NHS England

Clinical Commissioning Policy: Stereotactic radiosurgery/radiotherapy for ependymoma, haemangioblastoma, pilocytic astrocytoma and trigeminal schwannoma (adults)

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Clinical Commissioning Policy: Stereotactic radiosurgery/radiotherapy for ependymoma, haemangioblastoma, pilocytic astrocytoma and trigeminal schwannoma (adults)

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Policy Statement

NHS England will commission stereotactic radiosurgery/radiotherapy for ependymoma, haemangioblastoma, pilocytic astrocytoma and trigeminal schwannoma (adults) 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 rare intracranial tumours

Intracranial tumours are tumours in the brain, base of the skull, or neck. They result from tissues of the brain, spinal cord or surrounding structures. This policy proposition looks at the following rare intracranial tumours:

- ependymoma
- haemangioblastoma
- pilocytic astrocytoma
- trigeminal schwannoma.

About the current treatment

Surgery is usually the first choice of treatment for these tumours. However, some tumours cannot be completely removed by surgery, or surgery is not possible for some other reason.

About the new treatment

Stereotactic radiosurgery (SRS) or stereotactic radiotherapy (SRT) may be considered for these patients. SRS and SRT aim to destroy the tumour through a strong and highly focused dose of radiation.

Treatment consists of between 1 and 5 sessions ('fractions').

What we have decided

NHS England has carefully reviewed the evidence to treat patients with rare intracranial tumours with stereotactic radiosurgery (SRS) or stereotactic radiotherapy (SRT). We have concluded that there is enough evidence to make the treatment available.

1 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission stereotactic radiosurgery (SRS) or stereotactic radiotherapy (SRT) for the treatment of adults with ependymoma, haemangioblastoma, pilocytic astrocytoma, and trigeminal schwannoma, where the commissioning criteria are met.

The basic principle of SRS and 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 five fractions. This policy applies to both of these approaches. Commissioning arrangements for fractionated treatments or larger tumour volumes 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 multi-disciplinary team (MDT) of neurosurgeons, neuro-oncologists and neuro-radiologists should be involved in SRS case selection, treatment planning and delivery.

Ependymomas are slow-growing tumours of the central nervous system and most commonly present in children. They belong to a group of tumours called gliomas, which start in the glial cells. Ependymomas arise from ependymal cells (a sub-type of glial cells) which line the cerebral ventricles and passageways in the brain and spinal cord. They can be infratentorial tumours (arising in the fourth ventricle, an area of the brain located below the tentorium) or supratentorial. Ependymomas are mostly infratentorial in adults, but not exclusively.

Haemangioblastomas are benign tumours of the central nervous system that develop from blood vessel cells. The tumours can be solid or cystic and symptoms are predominantly as a result of increased intracranial pressure, including headaches, vomiting, balance and coordination problems, visual disturbances, confusion and back and neck pain. They are most commonly infratentorial and can occur in association with a genetic condition, Von-Hipple Lindau disease.

Pilocytic astrocytomas are low-grade glial brain tumours categorized as WHO grade 1 astrocytomas. They are typically well-differentiated, slow-growing and non-invasive and are most commonly found in children and young adults. They can be cystic or solid tumours or a combination of both and are usually located in either the cerebellum or in proximity to the brainstem. The symptoms of pilocytic astrocytomas can include changes in behaviour, headaches and vomiting, lack of co-ordination and loss of balance, memory loss and seizures.

Trigeminal schwannomas are slow growing, benign, nerve sheath tumours associated with the 5th cranial nerve. They arise in the skull base and typically cause facial pain (trigeminal neuralgia) or numbness. As they enlarge they can grow further into the cavernous sinus or into the posterior fossa, causing double vision, loss of coordination and other symptoms of brainstem compression.

2 Definitions

Glioma: A tumour of the glial tissue of the nervous system

Hypofractionated: Radiation treatment in which the total dose of radiation is divided into large doses and treatments are given once a day or less often. Hypofractionated radiation therapy is given over a shorter period of time than standard radiation therapy.

Cerebral ventricles: a set of four interconnected cavities (ventricles) in the brain, where the cerebrospinal fluid (CSF) is produced.

