



# Photodynamic therapy for localised inoperable endobronchial cancer

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www.nice.org.uk/guidance/ipg137

# 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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

#### 1 Recommendations

- 1.1 Current evidence on the safety and efficacy of photodynamic therapy for localised inoperable endobronchial cancer appears adequate to support the use of this procedure provided that the normal arrangements are in place for audit and clinical governance.
- This procedure is a treatment option for patients with localised endobronchial cancer that is unsuitable for surgical resection. Clinicians should ensure that patients understand the aim of the treatment, especially when its purpose is palliation. Patients should also be informed of the alternative treatment options available. Clinicians should provide them with clear written information and, in addition, use of NICE's information for the public is recommended.
- 1.3 Further research and audit will be useful in clarifying the indications and benefits of this procedure.

## 2 The procedure

#### 2.1 Indications

2.1.1 Localised endobronchial (non-small-cell) lung cancer describes disease in which malignancy is confined within the bronchial wall, with no radiographic or endoscopic evidence of lymph node involvement. Patients for whom surgical resection may be considered unsuitable include those with bilateral lung cancer,

impaired respiratory function because of chronic obstructive pulmonary disease or other conditions posing high operative risk, those who have had previous resection for lung cancer, and those who refuse surgery.

The range of treatment options for lung cancer depends on the type and stage of the disease and the suitability of major surgery for the individual patient.

Treatment options include laser ablation, endobronchial brachytherapy and external-beam radiation.

### 2.2 Outline of the procedure

2.2.1 Photodynamic therapy (PDT) involves injection of a photosensitising agent, followed a few days later by photoradiation of the affected area through a bronchoscope. This aims to reduce tumour bulk, so reducing symptoms caused by bronchial obstruction. Endobronchial debridement of necrotic tumour is required, commonly 48 hours after each treatment. The procedure can be repeated if necessary.

## 2.3 Efficacy

- 2.3.1 There were no randomised controlled or comparative trials comparing the efficacy of PDT with other treatment modalities. There was considerable heterogeneity among the studies included in the systematic reviews, with regard to both outcome measurements used and follow-up times reported. The complete remission rates following PDT ranged from 62% (16/26) to 85% (50/59) of lesions in different case series. Some subgroup analyses suggested that small lesions (in terms of diameter or surface area) respond to PDT better than larger lesions.
- 2.3.2 Where reported in case series, 5-year survival ranged from 43% among 36 patients with poor pulmonary or cardiac function to 72% among 21 patients who were surgical candidates. Other studies reported reduction of airway obstruction and improvement in self-reported quality of life after PDT. For more details, refer to the Sources of evidence.

2.3.3 The Specialist Advisors stated that there were no long-term comparative data on the efficacy of this procedure.

## 2.4 Safety

- In one systematic review, eight studies reported adverse events. Mild to moderate symptoms of photosensitivity were reported in all studies. Very severe toxicity resulting from photosensitivity occurred in a minority of patients undergoing PDT.
- 2.4.2 Fatal haemoptysis within 1 month of treatment was recorded in 8% (3/38) of patients in one case series. Hypercapnic respiratory failure (requiring mechanical ventilation) occurred in 5% (2/38) and 4% (1/24) of patients following PDT. Some effects may be due to pre-existing pulmonary disease rather than the procedure. Other case series reported mild to moderate pulmonary events including short-term productive cough following PDT (the proportion of patients was not reported). For more details, refer to the Sources of evidence.
- 2.4.3 The Specialist Advisors listed photosensitivity as the main complication. Other potential adverse events were tissue necrosis leading to bleeding, and fistula formation.

#### 2.5 Other comments

- 2.5.1 It was noted that a variety of laser systems is available and different dosage schedules may be used. These variations may have an effect on safety and efficacy.
- 2.5.2 This procedure may be used in combination with other treatment modalities.
- 2.5.3 The heterogeneous groups of patients included in the studies and reviews made interpretation of the data difficult.

#### 3 Further information

3.1 NICE has published a guideline on the diagnosis and management of lung cancer and interventional procedures guidance on photodynamic therapy for advanced bronchial carcinoma and cryotherapy for malignant endobronchial obstruction.

#### Sources of evidence

The <u>evidence considered by the Interventional Procedures Advisory Committee is</u> described in the overview.

## Information for the public

NICE has produced <u>information describing its guidance on this procedure for patients,</u> <u>carers and those with a wider interest in healthcare</u>. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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# **Endorsing organisation**

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.