

**Clinical Commissioning
Policy: Vestibular
Schwannoma and Other
Cranial Nerve Neuromas**

April 2013

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NHS Commissioning Board

Clinical Commissioning Policy: Vestibular Schwannoma and Other Cranial Nerve Neuromas

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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) and stereotactic radiotherapy (SRT) for vestibular schwannomas (acoustic neuroma) and other cranial nerve neuromas 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

Vestibular schwannomas (also known as acoustic neuromas) affect the eighth cranial nerve which is responsible for transmitting sound and equilibrium (balance) information from the inner ear to the brain. About 5% of vestibular schwannomas are associated with the hereditary disease, neurofibromatosis-2 (NF2).

Stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) is used to administer a strong and highly focused dose of radiation limited to the target area of abnormal tissue, sparing the surrounding healthy tissues as much as possible. The scientific evidence regarding the clinical effectiveness, safety and cost effectiveness of SRS/SRT for treating acoustic neuroma has been used to define the criteria for its use in this commissioning policy. SRS/SRT can be used to treat acoustic neuroma where size constraints allow it to be done safely.

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) and stereotactic radiotherapy (SRT) 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/SRT for patients with vestibular schwannoma (acoustic neuroma) and other cranial nerve neuromas and states the criteria to identify which patients should be considered for SRS/SRT.

2. Definitions

Vestibular Schwannoma (acoustic neuroma)

Vestibular schwannomas arise from the Schwann cells surrounding the vestibular branch of the eighth cranial nerve. In some cases they may erode the internal auditory canal and compress the cranial nerves.¹

Vestibular schwannomas account for around 6% of all tumours inside the skull. Approximately 95% of cases occur as a random isolated event (sporadic), the remaining 5% are associated with the hereditary disease, neurofibromatosis-2 (NF2). Sporadic cases are unilateral, with onset around 45-50 years, whilst neurofibromatosis-2 associated cases are typically bilateral, with onset around 30 years.¹ All treatment for NF2 patients is covered by highly specialised services commissioning arrangements.³

Stereotactic Radiosurgery (SRS) and Stereotactic Radiotherapy (SRT)

The basic principle of stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) 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, and “SRT” as a hypofractionated treatment of not more than 5 fractions. This policy applies to both of these approaches. Commissioning arrangements for fractionated treatments utilising a larger number of fractions are beyond the remit of this policy.

SRS/SRT 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 and treatment planning.

3. Aim and Objectives

The aims of this policy are:

- To identify if there is sufficiently robust evidence of clinical and cost effectiveness and safety to support the use of SRS for patients with acoustic neuroma
- If the evidence is sufficiently robust, to establish the criteria which should be used to identify suitable patients to be considered for SRS treatment

4. Criteria for commissioning

Indications for radiosurgery include the following categories of vestibular schwannoma and other cranial nerve neuromas:

- Newly diagnosed
- Residual after microsurgery
- Recurrent

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

- All patients must have undergone prior assessment by the local neuroscience multi-disciplinary team (MDT). The selection of patients for SRS/SRT must be made by an MDT with an understanding of the systemic and neurological disease processes and must include the consideration of surgical treatment if appropriate.
- All patients being considered for SRS/SRT should be discussed by their disease- specific MDT to ensure that the criteria regarding systemic disease and prognosis are fulfilled and that there is clarity about the place of SRS/SRT in the patient's overall management plan.
- In centres where SRS/SRT is delivered, referral may be made directly to the SRS MDT. In centres where there is no local SRS service, referral should be initially to the local neuroscience MDT, who can decide on the appropriateness of onward referral to an agreed SRS centre.
- All patients being considered for SRS /SRT must be discussed by the specialist MDT at the stereotactic treatment centre and must have both specialist neurosurgery input. SRS/SRT must not be recommended without the collective agreement of the MDT.

Radiosurgery may be performed for intracanalicular tumours if tumour growth is documented following observation.⁴

The decision to use single dose SRS as compared to hypofractionated SRT should take the following expert opinion in to account. Expert opinion suggests that:

- SRS may be used where the tumour is less than 3.5cm in extracanalicular diameter AND there are no clinical signs of brainstem compression.
- SRT may be used where the tumour is larger than 2.5cm in extracanalicular diameter AND there are no clinical signs of brainstem decompression.

NB. There is an intentional overlap of tumour size stated above to allow physician discretion in treatment decisions for patient specific circumstances in the absence of definitive clinical evidence.

