

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Lung cancer: diagnosis and management (update)

This guideline will update the NICE guideline on Lung cancer: diagnosis and management (CG121). To see which areas will be covered in this update, see the [proposed outline for the guideline](#).

The guideline will be developed using the methods and processes outlined in [Developing NICE guidelines: the manual](#).

This guideline will also be used to update the NICE [quality standard](#) for lung cancer in adults.

1 Why the update is needed

New evidence that could affect existing recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the [surveillance review decision](#).

The update will also cover systemic anti-cancer therapies for treating non-small-cell lung cancer that were not covered in the original guideline.

Why the guideline is needed

Key facts and figures

Over 46,000 people were diagnosed with lung cancer in the UK in 2014. An estimated 89% of lung cancers are preventable, with 86% of these linked to smoking, 13% to occupational exposure, 9% to dietary factors and 7.8% to air pollution. Lung cancer can be linked to more than one cause.

In 2015 in England, over 28,000 people died from lung cancer. The overall mortality rate from lung cancer has decreased by 6% over the last decade. However, while there has been a decrease of 16% in men, there has been an increase of 6% in women; this is linked to lifestyle factors such as smoking and is driven by an increased incidence of lung cancer in older women. Lung cancer is responsible for 22% of all cancer-related deaths.

Lung cancer is more common in people of European family origin than in people of African or Asian family origin. It is strongly linked to socioeconomic deprivation. There are many risk factors for lung cancer, including age, genetics, lifestyle (especially smoking) and occupation. Lung cancer is estimated to cost the UK economy £2.4 billion per year.

Current practice

Lung cancer is diagnosed and staged using a variety of tests, including chest X-rays, CT or PET-CT. When biopsies are needed, they are commonly taken using bronchoscopy, endobronchial ultrasound (EBUS) or a percutaneous procedure (guided by CT or ultrasound).

Lung cancer has 2 main types:

- non-small-cell lung cancer (NSCLC), which is more common and spreads more slowly
- small-cell lung cancer (SCLC), which is rarer and spreads more quickly.

Treatment depends on the type, size, position and stage of the cancer, and the person's health. Possible treatments include radiotherapy, systemic anti-cancer therapies, surgery, cryotherapy, photodynamic therapy, and ablation.

Since 2011, when the NICE lung cancer guideline was last updated, there have been changes in the way that lung cancer is diagnosed and treated. The [2016 national lung cancer audit](#) identified that only 72% of people have pathological confirmation of their lung cancer. There is also inconsistency in the availability of molecular testing in lung cancer diagnosis. Generic versions of some systemic anti-cancer therapies have become available since 2011, and this may affect the cost effectiveness of treatment. For SCLC, there is

evidence that starting radiotherapy at different points during systemic anti-cancer therapy cycles may improve survival and reduce side effects.

NHS England has taken steps to improve access to and uptake of radiotherapy, and stereotactic ablative radiotherapy (SABR) is routinely used for certain subgroups of people with early-stage NSCLC. There are now a variety of licensed cytotoxic immunotherapies and biological targeted therapies for treating NSCLC, and NICE has published technology appraisals covering many of these.

Policy, legislation, regulation and commissioning

The [NHS outcomes framework 2015–16](#) identifies 1- and 5-year survival from lung cancer as key indicators of improvement in mortality.

In the [Five Year Forward View](#), NHS England identified prevention and earlier diagnosis of cancer as key strategic priorities. A new [Tobacco Control Plan for England](#) was published in 2017, a campaign to increase awareness of lung cancer ([Be Clear On Cancer](#)) is still running, and the evidence for lung cancer screening is being reviewed by the National Screening Committee.

NHS England has emphasised the importance of investment in radiotherapy, and their [radiotherapy service review](#) made proposals on how to upgrade services.

2 Who the guideline is for

This guideline is for:

- healthcare professionals in the NHS
- commissioners and providers of lung cancer services

It may also be relevant for:

- social care practitioners and commissioners
- voluntary organisations and patient support groups

People with lung cancer, their families and carers and the public will be able to use the guideline to find out more about what NICE recommends, and help them make decisions.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#) and [Northern Ireland Executive](#).

Equality considerations

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

Full details of the considerations are included in the equalities impact assessment form.

