

# **Clinical Commissioning Policy: The use of Stereotactic ablative radiotherapy (SABR) as a treatment option for patients with renal cancer**

Reference: NHS England: 16023/P



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**Additional Circulation List**

<b>Description</b>	Not Routinely Commissioned - NHS England will not routinely commission this specialised treatment in accordance with the criteria described in this policy.
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**Document Status**

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# **Clinical Commissioning Policy: The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for patients with renal cancer**

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## **Policy Statement**

NHS England will not routinely commission stereotactic ablative radiotherapy as a treatment option for patients with renal cancer 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**

The proposal aims to confirm NHS England's approach to the use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for kidney cancer, which is also called 'renal cancer'.

### **About SABR treatment**

Stereotactic Ablative Radiotherapy (SABR) is a highly targeted radiation therapy which aims to target a tumour with radiation beams from different angles at the same time so that:

- The tumour receives a high dose of radiation
- The tissues around the tumour receive a low dose

There are usually between 1 and 8 treatments, called 'fractions'.

**What we have decided**

NHS England has carefully reviewed the evidence to treat renal cancer with Stereotactic Ablative Radiotherapy (SABR). We have concluded that there is not enough evidence to make the treatment available at this time.

For the purpose of this policy Stereotactic Ablative Radiotherapy (SABR) refers to hypo-fractionated treatment of not more than 8 fractions. This policy concerns the use of SABR to treat renal cancer. Commissioning arrangements for fractionated treatments utilising a larger number of fractions are beyond the remit of this policy.

## 1 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission Stereotactic Ablative Radiotherapy (SABR) in the treatment of patients with renal cancer.

## 2 Definitions

Stereotactic Ablative Radiotherapy (SABR) refers to the precise irradiation of an image defined extra cranial lesion and is associated with the use of a high radiation dose delivered in a small number of fractions. The technique requires specialist positioning equipment and imaging to confirm correct targeting. It allows sparing of the surrounding healthy normal tissues.

Stereotactic radiation therapy has been used for benign and malignant lesions in the brain for many years. Stereotactic radiosurgery (SRS) is a single fraction of stereotactic directed radiation of a limited volume in the brain or other structure of the skull base, whereas stereotactic radiotherapy (SRT) has been defined as a fractionated stereotactic directed radiation of a limited volume in the brain. SABR refers to the use of stereotactically directed radiation therapy to structures outside the brain and skull.

### **Extra-cranial malignant disease**

Extra-cranial malignant disease is a catch all term for all malignancies excluding cerebral metastases, which is the subject of a separate policy.

## 3 Aims and Objectives

This policy considered whether there is sufficient robust evidence of clinical and cost-effectiveness and safety to support the use of Stereotactic Ablative Radiotherapy (SABR) to treat patients with renal cancer.

The objective was to identify whether the evidence is sufficiently robust and what criteria should be used to identify suitable patients to be considered for SABR.

## 4 Epidemiology and Needs Assessment

Renal cell carcinoma is a malignancy that originates in the lining of the proximal convoluted tubule of the kidney. The condition, usually described as renal carcinoma or renal cancer, is the most frequent malignant disorder of the kidney in adults, but is uncommon, accounting for only about 3% of cancers in the United Kingdom; its annual incidence is about 13 per 100,000. The incidence is apparently rising, but this probably reflects the incidental detection of radiological abnormalities in the kidney when patients are scanned for other reasons. This has led to annual increases in the detection of renal cancers of about three percent, with the incidence of small renal tumours increasing at a faster rate. Lesions detected in this way may have a more favourable prognosis than those which present with symptoms.

Initial treatment is most commonly a radical or partial nephrectomy. Where the tumour is confined to the renal parenchyma, the five-year survival rate is 60% to 70%, but it is much lower when metastasis has occurred. Small tumours may be treated non-invasively with cryotherapy and radio-frequency ablation, both of which are the subject of guidance from the National Institute for Health and Care Excellence. Renal cancer is relatively resistant to radiation therapy and chemotherapy, but sunitinib, temsirolimus, bevacizumab and other forms of immunotherapy can have some effect.

## 5 Evidence Base

The evidence regarding the effectiveness and safety of Stereotactic Ablative Radiotherapy (SABR) for treating patients with renal cancer has been used as a basis for this commissioning policy. The evidence base indicates that there is insufficient evidence to routinely commission SABR for this cohort of patients.

No studies were identified in the review commissioned for the development of this policy which was restricted to people with inoperable renal cancer. The search was therefore widened to include all studies of SABR for renal cancer. No randomised controlled trials were identified.

One systematic review of SABR for renal cancer Siva et al (2012) was identified:



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- The authors, Siva et al, found ten papers reporting a total of 126 participants; three studies were prospective and seven retrospective. None of the studies were controlled. Technique and dose fractionation “varied widely”, with three, four- and five-fraction regimes most commonly reported. The most common total dose was 40 Gy. Little further information is available, for example on the median ages of the participants or the use of other treatments. There is no information on whether the tumours were biopsied before treatment – this is not always the case with renal tumours, and some tumours are treated as malignant despite being histologically benign.
- After follow-up ranging from nine to fifty-eight months, local control rates varied from 84% to 100%. Without testing for heterogeneity, Siva et al crudely weighted the control rates according to the studies’ sizes, and calculated average rates of 93.1% for overall local control and 92.9% for local control at two years. A more sophisticated approach would have been to include studies’ duration in the weighting, though the heterogeneity of the studies casts doubt on the appropriateness of pooling the results at all.
- Siva et al note the inconsistent reporting of survival after treatment. Six of the ten studies did not report survival at all, while the results from the remaining four varied widely. They reported respectively median survival of “58+” months, a five-year survival rate of 74%, median survival of 32 months and that four of nine participants were still alive when the study closed.

No published studies since Siva et al’s search date (2012) were identified, nor any published before that date which the authors did not include.

## **6 Documents which have informed this Policy**

National Cancer Action Team. National Radiotherapy Implementation Group Report Stereotactic Body Radiotherapy Guidelines for Commissioners, Providers and Clinicians in England 2011. Available from:

Radiotherapy Guidelines for Commissioners, Providers and Clinicians in England 2011. Available from: Accessed September 2012.

National Cancer Action Team. National Radiotherapy Implementation Group Report Stereotactic Body Radiotherapy Clinical Review of the Evidence for SBRT 2011.

Yorkshire and the Humber Specialised Commissioning Group. Commissioning Policy Stereotactic radiosurgery/radiotherapy.

## **7 Date of Review**

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

## References

National Institute for Health and Care Excellence. Percutaneous radiofrequency ablation for renal cancer. London: NICE, 2010. (IPG 353).

National Institute for Health and Care Excellence. Percutaneous cryotherapy for renal cancer. London: NICE, 2011. (IPG 402).

National Institute for Health and Care Excellence. Laparoscopic cryotherapy for renal cancer. London: NICE, 2011. (IPG 405).

Siva S, Pham D, Gill S, et al. A systematic review of stereotactic radiotherapy ablation for primary renal cell carcinoma. *BJU Int* 2012; 110: E737-43.