NHS England

Interim Clinical Commissioning Policy Statement: Stereotactic Radiosurgery / Radiotherapy for Ocular Melanoma and Pituitary Adenoma

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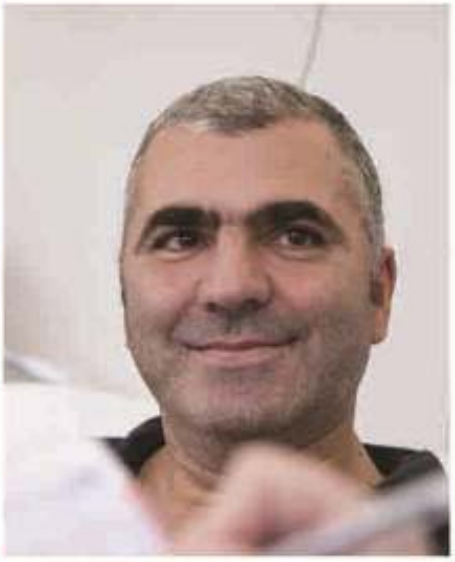

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Clinical Commissioning Policy Statement: Stereotactic Radiosurgery/Radiotherapy for Ocular Melanoma and Pituitary Adenoma

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Prepared by NHS England Clinical Reference Group for Stereotactic

Radiosurgery

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POLICY STATEMENT: Stereotactic Radiosurgery/Radiotherapy	**Policy Ref:** **NHS England** **D05/PS/a**

Background	Stereotactic radiation therapy describes the delivery of radiation therapy and includes both Stereotactic Radiotherapy (SRT) and Stereotactic Radiosurgery (SRS). The patient is immobilised in a rigid frame and the target volume is defined by the co-ordinates of the stereotactic space within. Both deliver high doses of radiation to tumour sites, and are used to stop the division of tumour cells. The accuracy of volume definition and machine set-up facilitates delivery of treatment with smaller margins and thus optimal sparing of surrounding tissues. This enhanced therapeutic index allows higher and potentially more effective doses to be delivered to small targets. In addition, stereotactic localisation may permit delivered doses to be delivered with fewer side effects. Stereotactic radiosurgery works in the same way as other forms of radiation treatment. It does not actually remove the tumour, rather it distorts the DNA of tumour cells. As a result, these cells lose their ability to reproduce. Following the treatment, benign tumours usually shrink over a period of 18 months to two years. Malignant and metastatic tumours may shrink more rapidly, even within a couple of months. When treated with radiosurgery, arteriovenous malformations (AVMs) begin to thicken and close off. Stereotactic radiosurgery uses non-invasive technology, so the risks involved are dramatically reduced over conventional surgery to offer a broad range of benefits: • No incisions mean minimal discomfort • Less risk of postoperative complications • Shorter recovery period • Patients return home the same day • Nearby healthy brain tissue is seldom affected • Uses local anaesthetic or sedation (for adults) for maximum patient comfort (children are anesthetised) • Usually only one treatment versus many over several weeks. Similarly for external beam radiotherapy the movement to SRS could reduce the number of daily attendances from 15-