3 What the updated guideline will cover

3.1 Who is the focus?

Groups that will be covered

- Adults (18 years and older) with suspected lung cancer.
- Adults (18 years and older) with newly diagnosed non-small-cell lung cancer (NSCLC).
- Adults with newly diagnosed small-cell lung cancer (SCLC).
- Adults with relapsed NSCLC.
- Adults with relapsed SCLC.

Specific consideration will be given to people with multifocal or synchronous adenocarcinoma.

Groups that will not be covered

- Adults with mesothelioma.

- Adults with lung metastases caused by primary cancers outside the lung.
- Children (younger than 18) with lung cancer.
- Adults with rare lung tumours (for example, pulmonary blastoma).
- Adults with benign lung tumours (for example, bronchial adenoma).

3.2 Settings

Settings that will be covered

The guideline will cover all settings where NHS-funded care is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered in this update

We will look at evidence in the areas below when developing this update. We will consider making new recommendations or updating existing recommendations in these areas only.

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

- 1 Diagnosis and staging
 - Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-guided TBNA), endoscopic ultrasound-guided fine-needle aspiration (EUS-guided FNA), or non-ultrasound-guided TBNA as the first test for people with a risk of mediastinal malignancy
 - EBUS-guided TBNA and EUS-guided FNA (alone or in combination) as an alternative to surgical staging for the initial staging of the mediastinum
 - Routine MRI or CT of the brain prior radical therapy with curative intent
- 2 Testing to inform treatment decisions

- Phenotypic and molecular tests to inform treatment choices (cross-referral to relevant NICE technology appraisal and diagnostics guidance)
- 3 Treatment
- First-line treatment for limited-stage small-cell lung cancer (SCLC)
 - First-line treatment for extensive-stage disease SCLC
 - Treatment for N2 stage non-small-cell lung cancer (NSCLC)
 - Radiotherapy for early-stage NSCLC
 - Systemic anti-cancer therapies for advanced NSCLC (incorporate or cross refer to relevant NICE technology appraisal guidance unchanged)
 - Targeted therapies for NSCLC (incorporate or cross refer to relevant NICE technology appraisal guidance unchanged)
- 4 Palliative interventions and supportive and palliative care
- Cross reference to the NICE guideline on brain tumours (primary and brain metastases in adults)
 - Prophylactic cranial irradiation for people with SCLC

Proposed outline for the guideline

The table below outlines all the areas that will be included in the guideline. It sets out what NICE plans to do for each area.

Area in the guideline	What NICE plans to do
1.1 Access to services and referral	
<ul style="list-style-type: none"> • The importance of early diagnosis • Referral and indications for chest radiography 	<p>No evidence review: retain recommendations from existing guideline.</p> <p>The reference to the NICE guideline on suspected cancer in the recommendations on referral for chest radiography will be kept.</p>
1.2 Communication	
<ul style="list-style-type: none"> • Communication 	<p>No evidence review: retain recommendations from existing guideline.</p>

1.3 Diagnosis and staging	
<ul style="list-style-type: none"> • Effectiveness of diagnosis and staging investigations • Sequence of investigations <ul style="list-style-type: none"> - Peripheral primary tumour - Central primary tumour - Mediastinal lymph node assessment - Stage M1b 	Review evidence on non-ultrasound-guided TBNA, EBUS-TBNA and EUS-FNA in diagnosis and staging and on routine MRI or CT of the brain prior radical therapy with curative intent: update existing recommendations as needed.
<ul style="list-style-type: none"> • Organisational factors relating to diagnosis and staging <ul style="list-style-type: none"> - Multidisciplinary teams - Rapid-access lung clinics - Cancer clinical nurse specialists 	No evidence review: retain recommendations from existing guideline.
1.4 Treatment	
<ul style="list-style-type: none"> • Smoking cessation • Selection of patients with NSCLC for treatment with curative intent <ul style="list-style-type: none"> - Perioperative mortality - Cardiovascular function - Lung function - Assessment before radiotherapy with curative intent • Assessing patients with SCLC • Surgical treatment for patients with SCLC • Maintenance treatment for SCLC • Prophylactic cranial irradiation in SCLC • Second-line treatment for patients with SCLC that has relapsed after first-line treatment 	No evidence review: retain recommendations from existing guideline.
<ul style="list-style-type: none"> • Radiotherapy with curative intent for NSCLC • Systemic anti-cancer therapies for NSCLC • First-line treatment for limited-stage disease SCLC • First-line treatment for extensive-stage disease SCLC 	Review evidence: update existing recommendations as needed. Incorporate or cross refer to relevant NICE technology appraisal guidance on systemic anti-cancer therapies for NSCLC unchanged into the guideline.