Infratentorial / Posterior fossa: the area located below the tentorium cerebelli which contains the brain stem and cerebellum

Supratentorial: the area located above the tentorium cerebellum containing the cerebral hemispheres

Cerebellum: a region of the brain, in the posterior fossa which plays an important role in motor control and balance

Cavernous sinus: a large collection of thin-walled veins creating a cavity bordered by the temporal bone of the skull and the sphenoid bone

Intracranial: within the cranial cavity (skull)

3 Aims and Objectives

This policy aims to define the current commissioning position for SRS/SRT for specific rare intracranial tumours in adults.

The objective is to ensure evidence based commissioning, with a view to improving outcomes for patients with rare intracranial tumours in adults.

4 Epidemiology and Needs Assessment

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 for all ages (Iqbal et al., 2013; Cancer Research UK, 2015). Of these, it is estimated around 75-190 cases per year are adults.

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 (Cancer Research UK). They usually develop in middle age.

Pilocytic Astrocytoma: The incidence of pilocytic astrocytomas is 0.37 per 100,000 persons per year (The Brain Tumour Foundation of Canada). This equates to approximately 200 cases per year in England for all ages, and is estimated at around 100 cases per year for adults. It is most commonly found in children but can occur in adults (Boethius et al., 2002). The cystic form of pilocytic astrocytoma is found in more than 75% of patients (Kano et al., 2009).

Trigeminal Schwannoma: Trigeminal schwannomas are rare and figures from a number of case series suggest they account for between 1% and 8% of all intracranial schwannomas (Ramina et al., 2008). In a large case series of 111 patients seen between 1961 and 1994 at one Russian hospital, 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 (NHS England, Cancer UK).

Surgical resection is the standard first line treatment for all of these tumour types. 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. 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.

Clinicians estimate that approximately 20% of new cases might be suitable for SRS/SRT for recurrent, progressive or residual disease – this would equate to a total of approximately 90 patients per year across all four indications. Of these, approximately 60 are estimated to be adult patients.

5 Evidence base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of SRS/SRT for the treatment of ependymoma, haemangioblastoma, pilocytic astrocytoma, and trigeminal schwannoma. Whilst the evidence available to support routine commissioning is limited, high grade evidence is very unlikely to become available due to the small patient numbers for each indication. In addition, as set out in the patient pathway, the alternative treatments for these patients may be very high risk and also do not have an associated high grade evidence base.

The evidence base for vestibular schwannoma (a very similar disease to trigeminal schwannoma, but affecting a different nerve) was considered in NHS England's policy D5/p/a. The evidence review into acoustic neuroma by the Birmingham University Health Technology Assessment Collaboration showed that SRS/SRT appears to provide: similar levels of tumour control; a less detrimental impact on quality of life; and lower rates of procedural mortality and medium-term treatment-related complications.

EVIDENCE REVIEW SUMMARY

Ependymoma

There is a paucity of evidence surrounding the effectiveness of SRS/SRT for patients with residual, recurrent or progressive ependymoma after previous surgery where further surgery was deemed too high risk. The literature search found one systematic review of case series and two additional case series.

The systematic review assessed the effectiveness of SRS/SRT in children with intracranial ependymoma, but it also included studies looking at adults. The review included 13 case series (with a total of 138 patients) that specifically looked at the effectiveness of SRS/SRT at time of recurrence. The studies were mostly small, retrospective, case series which ranged in size from 2-39 patients and had a wide range of follow-up times ranging from 2.5 months to 10 years. The systematic review only clearly reports the overall survival rate for each study (range 12% - 100%), which makes comparisons across the studies difficult as they have different follow-up

times. They do, however, report the 3-year survival rate range for studies that included patients of all ages and reported the rate separately for recurrent cases and this was 32-45%. The case series included in the systematic review (Kano et al., 2009) with 39 patients (age range = 3-71 years) observed overall survival rates after SRS of 60%, 36% and 32% at 2, 3 and 5 years, respectively. The quality of the reporting of the systematic review was poor making it difficult to critically appraise and extract results. Furthermore, the searches were carried out in October 2008.

In addition to the systematic review, the evidence review found two retrospective case series, one of which (Stauder et al., 2011) was published after the searches were conducted for the systematic review, and one appears to be missed from the review (Combs et al., 2006).

The largest of the two (Stauder et al. 2011), with 26 patients with recurrent ependymoma, observed survival rates of 96% and 69% at 1 and 3 years, respectively; progression-free survival rates of 80% and 66% at 1 and 3 years, respectively; and local tumour control rates of 85% and 72% at 1 and 3 years, respectively. Based on this series, there does appear to be a need for further intervention after initial SRS/SRT as the majority of patients (possibly all required either repeat SRS or alternative procedures after initial SRS.

