Liver tumours can start in the liver (primary) or spread to the liver from another part of the body (secondary). In this procedure, thin optical fibres are inserted through the skin (percutaneous) using a fine needle and into the liver tumour. The fibres deliver laser energy for several minutes, which heats the liver tissue until it is destroyed (laser ablation). Image guidance (such as ultrasound) is used to check the position of the fibres and to monitor the procedure. The aim is to destroy the tumour.

NICE is looking at image-guided percutaneous laser ablation for primary and secondary liver tumours.

NICE’s interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE’s final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.
Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 25 January 2024

Target date for publication of guidance: May 2024
1 Draft recommendations

1.1 Image-guided percutaneous laser ablation for primary and secondary liver tumours can be used in the NHS while more evidence is generated. It can only be used with special arrangements in place for clinical governance, informed consent and audit.

1.2 Clinicians wanting to do image-guided percutaneous laser ablation for primary and secondary liver tumours should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure’s safety and efficacy, and any uncertainties about these.
- Take account of NICE’s advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE’s interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team experienced in managing primary and secondary liver tumours.
More research

1.5 More research is needed on:

- patient selection
- ablation success
- longer-term outcomes.

Why the committee made these recommendations

The evidence raises no major safety concerns. There is some evidence that the procedure can destroy tumours (tumour ablation), but more evidence is needed on longer-term outcomes. The procedure may benefit particular groups of patients, but more evidence is needed to confirm this.

2 The condition, current treatments and procedure

The condition

2.1 The most common type of primary liver cancer is hepatocellular carcinoma (HCC). Secondary cancer in the liver can arise from any primary site, but it most commonly spreads from cancers of the breast, bowel, lung, pancreas, stomach, ovary, and neuroendocrine tumours.

Current treatments

2.2 Treatment for primary liver cancer depends on several factors, including the exact location and stage of the cancer, the person’s liver function and any patient-related comorbidities. The treatment options include:

- surgical excision
- chemotherapy (conventional or hepatic artery infusion)
- transarterial chemoembolisation (TACE)
- selective internal radiation therapy
• percutaneous ethanol injection
• local ablation techniques such as cryotherapy, radiofrequency, and microwave ablation.

Liver transplant (with curative intent) may be appropriate for some people.

2.3 Treatment for secondary liver cancer depends on the site of the primary cancer, which parts of the liver are affected and whether the cancer has metastasised further. The most common treatment is chemotherapy, but other treatments include surgery, hormonal therapies, targeted therapies, ablation and embolisation treatments.

The procedure

2.4 Image-guided percutaneous laser ablation is usually done under sedation. Depending on the size of the tumour, 1 or more (usually up to 4) optical fibres are percutaneously inserted into the liver using a small introducer needle. The fibre distance and energy delivery per fibre are adjusted to shape the area to be ablated. The fibres deliver laser energy for several minutes to heat the tissue until it is destroyed with a sufficient safety margin. Image guidance is used to check the positioning of the fibres, monitor the treatment, and verify the effective ablation area. The aim is to destroy the tumour.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 13 sources, which was discussed by the committee. The evidence included 4 randomised controlled trials, 1 quasi-randomised controlled trial, 1 retrospective non-randomised comparative study,
1 case-control study, 5 cohort studies and 1 case report. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: complete tumour ablation, local tumour progression, local or distant recurrence, overall survival and disease-free survival.

3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, bleeding, infection and damage to surrounding tissues.

3.4 Patient commentary was sought but none was received.

**Committee comments**

3.5 A clinical expert advised that this procedure could allow better control of the ablation area.

3.6 Multiple laser fibres can be used for each treatment session and the fibres can be moved.

3.7 Tumour ablation procedures are commonly done under general anaesthesia to prevent the person moving during treatment.

3.8 The committee was informed that a software planning system can be used to help with planning the size and location of ablation.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
December 2023