NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 21st February 2024

Intervention: Stereotactic ablative body radiotherapy

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

URN: 2332

Gateway: 2, Round 1

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. SABR is a highly targeted form of external radiation therapy delivered in fewer numbers of treatments than conventional radiotherapy and delivered in outpatient day case settings. There are currently no treatment options available for this population until the development of metastatic disease. An estimated 1900 patients per year would be eligible.

The clinical condition, proposition and the supporting evidence review were presented to Panel members. Three prospective case series and three retrospective case series were included in the evidence review, none of which included a comparator group. One cost effectiveness analysis was identified. An evidence evaluation considering IDEAL was completed which considered the evidence staging to be 2a/2b.

The critical outcomes for clinical effectiveness were local control, overall survival (OS), progression free survival (PFS. Important outcomes identified were cancer specific survival, time to further intervention, health related quality of life (QoL), and organ specific disease response. The presentation to Panel members covered all elements of the evidence. The evidence presented across all critical and important outcomes was reported as very low using modified GRADE. Limitations of the studies presented were discussed including the lack of

comparison with other treatments or supportive care. The cost effectiveness analysis was from a Canadian health system perspective, so not necessarily generalisable to the NHS, and which referred to older literature, which may not relate to newer treatments now available.

It was highlighted that one study reported statistically significant reduction in tumour size and mean growth rate at one year. In five studies rates of failure of local control were under 10% for up to four years. Without comparisons, it was difficult to draw any conclusions. Two studies reported overall survival rates of over 90% up to four years however due to the small size of these studies, the confidence intervals were wide. It was noted that, in general, survival rates for these patients without treatment is relatively high at 5 years. Progression-free survival rates and cancer specific survival rates were reported across studies as high, however, the confidence intervals for these rates were wide. It was noted that a large amount of data was missing at each time point in the QOL study, therefore reducing the certainty of any reported results. Adverse events were reported within the studies, with a few rated at Grade 3.

Discussion took place regarding the lack of comparative data and the lack of clarity regarding the population who would benefit from this treatment, given the natural history of this condition. Clarification is required whether this would be for a population who were symptomatic rather than asymptomatic, members considered it is not currently clear what the proposition is. Patients with this level of disease are often monitored without the need for treatment.

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

EHIA was not included in the papers and will need to be considered at the next meeting.

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 there needs to be more consideration particularly regarding the population who would be benefit most from this proposition as this is not currently clear.

Documentation amendments required

General:

- Policy Working Group – to include a urologist within the group.
- Review whether this is a proposition for a population who were symptomatic rather than asymptomatic.

Policy Proposition:

- Change the title to ‘medically unfit for surgery’ and define what medically unfit means clearly in the proposition.
- Dosing – the dosing range within the proposition is different to that reported in the studies. Policy Working Group to review.

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

Panel Chair: James Palmer, Medical Director, Specialised Services

Post Panel Amendments

General comments		
Panel Comment	**Amendment**	**Page number (if applicable)**
Policy Working Group – to include a urologist within the group	3 urologists approached. 1 agreed to join the PWG and has been consulted on the policy proposition in joint discussion with existing clinical members of the PWG.	N/A
Review whether this is a proposition for a population who were symptomatic rather than asymptomatic	The PWG consensus was that 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. Active surveillance is not recommended in patients with T1b, N0, M0 renal cancers, and these patients should be assessed for suitability for active treatments. NICE-approved invasive ablative procedures are not active treatment options for these patients as eligibility is for T1a, N0, M0 tumours only. Therefore, there are currently no 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. Therefore, the inclusion criteria was amended as follows: • Have a diagnosis of T1b (>4cm but ≤7cm),	p5

	N0, M0 renal cancer and a specialist renal MDT has confirmed that the patient is medically unfit for surgery. This change has resulted in the estimated eligible number of patients per year reducing from 1900 to 950.	
Policy Proposition		
Panel Comment	**Amendment**	**Page number (if applicable)**
Change the title to 'medically unfit for surgery' and define what medically unfit means clearly in the proposition	Change form completed, new title now: Stereotactic ablative body radiotherapy for patients with localised, non-metastatic renal cancer who are medically unfit for surgery (adults). Definition of 'medically unfit': 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.	Definition of 'medically unfit' described on p5.
Dosing – the dosing range within the proposition is different to that reported in the studies. Policy Working Group to review.	There were a number of different SABR dose and fractionations from the evidence review. The most common internationally used SABR dose and fractionations in renal cell cancer are 26Gy in one fraction, 42Gy in three fractions or 40Gy in five fractions on alternate days. This is supported by the Royal College of Radiologists Radiotherapy Dose fractionation guideline (Fourth edition). The dose and fractionation of 40Gy in five fractions has been added to the policy proposition.	p6