

Clinical Commissioning Policy

Stereotactic ablative body radiotherapy for patients with localised, non-metastatic, renal cancer who are medically unfit for surgery (adults) [2332]

Summary

Stereotactic ablative body radiotherapy (SABR) is recommended to be available as a routinely commissioned treatment option for adults with localised, non-metastatic T1b, N0, M0 renal cancer and who are medically unfit for surgery within the criteria set out in this document.

The policy is restricted to certain age groups (adults) as there is insufficient evidence to confirm safety in those age groups not included in the proposition.

Committee discussion

Clinical Panel agreed with the policy and recommended that this proceeds as a routine commissioning policy proposition. Panel members agreed that it is important to ensure that clinical and safety outcomes prioritised for the evidence review are captured in an appropriate registry for the medically inoperable 1b population in the policy proposition.

Please see Clinical Panel reports for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group committee papers can be accessed here: [Clinical Commissioning Policy: Stereotactic ablative body radiotherapy for patients with localised, non-metastatic, renal cancer who are medically unfit for surgery \(adults\)](#)

What we have decided

NHS England has carefully reviewed the evidence to treat patients with localised, non-metastatic T1b, N0, M0 renal cancer who are medically unfit for surgery with SABR. We have concluded that there is enough evidence to make the treatment available at this time.

The evidence review which informs this commissioning position can be accessed here: [Clinical Commissioning Policy: Stereotactic ablative body radiotherapy for patients with localised, non-metastatic, renal cancer who are medically unfit for surgery \(adults\)](#)

Links and updates to other policies

This document updates Clinical Commissioning Policy: [The use of Stereotactic ablative radiotherapy \(SABR\) as a treatment option for patients with renal cancer](#), published on 13 July 2016.

Plain language summary

About renal cancer

Renal cancer, also called renal cell carcinoma or primary kidney cancer, is a malignancy that originates in the lining of the proximal convoluted tubule of the kidney. Once localised renal cancer has been confirmed by the appropriate imaging, biopsies are usually performed to confirm the diagnosis.

Tumour Node Metastasis (TNM) staging system (CRUK, 2020):

T – describes the size and extent of the tumour from 1 (tumour less than 7cm) to 4 (involving adjacent structures)

N – describes the presence of involved lymph nodes from 0 (none) to 1 (present)

M – describes whether the cancer has metastasised from 0 (non-metastatic) to 1 (metastatic)

Renal cancer is strongly associated with age, with the highest incidence rates in patients between 85-89 years (CRUK, 2023). Each year around a third (34%) of all new kidney cancer cases in the UK are diagnosed in people aged 75 years and over (CRUK, 2023). Additional risk factors include smoking and obesity.

About current treatments

Patients with localised, non-metastatic renal cancer will be discussed at a specialist renal multi-disciplinary team (MDT) meeting (which may form part of a uro-oncology MDT), where a decision is made about treatment.

The European Association of Urology recommends in the elderly and/or comorbid patients with small renal masses (≤ 4 cm, T1a) and limited life expectancy, active surveillance, radio-frequency ablation and cryoablation can be offered (Ljungberg et al, 2015). This is supported by Getting It Right First Time (GIRFT, 2023).

However, T1b, N0, M0 renal cancers, compared with T1a, N0, M0 renal cancers, are faster growing and more aggressive, with a higher risk of complications from local disease progression, such as bleeding and pain, and a higher risk of progression to metastatic disease (Volpe et al, 2018; Touma et al, 2019). Active surveillance is not recommended in patients with T1b, N0, M0 renal cancers, and these patients should be assessed for suitability for active treatments (Ljungberg et al, 2015; GIRFT, 2023).

As per current NICE guidance, partial nephrectomy is considered the standard of care for stage I renal cancer (stage I includes T1a (≤ 4 cm) and T1b (> 4 cm but ≤ 7 cm), N0, M0 cancers), for patients with bilateral cancers, solitary kidneys, or renal impairment (NICE, 2006). If partial nephrectomy is not possible, radical nephrectomy is considered (NICE, 2005). These procedures are major surgical undertakings and require significant inpatient stay, sometimes needing high dependency unit support.

NICE have not approved ablative procedures for these patients. Therefore, there are currently no alternative treatment options available for patients with T1b, N0, M0 renal cancers who are medically unfit for surgery until the development of metastatic disease, for which there is no curative treatment.

