NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANELREPORT

Date: March 2021

Intervention: Stereotactic ablative body radiotherapy (SABR)

Indication: locally advanced inoperable, non-metastatic pancreatic carcinoma (LANPC)

URN: 2011

Gateway: 2, Round 1

Programme: Cancer

CRG: Radiotherapy

Information provided to the Panel

Policy Statement Proposition

Three supporting evidence papers

Preliminary Policy Proposition Clinical Panel Report

Equality and Health Inequalities Assessment (EHIA) Report

Clinical Priorities Advisory Group (CPAG) Summary Report

Patient Impact Form

Key elements discussed

This policy statement proposition recommends the routine commissioning of stereotactic ablative body radiotherapy (SABR) as a treatment option for adults with locally advanced, inoperable, non-metastatic pancreatic carcinoma (LANPC) where the disease remains localised following ≥3 months of systemic chemotherapy.

The use of SABR as an alternative treatment option to chemoradiotherapy means that patients will require fewer daily hospital visits for their radiotherapy and, as concurrent daily oral chemotherapy is not required, are also spared the side effects of the chemotherapy.

Clinical Panel were presented with a summary of three evidence papers instead of a full evidence review as it was considered that it would not have provided any material additional evidence. There was no comparison between SABR and the chemoradiotherapy in the presented evidence. It was clear that there was an overlap of evidence between the studies presented. Overall effectiveness can be observed around overall survival and progression free survival. Toxicity effects were reported to be improved relating to acute toxicity in the use of SABR but not statistically significant for late grade toxicity.

Inclusion criteria were considered to be consistent with the published studies however, clarification is needed as to whether all are to be met as there is the use of ‘ORs’ in the list.

Exclusion criteria - the Panel were unsure whether the wording used regarding renal impairment was an actual caution and therefore be pulled out of this section or renal impairment is an exclusion, and so the wording be amended.

Dosage – there are a range of doses in the three papers. Panel heard that the amount given in one fraction determines the effectiveness the treatment has. The overall dose isn't necessarily representative. Page 8 of the proposition attempts to explain this further. A range of dosing may have been put in to allow flexibility. The Panel asked that the Policy Working Group (PWG) need to confirm how the dosing has been arrived at in the proposition.

Panel considered that the wording in the flow diagram needs to be revised to match that in the inclusion criteria relating to chemotherapy toxicity.

Within NICE guidance there is a reference to the UK SABR Consortium Guidance 2019 however this is not mentioned in the Governance Arrangements section of the proposition. This needs to be checked.

EHIA – no comments received.

Patient Impact Form – no comments received.

Recommendation

Clinical Panel recommends that this proposition progresses as a routine commissioning proposition, subject to a few amendments.

Why the panel made these recommendations

The Panel considered clinical effectiveness could be observed from the evidence base presented.

Documentation amendments required

Policy Proposition:

- Page 2 - under the section 'The Condition' it states there are 2 types of pancreatic cancer but then doesn't mention the second – either state it or remove the comment.
- Inclusion criteria – needs clarification regarding 'ORs' – if they should read 'AND'.
- Exclusion criteria – renal impairment - is this a caution and so move to different section or to be listed as an exclusion?
- Exclusion criteria – adjust wording in the first sentence of this section.
- Dosing – PWG to confirm how they have decided on the dosing.
- Flow diagram – amend wording to reflect the inclusion criteria more accurately.
- Flow diagram – include 'HPB' between the words 'pancreatic' and 'MDT'
- PWG to confirm if a reference to UK SABR Consortium guidance is required.

Declarations of Interest of Panel Members: None received.

Panel Chair: James Palmer, Medical Director Specialised Services

Post Panel Amendments

Policy Proposition

The policy proposition was amended as per Clinical Panel's recommendations and reviewed/amended by the Policy Working Group.

- Page 2 has been amended and the reference to 2 types of pancreatic cancer has been removed.

- The inclusion criteria have been amended to reaffirm that all the eligibility criteria must be met and the use of “OR” is confined to specific criteria.
- The reference to renal impairment has been removed.
- Exclusion criteria – The wording has been amended.
- Dosing – A summary based on evidence has now been included.
- Flow diagram has been amended to reflect the inclusion criteria and the words ‘pancreatic’ and ‘MDT’ have been replaced with HPB MDT.
- A reference to UK SABR Consortium guidance has been included in the governance arrangements section.