NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 17 April 2024

Intervention: Stereotactic ablative body radiotherapy

Indication: localised, non-metastatic, medically inoperable renal cancer (adults)

URN: 2332

Gateway: 2, Round 2

Programme: Cancer

CRG: Chemotherapy

Information provided to the Panel

Policy Proposition

Evidence Review completed by Solutions for Public Health

Evidence Review IDEAL Evaluation Report

Clinical Priorities Advisory Group (CPAG) Summary Report

Evidence to Decision (EtD) Summary

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Assessment

Blueteq® Form

Policy Working Group (PWG) Appendix

This Policy Proposition recommends stereotactic ablative body radiotherapy (SABR) for adults with localised, non-metastatic, medically inoperable renal cell carcinoma, where NICE-approved invasive ablative procedures are not suitable or not available. This proposition is returning to Panel following recent consideration at a meeting in February 2024 where amendments were requested, and resubmission required.

A brief summary of the evidence was presented to remind Panel members. A summary of amendments and Policy Working Group (PWG) comments against each action requested by Panel was presented. The proposition had been revised to focus on those patients with T1b, N0, M0 renal cell carcinoma rather than T1a, N0, M0, as the PWG's consensus is that T1b are faster growing and more aggressive with a higher risk of complications.

Panel members thanked the PWG for their work on this and agreed that the majority of required revisions had been addressed. However, Panel members debated extensively the evidence supporting the proposition and the population selection, and still had significant concerns. They agreed it was more focused but could not identify the actual evidence to support this, only that it seemed to be based on PWG opinion. The epidemiology of the natural history and progression of the disease with an evidence base, not opinion, is needed to demonstrate that this is a clinically beneficial intervention for a subgroup of patients.

The proposition and supporting documents were considered and further clarifications and amendments requested.

EHIA was considered and the appropriate amendments had been made.

PIA – no comments received.

Recommendation

Clinical Panel agreed that the proposition needs to return to a future meeting.

Why the panel made these recommendations

Panel members agreed that most revisions made are appropriate, however, there needs to be more consideration regarding the population who would be benefit most from this proposition, with a supporting evidence base, as this is not currently clear. The Regional Medical Director who presented this to Panel members is more than happy to discuss the Panel's debate and outcome with the PWG.

Documentation amendments required

General:

- The epidemiology of the natural history and progression of the disease with an evidence base, not opinion, is needed to demonstrate that this is a clinically beneficial intervention for a particular subgroup of patients.

Policy Proposition:

- The definition of fitness needs further clarification.

Declarations of Interest of Panel Members: One received due to clinical practice.

Panel Chair: Anthony Kessel, Deputy Medical Director, Specialised Services

Post Panel Amendments

General		
Panel Comment	**Amendment**	**Page number (if applicable)**
The epidemiology of the natural history and progression of the disease with an evidence base, not opinion, is needed to demonstrate that this is a clinically beneficial intervention for a particular subgroup of patients.	The paragraph 'about current treatments' now has the additional evidence: 'the European Association of Urology recommends in the elderly and/or comorbid patients with small renal masses (≤4cm, T1a) and limited life expectancy, active surveillance, radio-frequency ablation and cryoablation can be offered (Ljungberg et al, 2015). This is	P3

	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 (Ljundberg et al, 2015; GIRFT, 2023).'	
Policy Proposition		
The definition of fitness needs further clarification	The policy working group expanded to include an additional four Consultant Urologists. The policy currently states '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.' The policy working group reviewed this definition and noted that the decision regarding fitness would sit with the multi-disciplinary team. Therefore, the exclusion criteria now has the additional statement 'are unfit for active treatment or not felt to be appropriate for active treatment as determined by the specialist renal MDT'.	P5