Standard treatment upon development of metastases is lifelong treatment with costly systemic anti-cancer treatments (EUA, 2023; NCCN, 2023). These patients, typically elderly and with comorbidities, may not be fit for systemic anti-cancer treatments on development of metastatic disease.

About stereotactic ablative radiotherapy

Stereotactic ablative radiotherapy (SABR), also called stereotactic body radiotherapy (SBRT) is a highly targeted and precise radiotherapy technique, which delivers higher overall doses of radiotherapy in a fewer number of treatments (hypofractionation) than conventional radiotherapy. SABR is delivered using one, three, five or eight treatments (or fractions) and usually delivered in an outpatient setting. The aim of treatment with SABR is to ensure that the tumour receives a high dose of radiation whilst the tissues close to the tumour receive a lower dose of radiation sparing the surrounding healthy normal tissues and reducing the risk of side effects. SABR has been used as a non-surgical intervention with curative intent in many cancer settings, such as hepatocellular carcinoma, for many years.

Renal cancer was historically considered radioresistant when treated with conventional radiotherapy, and for this reason radiotherapy has been used mainly to treat metastases with a palliative intent. SABR, compared to conventional radiotherapy, uses a higher dose per fraction with a higher biological effect that can overcome this perceived radio-resistance. This clinical commissioning policy recommends the use of SABR as a treatment option for adults with localised, non-metastatic T1b, N0, M0 renal cancer who are medically unfit for surgery.

Epidemiology and needs assessment

Renal cancer is the most frequent malignant disorder of the kidney in adults, but is uncommon, accounting for 4% of all new cancer cases in the UK (CRUK, 2023) with an incidence in 2020 of approximately 10,500 cases in England (CancerData, 2023).

According to CancerData statistics for 2020, 36% of renal cancers are stage I at diagnosis (CancerData, 2023), meaning an incidence of stage I cancer of approximately 3,800 patients per year in England. The Policy Working Group estimates that approximately half of these cases are T1b, N0, M0 renal cancers, meaning an incidence of approximately 1900 patients per year. Approximately 50% of patients with stage I renal cancer have surgery (CancerData, 2023). It is therefore estimated that approximately 950 patients per year in England are diagnosed with T1b, N0, M0 renal cancer and are medically unfit for surgery, and thus may be eligible for SABR.

Implementation

All patients with renal cancer, including stage 1b, should have their care managed by a number of specialists working together as part of a specialist renal MDT which is responsible for surgical and radiotherapy case selection, and should take into consideration patient comorbidities, potential adverse events and likely outcomes of treatment.

For T1b, N0, M0 renal cancer, surgery remains the standard of care and active surveillance is not recommended.

Inclusion criteria

For SABR, patients must meet ALL of the following inclusion criteria:

- Patients are confirmed as suitable for active treatment with a life expectancy of ≥ 24 months as determined by a specialist renal MDT;
- 18 years or over;

- Have a diagnosis of T1b (>4cm but ≤7cm), N0, M0 renal cancer and a specialist renal MDT has confirmed that the patient is medically unfit for surgery;
 - Patients medically unfit for surgery include patients medically unfit for a general anaesthetic and patients with inoperable tumours due to technical reasons, e.g. position of tumour.
- Histology confirming renal cancer; OR, if no tissue diagnosis, only where this has been agreed by the renal MDT as appropriate i.e. radiology and clinical presentation strongly support a diagnosis of malignancy and attempts at obtaining tissue have been unsuccessful or not deemed to be clinically appropriate;
- Single lesion within the target kidney >4cm but ≤7cm;
- Patients MUST be confirmed as suitable for renal SABR treatment by a SABR MDT;
- WHO performance status ≤ 2.

Exclusion criteria

Treatment with SABR is unsuitable for people who:

- Have a diagnosis of T1a (≤4cm), N0, M0 or ≥ stage II (≥ T2 / N1 / M1) renal cancer;
- Have received previous radiotherapy treatment to the upper abdomen and where the radiation dose from SABR to either the kidney or surrounding tissues is likely to exceed accepted dose limits.
- Are unfit for active treatment or not felt to be appropriate for active treatment as determined by the specialist renal MDT

Starting criteria

Patients that meet all of the inclusion criteria and do not meet any of the exclusion criteria can be considered for treatment with SABR.

