MANAGEMENT IN CONFIDENCE

CLINICAL PRIORITIES ADVISORY GROUP
02 April 2019

Agenda Item No	04.2
National Programme	Cancer
Clinical Reference Group	Radiotherapy
URN	1842

Title
Proton Beam Therapy for Hepatocellular Carcinoma (adults)

Actions Requested	1. Support the adoption of the policy proposition.
	2. Recommend its approval as an IYSD.

Proposition
This policy statement recommends that proton beam therapy, a form of radiotherapy, should not be routinely available for the treatment of hepatocellular carcinoma (also referred to as primary liver cancer). This treatment is not currently available in this indication and therefore does not alter the current commissioning position. On review of the available clinical evidence, Clinical Panel deemed that the clinical benefits of the treatment were not well demonstrated for this population and recommended a not for routine commissioning policy statement be developed.

Clinical Panel recommendation
The Clinical Panel recommended that the policy progress as a not for routine commissioning policy.

The committee is asked to receive the following assurance:	
1.	The Head of Clinical Effectiveness confirms the proposal has completed the appropriate sequence of governance steps and includes an: Evidence Review; Clinical Panel Report
2.	The Head of Cancer Programmes confirms the proposal is supported by an: Impact Assessment; Stakeholder Engagement Report; Equality Impact and Assessment Report; Clinical Policy Statement Proposition. The relevant National Programme of Care Board has approved these reports.

3.	The Director of Finance (Specialised Commissioning) confirms that the impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Clinical Programmes Director (Specialised Commissioning) confirms that the service and operational impacts have been completed.

The following documents are included (others available on request):	
1.	Clinical Policy Proposition
2.	Engagement Report
3.	Evidence Summary - 3 supporting papers included
4.	Clinical Panel Report
5.	Equality Impact and Assessment Report

The Benefits of the Proposition – Proton beam therapy (PBT) versus photon x-ray conventional radiotherapy (CRT) in <u>hepatocellular carcinoma (HCC)</u>		
No	*Outcome measures*	*Summary from evidence review*
1.	Survival	Dionisi et al (2014) in a systematic review reported the average overall survival at 5 years of 32%, with data comparable to surgery in the most favourable groups. There is limited data comparing PBT to conventional radiotherapy (CRT), however, there is evidence that dose escalation correlates with improved survival. Escalation of dose with CRT is limited due to toxicity, and therefore not a feasible option. Even for stereotactic body radiotherapy (SBRT), the rate of death due to hepatic toxicity was found to be 7%. In another systematic review, Qi et al (2015) reported pooled OS was significantly higher at 1, 3, 5 years for PBT than for CRT. Progression free survival (PFS) and local control (LC) at longest follow-up was also significantly higher for PBT than for CRT while comparable efficacy was found between CPT and SBRT in terms of overall survival (OS), PFS and LC at longest follow-up.
2.	Progression free survival	Dionisi et al (2014) showed that LC with PBT was approximately 80% at 3–5 years, with data comparable to surgery in the most favourable groups. Qi et al (2015) showed PFS and LC at longest follow-up was significantly higher for PBT than for CRT while comparable efficacy was found between PBT and SBRT in terms of OS, PFS and LC at longest follow-up.
3.	Mobility	Not measured
4.	Self-care	Not measured

5.	Usual activities	Not measured
6.	Pain	Not measured
7.	Anxiety / Depression	Not measured
8.	Replacement of more toxic treatment	Not measured
9.	Dependency on care giver / supporting independence	Not measured
10.	Safety	Dionisi et al in a systematic review, (Dionisi et al, 2014) reported treatment related toxicity of PBT to treat HCC was low in all the studies reviewed, and lower than that of CRT and SBRT. The good clinical results of the selected papers are counterbalanced by a low level of evidence. In the second systematic review, (Qi et al, 2015) high-grade acute and late toxicity associated with PBT was lower than that of CRT and SBRT.
11.	Delivery of intervention	Not measured

Considerations from review by Rare Disease Advisory Group
Not applicable.

Pharmaceutical considerations
Not applicable.

Considerations from review by National Programme of Care
1) The proposal received full support of the Cancer PoC Board on 7th March 2019.