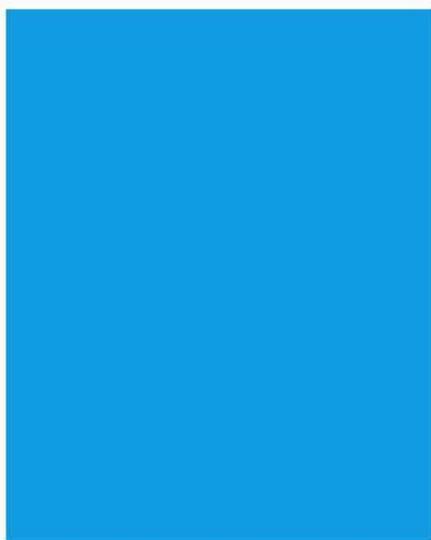


**Clinical Commissioning
Policy: Stereotactic
Radiosurgery for Trigeminal
Neuralgia**

April 2013

Reference : NHSCB/D05/P/b



NHS Commissioning Board

Clinical Commissioning Policy: Stereotactic Radiosurgery for Trigeminal Neuralgia

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**Prepared by the NHS Commissioning Board Clinical Reference Group for
Stereotactic Radiosurgery**

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Policy Statement

The NHS Commissioning Board (NHS CB) will commission stereotactic radiosurgery (SRS) for trigeminal neuralgia in accordance with the criteria outlined in this document.

In creating this policy the NHS CB 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

The NHS Commissioning Board (NHS CB) has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of different protected equality groups in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all the activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

The trigeminal nerve is the fifth of twelve cranial nerves and is responsible for sensation in the face and certain motor functions such as biting, chewing, and swallowing. Trigeminal Neuralgia (TN) is thought to be caused by a blood vessel pressing on the trigeminal nerve. This compression causes the wearing away of the myelin sheath (protective coating) around the nerve. Trigeminal neuralgia (TN) has a substantial impact on quality of life. It is characterised by sudden one sided facial pain.

Stereotactic radiosurgery (SRS) is the elimination of a functional disorder, or destruction of abnormal tissues, by a strong and highly focused dose of radiation.

The long term efficacy of different treatment techniques (including SRS) is unclear due to lack of evidence. Initial pain relief rates are lower for SRS than other techniques as this type of treatment takes longer to have an effect. Given the impact on quality of life of TN and the benefits from achieving more immediate pain relief rates, non SRS treatment methods should be considered first and SRS only where these are inappropriate for the patient.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

1. Introduction

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 target area and thus helps spare the surrounding tissues as much as possible.

This policy considers the use of SRS compared to other therapies and interventions for patients with trigeminal neuralgia and states the criteria to identify which patients should be considered for SRS.

2. Definitions

The trigeminal nerve has three branches, (i) the ophthalmic branch, which runs above the eye, forehead and front of the head, (ii) the maxillary branch, which runs through the cheek, upper jaw, teeth and gum and side of the nose and (iii) the mandibular branch, which runs through the lower jaw, teeth and gums. One or more branches can be involved in TN.¹

TN is thought to be caused by a blood vessel pressing on the trigeminal nerve; this compression causes the wearing away of the myelin sheath (protective coating) around the nerve. TN may be part of the normal ageing process with lengthening blood vessels coming to rest and pulsate against a nerve. TN can occur in patients with multiple sclerosis (MS), which is a disease caused by the deterioration of myelin throughout the body. A further cause of TN is damage to the myelin sheath by compression from a tumour. The cause can be unknown in some cases, where no vascular or other lesion is identified.

Trigeminal neuralgia (TN) is characterised by sudden one sided facial pain, which is described by patients as stabbing, shooting, excruciating, burning and extremely strong.² Pain usually lasts from a few seconds to around two minutes affecting one or more branches of the trigeminal nerve.³ Attacks can be repetitive and can last for several minutes or hours and the intensity of the pain can be physically and mentally incapacitating.^{2,4} Attacks can be triggered by routine daily activities such as brushing teeth, encountering a breeze, speaking, eating or smiling. TN is associated with an impairment of daily function and a reduced quality of life.

TN has been defined as follows by the International Headache Society⁵

Paroxysmal (sudden) attacks, lasting from 1 second to 2 minutes, affecting one or more branches of the trigeminal nerve

Pain that is intense, sharp, superficial, or stabbing, precipitated from trigger areas or factors

Attacks stereotyped to the individual patient

No clinically evident neurological deficit

Pain not attributed to another disorder

Diagnosis is largely based on the patient's medical history, description of symptoms and neurological examination. A standard magnetic imaging (MRI) scan to rule out a tumour or MS may also be performed.²

Subtypes

Type 1 (also known as idiopathic or typical TN). This is the largest group of patients. Type 1 is likely to involve abnormal vascular-compression of the root entry zone of the trigeminal nerve. These patients have the 'classic symptoms' described above.

Type 2 (atypical TN). This smaller group of patients experience additional pain consisting of a persisting ache or burning sensation which occurs more constantly beneath the episodic attacks of pain. Atypical TN is diagnosed when the background pain occurs more than 50% of the time.⁶

Patients with MS may also be seen as a sub-type.