	20 to a single visit, with less impact on the healthy brain tissue. There are also patients who currently are not suitable for surgery or external beam radiotherapy, due to the positioning of the tumour or mass, which may now have a treatment option available. Patients of all ages may benefit from SRS / SRT. The treatment is usually carried out with the patients awake and therefore the patient needs to be compliant. Young children and non-compliant adults can be treated using general anaesthesia. There is some evidence available for the benefits of SRS / SRT. Treatment for patients with the following conditions should be considered by the relevant MDT(s). **STEREOTACTIC RADIOSURGERY/RADIOTHERAPY FOR CRANIAL INDICATIONS** There are two methods of delivering high doses of radiation to tissue. Stereotactic Radiosurgery (SRS) is a single fraction, and stereotactically directed irradiation of a limited volume in the brain or other structures of the skull base. Stereotactic Radiotherapy (SRT) is fractionated, stereotactically directed irradiation of a limited volume in the brain. Stereotactic radiosurgery is an important alternative to invasive surgery, especially for tumours and blood vessel abnormalities located deep within or close to vital areas of the brain. Radiosurgery is used to treat many types of brain tumours, both benign or malignant and primary or metastatic. Additionally, radiosurgery is used to treat arteriovenous malformations (AVMs), a tangle of expanded blood vessels that disrupts normal blood flow in the brain and is the leading cause of stroke in young people. This policy includes radiation treatments that are stereotactically delivered to treat ocular melanomas and pituitary adenomas. This includes all modes of delivery such as Gamma Knife®, modified linear accelerators, Novalis® , Cyberknife®. It is technically possible for the Gamma Knife® to deliver SRT but the LINAC – based systems are more suited to providing fractionated treatment. However the policy does not cover other non SRS radiotherapy technologies, such as Intensity Modulated Radiotherapy (IMRT) and Proton Beam Therapy (PBT).
Commissioning position	Stereotactic Radiosurgery/Radiotherapy will be routinely commissioned for patients meeting the criteria for the appropriate clinical indications in this policy statement. Stereotactic Radiosurgery/Radiotherapy will not be routinely

	commissioned for patients who fall outside of the criteria stated for the clinical indication, except in exceptional circumstances. Such cases will be considered through the Individual Funding Request mechanism.
Effective from	August 2013
Evidence summary	**<u>Pituitary Adenoma</u>** Almost all patients with pituitary adenoma need some form of treatment. Surgery is, with the exception of the macro-prolactinomas, the treatment of first choice because it has a high cure rate and the beneficial effects are evident within a few days after surgery. Recurrent adenomas and persisting parts of the previously operated adenomas need additional treatment either by life long medical treatment with antisecretory drugs or with some form of radiation therapy. For non functioning adenomas, pharmacological control is not available. It is estimated that about 22% of all previously operated patients (7% persisting and 15% recurring) will sooner or later need radiation treatment. This is equivalent to about 4 persons per one million inhabitants. [i]The evidence available for the effectiveness of SRS/SRT is drawn primarily from case series and small cohort studies. However, the evidence suggests that gamma knife as an adjunct to surgery may provide better levels of tumour control and hormone normalisation than surgery alone, with no obvious detriment to patient safety. A literature review reports the following on the clinical effectiveness of SRS in medically and surgically refractory pituitary adenomas. It supports the use of radiosurgery, with endocrinologic remission rates and time to remission varying by tumor type [prolactinoma: 20-30%, growth hormone secreting adenomas: ~50%, adrenocorticotrophic hormone (ACTH)-secreting adenomas: 40-65%] and radiographic control rates almost universally greater than 90% with long-term follow-up [ii]. Evidence from the literature suggests SRS is a safe treatment option for recurrent or residual pituitary adenomas [ii, iii. iv] Clinical consensus is that external beam radiotherapy is an option for treatment of pituitary adenoma where the target is larger, less discrete or is difficult on imaging to evaluate the extension of the disease. Patients meeting all the following criteria will be routinely funded:

General

The relative risks and benefits of SRS/SRT over conventional fractionated radiotherapy should be discussed with patients on a case by case basis and documented in the case notes.

Stereotactic Radiosurgery

- Not suitable for open surgery OR
- for residual or recurrent pituitary lesions that have undergone maximal safe surgical resection and/or radiotherapy, that are less than 4 cm^3 , and are more than 3 mm away from the optic apparatus [ii] AND / OR
- Extension of the tumour into the cavernous sinus

Stereotactic Radiotherapy:

- Inability to achieve radiation to optic apparatus within dose tolerance with radiosurgery.

<u>Ocular Melanoma</u>

Stereotactic Radiosurgery is an option for treatment for this rare condition. Removal of the eye, plaque therapy and proton therapy are alternatives. Management of these cases utilises a number of modalities. Decision about the option used depends on several factors (e.g. age, size of tumour, the position in relation to the optic nerve, the presence or absence of vision, the state of the fellow eye and the general health of the patient).