The final case series (Combs et al., 2006) included seven patients with confirmed ependymomas who were given SRT as re-irradiation for tumour progression after previous surgery. The 3 and 5-year survival rates after SRT were 83% and 50%.

There were inconsistencies found with the progression-free survival rates reported for Kano et al. (2009) and Combs et al. (2006), as they were higher than the studies' overall survival rates which is not possible.

In summary, across the case series included in the systematic review and the additional two case series, a wide range of survival rates was observed, with 3-year survival rates ranging from 32% to 83%. This large range is to be expected, as the included studies were mostly small, retrospective, case series and therefore prone to selection bias. Their samples are likely to differ from each other and may not be

representative of the wider ependymoma population. In addition, the lack of a control arm inherent in case series means that the results of those who received no treatment for recurrent ependymoma after previous surgery cannot be compared to patients who received alternative interventions. In the absence of an RCT, it is not possible to reliably determine the effectiveness of SRS/SRT for patients with ependymoma. The evidence review found an ongoing RCT which compares stereotactic conformal radiotherapy to conventional radiotherapy in 200 patients with primary intracranial tumours including ependymomas. These results are expected to be released in June 2017.

Across the studies, few adverse events were reported, all of which were radiation necrosis. In total, two fatalities due to radiation necrosis were reported and three cases of craniotomies being required as a result of radiation necrosis.

Unsurprisingly given the limited evidence base, no studies were found assessing the cost effectiveness of SRS/SRT for ependymoma.

1. Evidence for the clinical effectiveness of stereotactic radiosurgery/stereotactic radiotherapy for ependymoma compared to other treatment modalities

The evidence surrounding the clinical effectiveness of SRS/SRT for ependymoma is limited. No randomised controlled trials, only small retrospective case series were found. Lack of a control arm and the introduction of selection bias inherent in case series means that it is not possible to determine the clinical effectiveness of SRS/SRT for ependymoma compared to other treatments.

2. Evidence for the cost-effectiveness of stereotactic radiosurgery / stereotactic radiotherapy for ependymoma compared to other treatment modalities

No studies were found assessing the cost effectiveness of SRS/SRT for ependymoma. In the absence of reliable data on clinical effectiveness, it is impossible to establish cost-effectiveness.

Haemangioblastoma

The evidence surrounding the clinical effectiveness of SRS/SRT for patients with residual, recurrent or progressive haemangioblastoma after previous surgery where further surgery was deemed too high risk is limited. The evidence review found five retrospective case series in which patients with haemangioblastoma were treated with SRS and a large proportion of these had previous surgery. The majority of results were not reported separately for those patients with residual, recurrent or progressive tumours after prior surgery and it was not a condition of the studies for SRS to be only given in cases where further surgery was too risky.

The most recently published case series and also the largest (Kano et al., 2015) included 186 patients (517 tumours) with intracranial haemangioblastomas treated with SRS in six centres in the USA and Japan between 1990 and 2010. Eighty-four percent of patients had prior surgery with 85 patients having had previous single surgery and 71 patient shaving had multiple surgeries. The median follow-up after SRS was 5 years (range 0.5 – 18 years).

The overall survival rate after SRS was 94%, 90% and 74% at 3, 5 and 10 years, respectively. For those patients that underwent SRS for recurrent or residual tumours, the 5-year local tumour control rate was just over 85%. For the entire series, the rate of developing a new tumour or recurrence of residual tumour was 5% at 1 year, 18% at 3 years, 33% at 5 years, and 54% at 10 years. Around 40% of patients required additional treatment (SRS, resection or cyst aspiration) for tumour progression (38/186 patients) or for new tumours or recurrence (37/186 patients).

The smaller case series ranged in size from 21 to 35 patients. The results reported across these smaller case series are consistent with those of Kano et al. (2015), with the 3-year tumour control rates ranging from 82% to 92% and the 5-year tumour control rates ranging from 71% to 92%. Kano et al. (2015) observed tumour control rates at the higher end of these ranges, and this large case series is likely to give a more reliable estimate of the treatment effect as it is less prone to selection bias and chance findings. However, the reliance of the studies on case notes, as is the case for all these retrospective case series, means that reporting bias may have been introduced with patients with worse outcomes being likely to have more complete

notes. Few adverse radiation effects were reported across all the included series, although there was one death due to refractory peritumoral oedema observed in Kano et al. (2015).

