

**AMMF Response to NHS England Radiotherapy Clinical Reference Group re their draft clinical commissioning policy following their review of the evidence to treat 'chemotherapy refractory or chemotherapy intolerant, unresectable primary intrahepatic cholangiocarcinoma with selective internal radiation therapy'.**

We at AMMF – The Cholangiocarcinoma Charity have serious concerns on the decision made and find it difficult to understand how this conclusion was reached. We believe this is an injustice to this group of inoperable patients who, following receiving standard chemotherapies, have no further clinically proven treatment options available to them. We believe that SIRT can provide these patients with additional months of life, which are free from debilitating treatment-related adverse events.

The NHS England decision made has not taken into account two current national guidelines:

- The European Society of Medical Oncology (ESMO) Biliary Cancer Guidelines were published in September 2016. They were based on the study by Al-Adra (2014) which was included in the IPG review. This was a pooled analysis of 12 studies (298 patients), which reported median overall survival of 15.5 months, and treatment response rate of 28% in patients treated with SIRT. Furthermore, within this study 10% of patients were converted to resectable disease.  
[https://academic.oup.com/annonc/article-pdf/27/suppl\\_5/v28/6678340/mdw324.pdf](https://academic.oup.com/annonc/article-pdf/27/suppl_5/v28/6678340/mdw324.pdf)
- The National Comprehensive Cancer Network (NCCN) Clinical practice guidelines in oncology, for hepatobiliary cancers, also recommend the use of “Locoregional therapy” including “Arterially directed therapies” for the treatment of ICC. These were published very recently, in February 2018. [https://www.nccn.org/professionals/physician\\_gls/default.aspx](https://www.nccn.org/professionals/physician_gls/default.aspx)

Were these guidelines, which are developed with strong clinical support from international experts, reviewed within the NHS England process? We ask how NHS England’s decision has been made, as it goes against both of these clinical guidelines?

We would also like to stress that ICC is a rare disease, and so the evidence should be reviewed appropriately. Although most of the clinical studies are retrospective and non-comparative, they still provide invaluable evidence on the safety and efficacy of SIRT, and include substantial patient numbers. This information should not be discarded as inadequate due to the research methods used.

We feel that the current lack of funding for SIRT in England is inexcusable because, as mentioned, this is the only treatment option open to these patients following standard chemotherapies, and because clinical studies have shown it to increase median overall survival.

Based on these points, we strongly ask that you re-consider your draft recommendations.