Patient pathway

The Service Specification for External Beam Radiotherapy Services ([NHS England Reference: 170091S](#)) describes the detail of the care pathways for this service. Radiotherapy is part of an overall cancer management and treatment pathway.

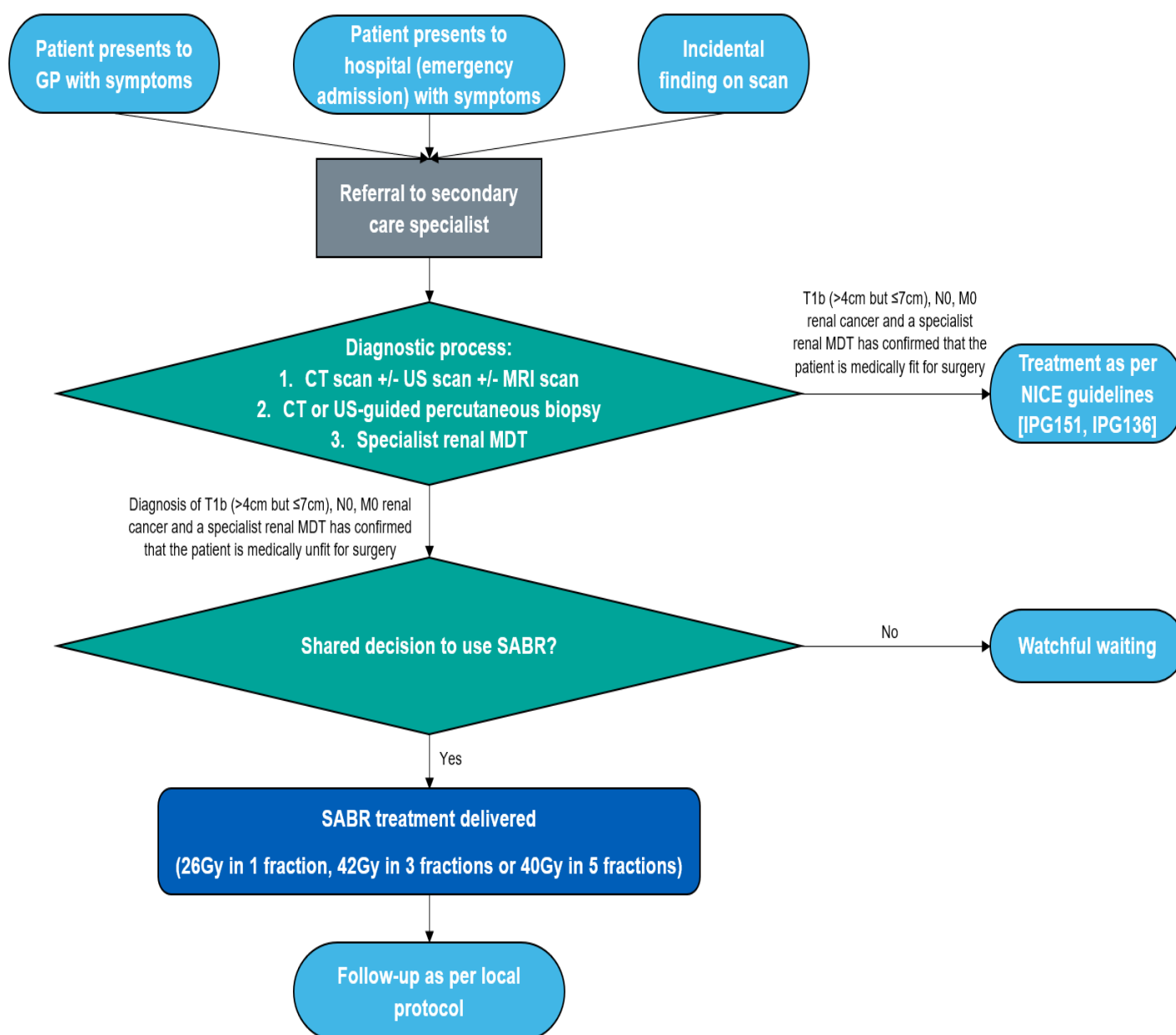
Decisions on the overall treatment plan should relate back to a specialist renal MDT discussion and decision. Patients suitable for radiotherapy are referred to a clinical oncologist for assessment and full explanation of the advantages and side effects of treatment (including the risk of renal replacement therapy in consultation with a nephrologist) with adequate time for decision making. The clinical oncologist will then arrange treatment planning and delivery of radiation fractions as appropriate. Each fraction of radiation is delivered on one visit, usually on an outpatient basis.

