Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with
those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of interstitial laser therapy for breast cancer does not appear adequate to support the routine use of this procedure. It is suitable for use only within good-quality research studies approved by a research ethics committee and with explicit patient consent.

1.2 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Interstitial laser therapy is used to treat small tumours of the breast. Standard treatments include lumpectomy or mastectomy (without preceding laser therapy), and minimally invasive techniques such as radiofrequency ablation or cryotherapy.

2.2 Outline of the procedure

2.2.1 Interstitial laser therapy is a minimally invasive technique for treating small breast cancers. After locating the tumour using stereotactic techniques or ultrasound, laser energy is delivered into the tumour via a needle probe. This destroys tumour tissue – the aim is to ablate the tumour entirely.
2.3 Efficacy

2.3.1 The evidence was limited to three small case series and one case report. One study of interstitial laser therapy followed by surgery reported that 98% (43/44) of patients were disease-free at follow-up. However, follow-up ranged from 2 to 26 months, and it was difficult to determine whether the results were attributable to the laser therapy or the surgery. This study also found no histological sign of laser damage in the tumours of 9% (4/44) of patients. For more details, refer to the Sources of evidence section.

2.3.2 The Specialist Advisors noted that it was still uncertain whether the procedure could achieve thermal ablation of all malignant tissue. They also noted that there were no data comparing outcomes of the procedure with those of wide excision and radiotherapy.

2.4 Safety

2.4.1 The following complications were reported in the identified studies: small skin burns 11% (4/35); necrosis of non-tumour tissue caused by incorrectly placed laser 10% (2/20); pain sufficient to stop treatment 7% (3/44); gaseous rupture of tumour 3% (1/35); and haemorrhage 2% (1/44). For more details, refer to the Sources of evidence section.

2.4.2 One Specialist Advisor considered that this procedure should not be used outside a clinical trial; another listed the potential adverse effects of the procedure as necrosis, haemorrhage, and liquefaction caused by overheating of the tissue.

3 Further information

3.1 The Institute has published technology appraisals on the use of the following drugs for breast cancer: temozolomide, capecitabine, taxanes, trastuzumab and vinorelbine. For further information, visit our website.

3.2 The Institute issued cancer service guidance called 'Improving Outcomes in Breast Cancer' in August 2002 and is developing a clinical guideline on
breast cancer, called 'Breast cancer: diagnosis and treatment'. The expected date of issue of this guideline is September 2007 [Now published as ‘Breast cancer (early and locally advanced): diagnosis and treatment’].

Andrew Dillon  
Chief Executive  
September 2004

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.


Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in January 2011 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

26 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical
effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It has been incorporated into the NICE pathway on early and locally advanced breast cancer, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Contact NICE
Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.