MANAGEMENT IN CONFIDENCE

CLINICAL PRIORITIES ADVISORY GROUP
04 12 2018

Agenda Item No	02.2
National Programme	Cancer
Clinical Reference Group	Radiotherapy
URN	1771

Title
Selective internal radiation therapy (SIRT) for the treatment of chemotherapy refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma (all ages)

Actions Requested	1. Support the policy proposition
	2. Recommend for adoption as an in-year service development decision

Proposition
The policy recommends that SIRT should not be routinely available for the treatment of chemotherapy refractory or intolerant, unresectable intrahepatic cholangiocarcinoma. SIRT was previously available via a Commissioning through Evaluation (CtE) scheme for this clinical indication and the policy proposition has been developed following consideration of the CtE findings, together with an independent Evidence Review. Neither published research nor the CtE findings provided convincing evidence about the benefits of SIRT compared to best supportive care.

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 Programme confirms the proposal is supported by an: Impact Assessment; Stakeholder Engagement Report; Consultation Report; Equality Impact and Assessment Report; Clinical Policy 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 Operational Delivery 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.	Consultation Report
3.	Evidence Summary and a CtE Report
4.	Clinical Panel Report
5.	Equality Impact and Assessment Report

The Benefits of the Proposition – Use of yttrium-90 SIRT to treat unresectable chemotherapy-refractory liver-dominant intrahepatic cholangiocarcinoma		
No	*Outcome measures*	*Summary from evidence review*
1.	Survival	Median overall survival (OS) for patients with unresectable intrahepatic cholangiocarcinoma was 22 months after treatment with SIRT with yttrium-90 (from "best study"). However, this study is at high risk of bias from its retrospective design, small sample size and absence of control group. Therefore 'survival benefit' cannot be determined.
2.	Progression free survival	Not measured
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	Adverse events were poorly reported. The retrospective design of the study is likely to limit the quality of adverse event recording. The absence of a control group means that it cannot be determined whether the adverse events are solely due to SIRT treatment.
11.	Delivery of intervention	Not measured

Other health outcome measures determined by the evidence review		
No	Outcome measure	Summary from evidence review
1.	Time to progression	Median time to progression (TTP) was 9.8 months after treatment with SIRT with yttrium-90 (only 1 study reported this data). However, as there was no control group in the study efficacy of the treatment cannot be determined. TTP may be biased by the retrospective design of this study as it relies on accurate recording of date of progression.
2.	Overall response rate	Overall response rate was 12 (36%) (from "best study"). However, as there was no control group in the study efficacy of the treatment cannot be determined.
3.	Disease control rate	Disease control rate was 19 (58%) (from "best study"). However, as there was no control group in the study efficacy of the treatment cannot be determined.

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 the full support of the Cancer PoC Board on 15th November 2018.

SECTION 2 – IMPACT REPORT

No	Item	N/Cost £K	Level of uncertainty
1.	Number of patients affected in England	15-20	
2.	Total cost per patient over 5 years	0	This treatment is currently not commissioned and the policy is not for routine commissioning.
3.	Budget impact year 1	0	See above.
4.	Budget impact year 2	0	See above.
5.	Budget impact year 3	0	See above.
6.	Budget impact year 4	0	See above.
7.	Budget impact year 5	0	See above.
8.	Total number of patients treated over 5 years	0	See above.
9.	Net cost per patient treated over 5 years	0	See above.
Key additional information			
None.			