A dose range of 26Gy in one fraction, 42Gy in three fractions or 40Gy in five fractions on alternate days should be used. This dose range is based on the published data, supported by [The Royal College of Radiologists Radiotherapy Dose and fractionation guideline \(Fourth edition\)](#) (RCR, 2024), which demonstrates efficacy of these doses. However, it is recognised that at an individual patient level, the ability to deliver doses at the higher end of this range will depend on the proximity of the tumour to normal tissues and the SABR delivery technique available at the treating radiotherapy centre.

In addition, all providers of treatment with SABR must:

- Ensure all patients treated are subject to an MDT approach to patient selection and treatment including discussion at a specialist renal MDT and SABR MDT;
- Have an adequate technical multi-professional radiotherapy SABR team present and able to deliver SABR radiotherapy; and
- Have a minimum of two subspecialist clinical oncologists with experience in treating renal SABR.

Patients that receive SABR for renal cancer should have follow-up as per their organisation's local protocol.



Governance arrangements

The Service Specification for External Beam Radiotherapy ([NHS England Reference: 170091S](#)) describes the governance arrangements for this service. It is imperative that the

radiotherapy service is fully compliant with this Service Specification and in particular, with the [The Ionising Radiation \(Medical Exposure\) Regulations 2017](#).

Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined. Clinical governance systems and policies should be in place and integrated into the organisational governance with clear lines of accountability and responsibility for all clinical governance functions. Providers should produce annual clinical governance reports as part of the NHS clinical governance reporting system. Providers must have an externally accredited quality management system (such as BSI) in place.

All providers must be compliant with Radiotherapy Quality Assurance (RTTQA) for contouring and outlining prior to offering this treatment. A national approach to regular peer review of patient eligibility and treatment plans will be required.

The SABR Consortium Guidelines 2024 provide detailed information on each indication contained within this policy.

Mechanism for funding

SABR is reimbursed at national unit prices. A new local HRG code (SABR 7) and price will be added to Annex A, tab 4 of the NHS Payment Scheme in 2027/28.

Audit requirements

Radiotherapy providers must submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. NHS England will work with providers and the National Disease Registration Service (NDRS) to enable providers to collect and submit data for national audit for all SABR activity using the NDRS. Providers should participate in national audits and National Quality Improvement Toolkits including ProKnow, where available.

Radiotherapy services are subject to regular self-assessment by the national Specialised Commissioning Quality Surveillance. The quality system and its treatment protocols will be subject to regular clinical management and audit as part of the development of radiotherapy networks in England.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

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.

Definitions

Fraction	The term that describes how the full dose of radiation is divided into a number of small doses (called fractions). The fractions are given as a series of treatment sessions which make up a radiotherapy course.
Hypofractionation	A treatment regimen that delivers high doses of radiation using a shorter number of treatments as compared to conventional treatment regimens.
Medically unfit for surgery	Patients medically unfit for surgery include patients with multiple co-morbidities where surgery is considered high risk, patients medically unfit for a general anaesthetic and patients with inoperable tumours due to technical reasons, e.g. position of tumour.
Metastatic disease / metastases	Metastatic disease describes a cancer that has spread from the part of the body where it started (the primary site) to other parts of the body. Metastases is the plural form of metastasis and indicates that the cancer spread to more than one other site in the body.
Nephrectomy	Surgery to remove part (partial) or all (total) of a kidney.
NICE-approved invasive ablative procedures	Invasive ablative procedures are medical procedures, such as cryotherapy or radio-frequency ablation, which use extremes of temperatures to destroy abnormal tissues. NICE-approved invasive ablative procedures include cryotherapy (NICE, 2011) and radio-frequency ablation (NICE, 2010).
Radioresistant / radioresistance	The relative resistance of cells and tissues to irreversible damage by ionising radiation.
Radiotherapy	The safe use of ionising radiation to destroy cancer cells with the aim of cure or effective palliation.
Stereotactic ablative radiotherapy (SABR)	Refers to the irradiation of a lesion and is associated with the use of high radiation dose delivered in a small number of fractions. The technique requires specialist positioning of equipment and imaging to confirm correct targeting. It allows sparing of the healthy normal tissues. This is also known as stereotactic body radiotherapy (SBRT).
Systemic anti-cancer treatment	Treatments for cancer using substances that travel through the blood stream to reach and affect cells all over the body. Chemotherapy, immunotherapy and targeted agents are types of systemic anti-cancer treatments.
WHO performance status	A recognised system developed by the World Health Organisation and other bodies to describe the general health and daily activity of patients. The WHO performance status classification categorises patients as:

