NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 18th December 2024

Intervention: Stereotactic ablative body radiotherapy

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

URN: 2332

Gateway: 2, Round 4

Programme: Cancer

CRG: Chemotherapy

Information provided to the Panel

Policy Proposition

Evidence Review completed by Solutions for Public Health

Public Health Review Report

Cover Note

Formal Challenge Letter

Two Lancet Study Papers

Clinical Priorities Advisory Group (CPAG) Summary Report

Clinical Panel Reports – February, April and July 2024

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.

Following a third consideration at the July Clinical Panel meeting where the proposition was recommended as not for routine commissioning, a formal challenge letter has been received from the National Specialty Advisor for Radiotherapy / Clinical Reference Group Chair outlining several areas of dispute. Hence this proposition is returning to Panel for consideration of the points raised along with two study papers which have been published since the evidence review was completed, and a Public Health Evidence Review Report regarding those. It was agreed that the new evidence regarding the FASTRACK II study met the original PICO parameters, however, it did not materially change what was already included in the evidence review although added some weight to it.

A brief summary of the condition, intervention, and evidence base was presented to remind Panel members. A summary of Clinical Panel requests and amendments previously made by the Policy Working Group (PWG) was presented. The points of challenge were then outlined.

The Panel members debated extensively the points of challenge and the evidence supporting the proposition and still had significant concerns. The point that no comparator research could be undertaken was challenged by members. The heterogeneity of the eligible population from the inclusion criteria was raised again and that this had not been adequately addressed by the PWG. Some members considered that three sub-groups within the population should be reconsidered as patients would experience different outcomes: those medically unfit for surgery, those with an inoperable tumour, and those where removing a kidney would cause a more generalised risk such as renal failure.

Panel members debated the risk of metastatic disease at some length and the effect of the proposed treatment on reducing the risk of this. Members were informed that the PICO did not include this as a critical or important outcome for the evidence review so it was not specifically reported. Panel members considered this was important evidence to support their decision making on this proposition given the lack of comparator evidence regarding the natural history of the condition.

EHIA – no comments received.

PIA – no comments received.

Recommendation

Clinical Panel recommends that a further evidence review is undertaken to include disease progression to metastases as reported outcome.

Why the panel made these recommendations

The debate amongst Panel members was again extensive, and resulted in a vote where the majority supported the drafting of a revised PICO and another independent evidence review be undertaken to try to address Panel members concerns. The National Clinical Director for Cancer was asked to support the PWG in drafting the PICO

Documentation amendments required

PICO

- Revise focus on disease progression to metastases as a reported outcome.

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

Panel Chair: James Palmer, Medical Director, Specialised Services

Post Panel Amendments

Panel comments	Action
PICO	

Revise focus on disease progression to metastases as a reported outcome.	The Policy Working Group (PWG) advised that revising the PICO is unlikely to be of benefit as there is a lack of high-quality data in the literature for the natural history of kidney cancer as kidney cancer is rare, the follow-up of patients is limited and any estimates will be confounded by interventions, which means that the highest risk patients on active surveillance end up being treated and this distorts the true natural history of the disease. Instead of revising the PICO, the PWG have identified the following 3 research studies that provide evidence of the natural history of localised kidney cancer.