Case series do not have a control arm, so in the absence of a randomised controlled trial, it was not possible to compare results to no intervention or alternative interventions and hence reliably determine the comparative clinical effectiveness of SRS/SRT in patients with haemangioblastoma. No ongoing relevant randomised controlled trials or other study designs were found. The cost-effectiveness of SRS/SRT cannot be determined because the data do not allow us to reliably quantify the clinical effectiveness.

1. Evidence for the clinical effectiveness of stereotactic radiosurgery stereotactic radiotherapy for haemangioblastoma compared to other treatment modalities

The evidence surrounding the clinical effectiveness of SRS/SRT for haemangioblastoma is limited. No randomised controlled trials were found. Only one large retrospective case series and four small retrospective case series were found, all of which reported high tumour control and survival rates over many years of follow up. However, lack of a control arm and the possibility of selection bias inherent in case series means that it was not possible to determine the clinical effectiveness of SRS/SRT for haemangioblastoma compared to other treatments.

2. Evidence for the cost-effectiveness of stereotactic radiosurgery / stereotactic radiotherapy for haemangioblastoma compared to other treatment modalities

No studies were found assessing the cost-effectiveness of SRS/SRT for haemangioblastoma.

Pilocytic Astrocytoma

The questions posed at the outset of this review are addressed in turn below.

1. Evidence for the clinical effectiveness of stereotactic radiosurgery/stereotactic radiotherapy for pilocytic astrocytoma compared to other treatment modalities

The evidence review did not identify any studies comparing SRS/ SRT for pilocytic astrocytoma to other treatment modalities. Evidence for the clinical effectiveness of SRS and SRT for pilocytic astrocytoma comes from small uncontrolled observational studies which involved heterogeneous populations and showed variable results. All studies reported tumour control in at least 50% of patients although the follow-up period for different patients varied considerably. Analysis of sub-groups of patients found that worse outcomes were associated with previous radiotherapy, multifocal tumours, older patient age and lower radiosurgical tumour dose, whereas better outcomes were associated with non-cystic lesions, smaller tumour volume, newly diagnosed or residual tumour (versus recurrence), prior surgical intervention of total or partial resection (versus prior surgical intervention of biopsy) and no brainstem involvement. Data for the impact of SRS and SRT for pilocytic astrocytoma on quality of life were limited but improvements in measures of activities of daily living were observed in one study. Rates of adverse events attributed to SRS or SRT were generally low.

Because this evidence is from uncontrolled observational studies it is not possible to draw any strong conclusions about the effectiveness of SRS or SRT in patients with pilocytic astrocytoma who have had prior surgery.

2. Evidence for the cost-effectiveness of stereotactic radiosurgery / stereotactic radiotherapy for pilocytic astrocytoma compared to other treatment modalities

The evidence review did not identify any studies assessing the cost-effectiveness of SRS or SRT for pilocytic astrocytoma.

Trigeminal Schwannoma

The questions posed at the outset of this review are addressed in turn below.

1. Evidence for the clinical effectiveness of stereotactic radiosurgery / stereotactic radiotherapy for trigeminal schwannoma compared to other treatment modalities

There is an absence of reliable appropriately controlled studies with which to assess the effectiveness of SRS/SRT to treat the recurrence or residual tumours following surgery. Across the studies patients with a decrease in tumour size outnumber patients with an increase in tumour size (15 vs 2); patients with a reduction in symptoms were similar in number to those whose symptoms worsened (10 vs 9), with seven patients having unchanged symptoms. Worsening symptoms as a result of SRS/SRT resolved themselves by last follow-up.

All small case series such as those identified in this review (retrospective, uncontrolled, unblinded, observational studies) are confounded by a high likelihood of bias and are considered low grade evidence. On balance the findings of the seven case series indicate the merit in pursuing more rigorous studies focussed on efficacy and safety. Given the rare occurrence of these tumours, multi-site studies would be necessary to gather statistically useful information.

2. Evidence for the cost effectiveness of stereotactic radiosurgery / stereotactic radiotherapy for trigeminal schwannoma compared to other treatment modalities

The evidence review did not identify any studies on the cost-effectiveness of SRS/SRT for trigeminal schwannoma for patients with residual, recurrent or progressive tumours, after previous surgery, where further surgery is deemed too high risk.