	0. Able to carry out all normal activity without restriction 1. Restricted in strenuous activity but ambulatory and able to carry out light work 2. Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours 3. Symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden 4. Completely disabled; cannot carry out any self-care; totally confined to bed or chair.
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References

CancerData (2023). Chemotherapy, Radiotherapy and Surgical Tumour Resections in England. Available from <https://www.cancerdata.nhs.uk/treatments>

Cancer Research UK (CRUK) (2020). TNM stages. Available from: <https://www.cancerresearchuk.org/about-cancer/kidney-cancer/stages-types-grades/tnm>

Cancer Research UK (CRUK) (2023). Kidney cancer statistics. Available from <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/kidney-cancer#heading-Four>

Early Diagnosis Data Hub, Cancer Research UK (2023). Survival and Incidence by Stage at Diagnosis. Available from <https://crukcanerintelligence.shinyapps.io/EarlyDiagnosis/>

European Association of Urology Guidelines (2023). Renal Cell Carcinoma. Available from <https://uroweb.org/guidelines/renal-cell-carcinoma/chapter/citation-information>

Ljungberg B, Albiges L, Abu-Ghanem Y, Bedke J, Capitanio U, Dabestani S, Fernández-Pello S, Giles RH, Hofmann F, Hora M, Klatte T, Kuusk T, Lam TB, Marconi L, Powles T, Tahbaz R, Volpe A, Bex A. European Association of Urology Guidelines on Renal Cell Carcinoma: The 2022 Update. *Eur Urol*. 2022 Oct;82(4):399-410. doi: 10.1016/j.eururo.2022.03.006. Epub 2022 Mar 26. PMID: 35346519.

National Comprehensive Cancer Network (NCCN) (2023). Kidney Cancer. Available from https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf

National Institute for Health and Care Excellence (NICE) (2005). Laparoscopic nephrectomy (including nephroureterectomy) [IPG136]. Available from <https://www.nice.org.uk/guidance/ipg136/chapter/2-The-procedure>

National Institute for Health and Care Excellence (NICE) (2006). Laparoscopic partial nephrectomy [IPG151]. Available from <https://www.nice.org.uk/guidance/ipg151/chapter/2-The-procedure#indications>

National Institute for Health and Care Excellence (NICE) (2011). Percutaneous cryotherapy for renal cancer, Interventional procedures guidance [IPG402]. Available from <https://www.nice.org.uk/guidance/ipg402/chapter/1-Guidance>

National Institute for Health and Care Excellence (NICE) (2010). Percutaneous radiofrequency ablation for renal cancer, Interventional procedures guidance [IPG353]. Available from <https://www.nice.org.uk/guidance/ipg353/chapter/1-Guidance>

Touma NJ, Hosier GW, Di Lena MA, Leslie RJ, Ho L, Menard A, Siemens DR. Growth rates and outcomes of observed large renal masses. *Can Urol Assoc J*. 2019 Aug;13(8):276-281. doi: 10.5489/cuaj.5545. PMID: 30526807; PMCID: PMC6737741.

The Royal College of Radiologists (RCR) (2024). Radiotherapy dose fractionation, Fourth edition. Available from: <https://www.rcr.ac.uk/our-services/all-our-publications/clinical-oncology-publications/radiotherapy-dose-fractionation-fourth-edition/>

Urology: Towards better care for patients with kidney cancer, June 2023. [Online]
[20230616 Urology Guidance Kidney-cancer-FINAL-V1.pdf \(gettingitrightfirsttime.co.uk\)](#)

Volpe, A. (2018). The Role of Active Surveillance for Small Renal Masses. In: Ahmed, K., Raison, N., Challacombe, B., Mottrie, A., Dasgupta, P. (eds) The Management of Small Renal Masses. Springer, Cham. https://doi.org/10.1007/978-3-319-65657-1_5