Stereotactic Radiosurgery (SRS)

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 target area and thus helps spare the surrounding tissues as much as possible.

For the purpose of this policy the term "SRS" is used to mean treatment given as a single dose. 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 neuroradiologists should be involved in SRS case selection, treatment planning and delivery.

3. Aim and objectives

The aim of this policy is to:

Identify whether there is sufficiently robust evidence of clinical effectiveness, safety and cost effectiveness to support the use of SRS for patients with acoustic neuroma.

If the evidence is sufficiently robust, to outline the clinical criteria that should be used to identify suitable patients to be considered for SRS treatment.

4. Criteria for commissioning

Patients meeting all the following criteria will be routinely funded for SRS:

Funding will be released only when ALL the following criteria are met:

Patient meets the diagnostic criteria for trigeminal neuralgia (TN) as described by the International Headache Society and have typical TN (type 1) OR Trigeminal Neuralgia Syndrome associated with known neuromedical predisposing conditions AND

Patient is unable to tolerate drug therapy, or has had intractable pain despite medication normally expected for a minimum period of at least six months AND

Patient has been reviewed by a neurosurgeon who has assessed the patient as requiring surgery AND

Other treatment modalities (microvascular decompression and ablative techniques) are deemed inappropriate for the patient.

5. Patient pathway

The service specification for SRS describes the detail of the care pathways and describes the key aspects of SRS services being commissioned and should be referred to in conjunction with this policy.

Referrals in to the service are accepted from consultant medical staff and appropriate medical MDTs 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.

First line therapy consists of drug treatment. Additional drugs or a change of drug is appropriate if pain relief is inadequate or a drug is not tolerated. If the TN is refractory to drug treatment then other interventions are then considered when referred to a neurosurgeon, neurologist or specialist in pain management. These can be divided in to ablative and non-ablative methods. SRS is one of several ablative methods.

The International Radiosurgery Association (IRSA) algorithm suggests treatment with SRS or Percutaneous Retrogasserian Rhizotomy (PRR, includes PGR, PCB and PRTR) in patients over 65 with significant medical risk, or in those patients under 65 (no significant medical risk) where TN recurs after previous treatment with MVD.⁷ There were no details in the guidelines regarding definitions of “significant” medical risk or on which case-series/evidence these recommendations are based. The guidelines state that the neurosurgeon’s experience is likely to influence any final treatment recommendation.

6. Governance arrangements

The service specification for SRS describes the care pathways and key aspects of SRS services being commissioned and should be referred to in conjunction with this policy.

7. Epidemiology and needs assessment

In the UK, a diagnosis of TN is made in approximately 27/100,000 people per year. Previous population based studies using a strict case definition estimates the rate at 4-13/100,000 per year.³ A prospective UK study estimated an incidence of 8/100,000.⁸ In England, based on a population of 53 million⁹ and the strict case definition, we would expect to see between 2120 and 6890 new cases diagnosed per year.

Incidence increases with age and TN is rare below the age of 40 years; average age of pain onset is typically in the sixth decade but it can occur at any age.^{3,7}

Symptomatic or secondary TN is more likely to occur in younger patients, whilst TN caused by arterial compression is more likely to occur in older patients.¹⁰ More women than men are effected by TN (3:2).⁹

The majority of cases can be managed using drugs. SRS would only be considered in patients where pharmaceutical management does not work or is not tolerated. In 1996 it was estimated that around 25% of patients fall into this category.¹⁰ This does not take in to account newer (combinations of) medications or the fact that some initially responding patients will become intolerant.

There is therefore an estimated potential pool of approximately 530 – 1723 patients per year across the England who may be considered suitable for other interventions, including SRS.

8. Evidence base

Evidence can be graded according to the robustness of the study design, giving an indication of the degree to which the evidence should be relied upon when making clinical decisions. The grades of evidence range from level 1 (the most robust) to level 4 (the least robust). The diagram in Appendix 1 outlines the levels of evidence.

A systematic review of the literature was commissioned from the West Midlands Health Technology Assessment Collaboration at the University of Birmingham to inform this policy.¹¹

There is a paucity of evidence on the natural history of trigeminal neuralgia due to

the fact that the severity of the pain requires treatment and placebo controlled studies are considered unethical.³ The variable pattern, and the fact that there are no studies of the natural course of the disease without intervention, makes it difficult to assess treatment effectiveness of a drug or surgical procedure in the absence of a control group (i.e. the proportion of patients that would have gone in or out of remission naturally, without treatment is unknown).

Drug treatment in the form of carbamazepine or gabapentin is the usual first line treatment. There are no specific UK guidelines on when surgery (and which type of surgery) is appropriate. Recommendations from the NHS Clinical Knowledge Summaries website¹² suggest referral to a neurosurgeon, neurologist, or specialist in pain management with an interest in trigeminal neuralgia where (i) neither carbamazepine nor gabapentin are effective, (ii) the drugs cause unacceptable adverse effects, (iii) there are atypical clinical feature or (iv) the patient is less than 40 years old. This should be done at the earliest possible stage if medical treatment fails.