6 Criteria for Commissioning

- Microsurgery should remain the first line treatment option of choice for ependymoma, haemangioblastoma and pilocytic astrocytoma. Microsurgery or SRS/SRT may be considered as first line treatments for trigeminal schwannoma after MDT assessment of the risks and benefits of each option.

- All patients being considered for SRS/SRT must have undergone prior assessment by the local brain & CNS tumours multi-disciplinary team (MDT), who should take into consideration the patients comorbidities, likely outcome of treatment and life expectancy.

Inclusion criteria

- Patients with sub-total resection who are deemed to be at high risk of future progression and in whom further surgery is not deemed safely feasible may be considered for SRS/SRT post-operatively for the residual; OR
- Patients with sub-total resection who on surveillance later develop progressive disease after resection and for whom repeat surgical resection is deemed too high-risk or unlikely to succeed; OR
- Patients with complete resection who later develop recurrent disease after surgery for whom repeat surgical resection is deemed too high-risk; OR
- Tumour deemed inoperable by the MDT; AND
- Tumour is expected to result in morbidity OR mortality without treatment; AND
- The disease process is focal (unifocal or multifocal; AND
- Decision to treat is shared with patient; AND
- Within volume limits deemed safely and effectively treated by SRS/SRT.

Exclusion criteria

- Patients who have previously tried and failed SRS; OR
- Patients with ependymoma eligible for proton beam therapy; OR
- Operable tumours; OR

- Stable tumours without progressive symptoms or progressive growth as assessed by serial imaging; OR
- The disease process is diffusely infiltrative; OR
- Larger or diffuse lesions more effectively treated with conventional fractionated external beam radiotherapy.

7 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.

Decision to refer to appropriate Tier 1/2 SRS/SRT centres will be taken by recognised local brain and CNS tumours MDT (neuro-oncology, skull-base, pituitary and spinal cord).

Decision to accept referrals will be taken by specialist MDT in the referral centre in line with eligibility and referral guidelines.

The six management options for patients are:

1. Surgical removal (the primary option for most tumours);
2. SRS or SRT;
3. Fractionated radiotherapy;
4. Proton beam therapy;
5. Chemotherapy; and
6. No intervention.

Management depends on the anatomical location of the tumour, its size, existing neurological deficits and the risks of surgery.

SRS/SRT would be considered in the patient pathway only after primary surgical resection has been performed, or the tumour has been deemed inoperable.

If SRS/SRT is not a safe or feasible option, patients may either be considered for surgery or to have conventional fractionated radiotherapy.

8 Governance Arrangements

The service specification for Intracranial SRS/SRT (NHS England, D05/S/a) describes the care pathways and key aspects of intracranial SRS/SRT services being commissioned, and should be referred to in conjunction with this policy.

9 Mechanism for Funding

The treatment is covered by the scope of the Intracranial Stereotactic Radiotherapy / Stereotactic Radiosurgery service specification and is the commissioning responsibility of NHS England. The clinical indication covered by this policy are classed as Tier 1 and Tier 2 indications within the service specification classification framework.

10 Audit Requirements

Audit requirements will include the following data items for each patient:

- Karnofsky Performance Status
- Tumour type and grade
- Prognostic factors, including demographic data and brainstem compression
- Whether the tumour is primary, residual or recurrent
- Estimated total tumour volume (cc)
- No. of tumours
- Size of largest tumour
- Dose
- Fractionation
- Treatment outcome (tumour control 1, 3 and 5 year)
- Side effects (radionecrosis, swelling requiring treatment, cranial nerve injury, neurological impairment)

- Patient reported quality of life improvements
- 30 day mortality
- Requirements for other treatments or interventions

11 Documents which have informed this Policy

NHS England Service Specification Intracranial Stereotactic Radiosurgery/ Stereotactic Radiosurgery (D05/s/a)

National Institute for Health and Care Excellence Clinical Guideline 10 Improving outcomes for people with brain and other CNS tumours. London: NICE, 2006.

National Institute for Health and Care Excellence Clinical Guideline 81 Advanced breast cancer: diagnosis and treatment. London: NICE, 2009.

NHS England Clinical Commissioning polices for the use of Intracranial Stereotactic Radiotherapy / Stereotactic Radiosurgery (D05/P/e; D05/P/f; D05/P/g; D05/P/a; D05/P/b; D05/P/c; D05/P/d).

NHS England Guidance for the referral of patients abroad for NHS Proton Treatment, version 2.3 July 2011.

12 Date of Review

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

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