5. Patient pathway

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

The service will accept referrals from consultant medical staff and appropriate specialist 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.

Treatment options for acoustic neuroma will depend on the size and growth rate of the tumour, with many small, slow growing tumours not requiring intervention. A watch and wait approach may be appropriate in some patients, including some older patients, although it is by no means certain that a neuroma will grow less aggressively in old people.⁴

The three management options for patients with acoustic neuroma are;

- Surgical removal of the neuroma
- Stereotactic radiosurgery/radiotherapy (SRS/SRT)
- No intervention with interval scanning

Patients with vestibular schwannoma and other cranial nerve neuromas have follow up at 1,2,3,5 years. Follow up includes MRI, audiology and facial nerve assessment.

6. Governance arrangements

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

7. Epidemiology and needs assessment

International studies have estimated the incidence rate of acoustic neuroma to be 1.1 per 100,000.⁵ Based on the current England population estimate of 53 million,⁶ we would expect 583 patients to be diagnosed with acoustic neuroma each year in England.

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 2 outlines the levels of evidence.

In 2010 a review of the evidence on the use of stereotactic surgery (SRS) and stereotactic radiotherapy (SRT) for acoustic neuroma (AN) was undertaken by Birmingham University's Health Technology Assessment Collaboration.²

The review, based on systematic reviews of case series and cohort studies highlighted the need for reliable answers on effectiveness, safety and cost effectiveness of SRS/SRT. In the absence of methodologically robust evidence the following statements should remain tentative.

SRS/SRT (principally Gamma Knife SRS) compared to surgery appears to provide:

- similar levels of tumour control
- better levels of facial nerve preservation
- better levels of hearing preservation
- a less detrimental impact on quality of life
- lower rates of procedural mortality and medium-term treatment-related complications

Gamma Knife, LINAC and CyberKnife appear to provide similar levels of clinical

effectiveness. No evidence was identified on which to base comparisons of the relative safety of Gamma Knife, LINAC and CyberKnife.

There is some evidence of differential effectiveness from SRS/SRT amongst different population subgroups:

- Younger patients (aged ≤ 60 years) may have better facial nerve preservation than older patients
- Patients with tumours $\leq 1.5\text{cm}^3$ may have better facial nerve preservation than those with tumours $> 1.5\text{cm}^3$
- Patients receiving lower radiation treatment doses (≤ 13 Gy) may have better facial nerve preservation than those receiving higher treatment doses
- Patients receiving lower radiation treatment doses (≤ 13 Gy) may have better hearing preservation than those receiving higher treatment doses

Cost-effectiveness

There is a lack of evidence addressing the cost-effectiveness of SRS/SRT compared to other treatment options in a UK setting. However, there is some evidence that the overall costs, including ancillary treatment and readmission costs are lower for patients treated with SRS/SRT than by microsurgery.⁷ In 1997 a cost/benefit estimation for conventional fractionated radiotherapy (RT), surgery and radiosurgery (RS) for patients with single brain metastases was undertaken.⁸ 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.⁹

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

9. Rationale behind the policy statement

- The evidence base regarding the effectiveness, cost effectiveness and safety of SRS/SRT for treating acoustic neuroma has been used as a basis for this commissioning policy.
- SRS/SRT can be used to treat acoustic neuroma where size constraints allow it to be done safely.

There is no available robust estimate of the cost effectiveness of SRS/SRT for treatment of acoustic neuroma and ongoing monitoring of numbers and outcomes must be undertaken

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

Clinical governance guidelines state that all British neurosurgical centres are required to audit their results.¹⁰

Audit requirements will require the following data requirements for each patient:

1. Tumour size
2. Presence of brainstem compression
3. Planning data
4. Pre and post hearing levels
5. Treatment complications (facial/trigeminal)
6. Hydrocephalus

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 (adult) (subsection 4.1 Neurosurgery) Stereotactic Radiosurgery and stereotactic radiotherapy.

International RadioSurgery Association Acoustic Neuroma (Vestibular Schwannoma) Guidelines.

13. Links to other policies

This policy is informed by the generic NHS CB commissioning policies covering experimental treatments and the process by which individual funding requests (IFR) are handled.

14. Date of Review

3 years (2015)

15. Abbreviations

LINAC	Linear Accelerator
MDT	Multi-disciplinary team
SCG	Specialised Commissioning Group
SRS	Stereotactic Radiosurgery
SRT	Stereotactic Radiotherapy

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Appendix 1: Grades of evidence

