NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: August 2019

Intervention: Stereotactic Ablative Body Radiotherapy (SABR)

Indication: Hepatocellular Carcinoma (HCC)

ID: 1913

Gateway: 2 Round 1

Programme: Cancer

CRG: Radiotherapy

Information provided to the panel

PPP Clinical Panel Report

Clinical Panel Report from Gateway 1 Round 1

Evidence Review undertaken by KiTEC (as part of the CtE Programme through NICE)

Commissioning through Evaluation Report by KiTEC (as part of the CtE programme through NICE)

Clinical Priorities Advisory Group Summary Report

Policy Proposition

Cover Note from the Clinical Policy Team

Key elements discussed

This proposition is proposed for routine commissioning and has been developed following a CtE study and a refreshed evidence review.

The Clinical Panel noted that due to provider data submission issues, the CtE report presented has some inaccuracies in the reporting of adverse events and Common Terminology Criteria for Adverse Events (CTCAE) grades. The impact was outlined and a revised report is expected 4th September 2019.

The policy proposition as currently written is for patients with HCC, either primary or recurrent. The Clinical Panel were unsure how this concorded with the evidence base as some studies only included treatment of primary tumours.

The evidence base presented included seven studies, five being retrospective comparative cohort studies, one systematic review and meta-analysis, one non-comparative prospective study. One study included compared SABR with sorafenib, 3 others compared with radiofrequency ablation (RFA). There are some discrepancies on what is reported in the evidence review – four studies in comparison with RFA but should say three.

The main bulk of the evidence is taken from the meta-analysis. The evidence suggests that SABR is superior to sorafenib and comparable to RFA in overall survival.

CPAG report says strongest evidence from one study (Bettinger et al) and the evidence review states another (Rim et al) in terms of survival, toxicity and safety.

The criteria in proposition has been derived from CtE report. The proposition currently states the treatment should be last line therapy. Panel considered whether this needs to be reviewed as the evidence presented suggests SABR is at least equivalent in effect to RFA, and therefore should be offered as option to RFA. Policy Working Group (PWG) to confirm. The access criteria also states eligibility with SABR if unsuitable for/refractory to sorafenib. However, the evidence suggests SABR is superior so this needs to be reviewed and amended by the PWG for sorafenib to be a lower line of treatment.

No evidence was reported on where this is comparable to TACE. RFA and TACE are both invasive procedures where as SABR is less invasive.

Recommendation

Clinical Panel recommended that this proposition progress as a for routine commissioning policy proposition. Amendments need to be made as requested by Panel and then for sign off by Chair's action. Allowing bridging access through the CtE study was agreed until the outcome of November prioritisation is known.

Why the panel made these recommendations

The Clinical Panel considered the evidence base in both the evidence review and the CtE report and, although limited and of low quality, the evidence did show clinical benefit of SABR when compared to sorafenib and at least equivalence when compared with RFA.

Documentation amendments required

Review and amend the discrepancies regarding the number of comparative studies reported within the evidence review.

Proposition:

- Correct typo 'low4' in paragraph 3 page 6.
- Correct typo final paragraph on page 6 – grade 36 toxicity and grade 47 toxicity, should read grade 3 and grade 4? Check through documentation carefully as the evidence summary in the proposition appears to include footnote numbers by mistake.
- Paragraph 4 page 6 – check against evidence review for typos.
- Review criteria and remove 'unsuitable for/refractory to sorafenib' (page 9) as SABR should be considered as a higher line of treatment choice, based on the evidence presented. PWG to confirm.
- Criteria amendment - the evidence presented suggests SABR is at least equivalent in effect to RFA, and therefore should be offered as option to RFA.
- Remove pre-treatment patient assessment section on page 9.

CPAG report and evidence review need to align in terms of strength of evidence studies reported. This needs to be reviewed and amended.

<u>Post Meeting Note</u>

The policy was amended in line with Clinical Panel feedback and Chair's action was sought to approve the policy to proceed to public consultation

Declarations of Interest of Panel Members: None.

Panel Chair: James Palmer, Medical Director