35 patients with uveal melanoma were treated with gamma knife SRS in a non-randomisned study. Patients were previously untreated in order to establish local long-term tumor control rates. Cumulative 1-year and 3-year local tumour growth control rates were 97% and 83%, respectively. The mean and median times to local tumor progression were 48.0 and 51.7 months, respectively. The most frequent complication was retinal detachment (17.1%) [V]

Gamma knife SRS was used to treat 78 patients with uveal melanoma in a non randomised study. It reported survival rate to be 88.8% at 3 years and 81.9% at 5 years in patients following treatment. Local tumour control was achieved in 91.0% of patients. The median tumour thickness reduction after treatment was 1.96 mm ($p<0.0001$) (-32.1%). The eye retention rate was 89.7%. A significant relative reduction of visual acuity was observed during follow-up. The most frequent treatment-related complications were: exudative

	retinopathy (33.3%), neovascular glaucoma (18.7%), radiogenic retinopathy (13.5%) and vitreous haemorrhages (10.4%) [vi]. 50 eyes with medium- or large-sized posterior uveal melanomas were treated with Gamma knife. Reduction in mean diameter from baseline at median follow up of 40 months was 1.6 mm and 2.5mm in apical height. Changes in both tumor height and diameter were statistically significant ($p < 0.001$). The tumor control rate was 90 %, and the eye retention rate was 82 %. A total of nine patients (18 %) developed metastasis, and seven (14 %) died due to metastasis during follow-up. Cataracts (34 %) and radiation maculopathy (30 %) were the most frequent complications, and 14 % of patients developed neovascular glaucoma. Visual acuity (VA) decreased significantly after treatment ($p < 0.0001$) [vii]. Patients meeting all the following criteria will be routinely funded: **General** Patients should only be considered where there is involvement of a specialist optic tumour team. **Stereotactic Radiosurgery or Stereotactic Radiotherapy** • Treatment identified as an option by the specialist ocular tumours MDT
Equality impact	Throughout the production of this document, due regard has been given 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 in under the Equality Act 2010) and those who do not share it.
Responsible CRG	D05 Stereotactic Radiosurgery
Mechanism for Funding	From July 2013 NHS England became responsible for commissioning Stereotactic Radiosurgery in line with this policy statement on behalf of the resident population of England. Funding is transacted as per local contract agreements and terms.
Date Approved by Clinical Priorities Advisory Group	12 July 2013
Policy review date	During 2013

References

[i] The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for pituitary adenomas: an evidence based review, Greenheld, Fry-Smith, Routh, Moore, Unit of Public Health and Epidemiology, University of Birmingham, 8/6/10

[ii] Kim W, Clelland C, Yang I, Pouratian N. Comprehensive review of stereotactic radiosurgery for medically and surgically refractory pituitary adenomas. Surg Neurol Int. 2012;3(Suppl 2):S79-89. doi: 10.4103/2152-7806.95419.

[iii] Laws ER, Sheehan JP, Sheehan JM, Jagnathan J, Jane JA Jr, Oskouian R. Stereotactic radiosurgery for pituitary adenomas: a review of the literature. J Neurooncol. 2004 Aug-Sep;69(1-3):257-72.

[iv] Sheehan JP, Niranjan A, Sheehan JM, Jane JA Jr, Laws ER, Kondziolka D, Flickinger J, Landolt AM, Loeffler JS, Lunsford LD. Stereotactic radiosurgery for pituitary adenomas: an intermediate review of its safety, efficacy, and role in the neurosurgical treatment armamentarium. J Neurosurg. 2005 Apr;102(4):678-91.

[v] Toktas ZO, Bicer A, Demirci G, Pazarli H, Abacioglu U, Peker S, Kilic T. Gamma knife stereotactic radiosurgery yields good long-term outcomes for low-volume uveal melanomas without intraocular complications. J Clin Neurosci. 2010 Apr;17(4):441-5.

[vi] Modorati G, Miserocchi E, Galli L, Picozzi P, Rama P. Gamma knife radiosurgery for uveal melanoma: 12 years of experience. Br J Ophthalmol. 2009 Jan;93(1):40-4.

[vii] Sarici AM, Pazarli H. Gamma-knife-based stereotactic radiosurgery for medium- and large-sized posterior uveal melanoma. Graefes Arch Clin Exp Ophthalmol. 2013 Jan;251(1):285-94