NICE guidance from 2004 supports the use of the Gamma Knife to treat TN in patients who experience severe pain despite medication or who have adverse effects from the medication.¹³ The guidance does not look at other forms of SRS (CyberKnife, LINAC) and does not make any recommendations on when/whether SRS should be used as an alternative to other techniques (PBC, PRTR, PGR or microvascular decompression (MVD)).

The American Academy of Neurology (AAN) and the European Federation of Neurological Societies (EFNS) guidelines¹⁴ from 2008 state that there are no studies looking at the evidence for when surgery should be offered. There is some evidence to suggest that patients who receive surgery in the form of MVD would have preferred to have had it earlier. Similarly, there is no good evidence on which surgical technique gives the best and longest pain relief and good quality of life. The guidelines suggest that percutaneous procedures, Gamma Knife and MVD are “*possibly effective*” in the treatment of TN, with MVD possibly providing the longest duration of pain freedom. There is no evidence relating to the relative effectiveness of Gamma Knife, CyberKnife and LINAC.

The International RadioSurgery Association (IRSA) issued Radiosurgery Practice Guidelines⁷ in 2009 for TN patients who have failed medical management. It should be noted that these guidelines are based on weak evidence from case-series only (or from studies where the study design has not been described) and as such any conclusions regarding specific treatment recommendations must be viewed cautiously. This management algorithm suggests treatment with SRS or Percutaneous Retrogasserian Rhizotomy (PRR, includes PGR, PCB and PRTR) in patients over 65 with significant medical risk, or in those patients under 65 (no significant medical risk) where TN recurs after previous treatment with MVD. Patients with MS related TN may also be considered for SRS. There were no details in the guidelines regarding definitions of “significant” medical risk or on which case-series/evidence these recommendations are based. The guidelines state that the neurosurgeon’s experience is likely to influence any final treatment recommendation.

Cost-effectiveness

There is a lack of evidence addressing the cost-effectiveness of SRS compared to other treatment options in a UK setting for this indication. However, there is some evidence for use of SRS for other pathologies that the overall costs, including ancillary treatment and readmission costs are lower for patients treated with SRS than by microsurgery.¹⁵ In 1997 an estimation of cost/benefit for conventional fractionated radiotherapy (RT), surgery and radiosurgery (RS) for patients with single brain metastases was undertaken.¹⁶ The cost per life year of median survivorship was \$16,250 for RT alone, \$13,729 for RS plus RT, and \$27,523 for resection plus RT. Hence, according to this study a surgical resection resulted in a 1.8-fold increase in cost, compared to radiosurgery. A similar American comparative cost analysis found that the cost per life year gained for radiosurgery was 30% lower than for surgical resection.¹⁷

To-date estimates of the cost-effectiveness of SRS in comparison with surgery have not been robustly determined from a UK NHS perspective.

9. Rationale behind the policy statement

Trigeminal neuralgia (TN) has a substantial impact on quality of life. It is characterised by sudden one sided facial pain.

The long term efficacy of different treatment techniques (including SRS) is unclear due to lack of evidence.

Initial pain relief rates are lower for SRS than other techniques as this type of treatment takes longer to have an effect.

Given the impact on quality of life of TN and the benefits from achieving more immediate pain relief rates, non SRS treatment methods should be considered first and SRS only where these are inappropriate for the patient.

10. Mechanism for funding

From April 2013 the NHS CB will be responsible for commissioning in line with this policy on behalf of the population of England.

11. Audit requirements

The following data for each patient will be required for audit:

1. Pharmaceutical treatment – drugs, length of treatments, reason for stopping.
2. Maximum point dose to brain stem.
3. Target dose
4. Complications from treatment
5. Success rate (NB this will need to be defined for consistency)

Changes, including addition and/or removal of audit criteria will be negotiated as required to reflect up-to-date practice.

12. Documents which have informed this policy

2012/13 NHS Standard Contract: Service Specification Contract NSSD 8 Neurosciences (adult0 (subsection 4.1 Neurosurgery) Stereotactic Radiosurgery and stereotactic radiotherapy.

NICE Interventional Procedure Guidance – Trigeminal Neuralgia

13. Links to other policies

The mechanism operated by the NHS CB for funding requests outside of the clinical criteria in this policy is yet to be finalised.

14. Date of review

3 years (2015)

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Amendment to the Published Products

Product Name

Stereotactic Radiosurgery for Trigeminal Neuralgia

Ref No

D05/P/b

CRG Lead

Stereotactic Radiosurgery

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
D5/P/b	D05/P/b	Title page and throughout document	To standardise naming and coding of products	Programme of Care Director for Trauma	September 2013

Appendix 1: Grades of evidence

evidence for clinical application

*Level 1- formal, open, clinical
randomised-controlled trials*

*Level 2- esse controlled trials
(comparisons made but not randomised)*

*Level 3.observational studies (including
surveys and questionnaires)*

*Level 4- anecdotal evidence (including
independent user comments and reviews)*

Level 5- methodological verification and validation studies