<ul style="list-style-type: none"> • Targeted therapies for NSCLC 	Incorporate or cross refer to relevant NICE technology appraisal guidance unchanged into the guideline.
<ul style="list-style-type: none"> • Surgery with curative intent for NSCLC • Combination treatment for NSCLC 	Review evidence for treatment of N2 stage NSCLC only: update existing recommendations as needed.
1.5 Palliative interventions and supportive and palliative care	
<ul style="list-style-type: none"> • Managing brain metastases 	<p>Review evidence on prophylactic cranial irradiation for people with SCLC: update existing recommendations as needed.</p> <p>A cross reference to the NICE guideline on brain tumours (primary) and brain metastases in adults to be added.</p>
<ul style="list-style-type: none"> • Providing palliative care • Palliative radiotherapy • Managing endobronchial obstruction • Other palliative treatments • Hypercalcaemia, bone pain and pathological fractures • Managing other symptoms: weight loss, loss of appetite, difficulty swallowing, fatigue and depression 	No evidence review: retain recommendations from existing guideline.
1.6 Follow-up and patient perspectives	
<ul style="list-style-type: none"> • Follow-up and patient perspectives 	No evidence review: retain recommendations from existing guideline.
1.7 Testing to inform treatment decisions	
<ul style="list-style-type: none"> • Using phenotypic and molecular testing to inform treatment decisions 	No evidence review: cross-refer to relevant NICE technology appraisals and diagnostics guidance.

Recommendations in areas that are being retained from the existing guideline may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.

Related NICE guidance

- [Rovalpituzumab tesarine for treating small-cell lung cancer after 2 therapies](#) (publication date to be confirmed) NICE technology appraisal guidance
- [Lung cancer \(non-small cell, advanced, inoperable\) – liposomal cisplatin \(with chemotherapy\)](#) (publication date to be confirmed) NICE technology appraisal guidance
- [Nivolumab for small-cell lung cancer after platinum-based chemotherapy](#) (publication expected July 2018) NICE technology appraisal guidance
- [Anamorelin for treating anorexia and cachexia associated with non-small cell lung cancer](#) (publication expected October 2017) NICE technology appraisal guidance
- [Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin](#) (2016) NICE technology appraisal guidance 402
- [Suspected cancer](#) (2016) NICE quality standard 124
- [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12
- [Irreversible electroporation for treating primary lung cancer and metastases in the lung](#) (2013) NICE interventional procedure guidance 441
- [Microwave ablation for treating primary lung cancer and metastases in the lung](#) (2013) NICE interventional procedure guidance 469
- [Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours](#) (2012) NICE technology appraisal guidance 265
- [Lung cancer in adults](#) (2012) NICE quality standard 17
- [The PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites](#) (2012) NICE medical technologies guidance 9
- [Percutaneous radiofrequency ablation for primary or secondary lung cancers](#) (2010) NICE interventional procedure guidance 372
- [Endobronchial ultrasound-guided transbronchial biopsy for peripheral lung lesions](#) (2010) NICE interventional procedure guidance 337

- [Topotecan for the treatment of relapsed small-cell lung cancer](#) (2009) NICE technology appraisal guidance 184
- [Endobronchial ultrasound-guided transbronchial needle aspiration for mediastinal masses](#) (2008) NICE interventional procedure guidance 254
- [Pemetrexed for the treatment of malignant pleural mesothelioma](#) (2008) NICE technology appraisal guidance 135
- [Pemetrexed for the treatment of non-small-cell lung cancer](#) (2007) NICE technology appraisal guidance 124
- [Cryotherapy for malignant endobronchial obstruction](#) (2005) NICE interventional procedure guidance 142
- [Photodynamic therapy for localised inoperable endobronchial cancer](#) (2005) NICE interventional procedure guidance 137
- [Photodynamic therapy for advanced bronchial carcinoma](#) (2004) NICE interventional procedure guidance 87
- [Stent placement for vena caval obstruction](#) (2004) NICE interventional procedure guidance 79

NICE guidance that will be updated by this guideline

- [Lung cancer: diagnosis and management](#) (2011) NICE guideline CG121

NICE guidance that will be incorporated unchanged in this guideline

- [Erlotinib monotherapy for maintenance treatment of non-small-cell lung cancer](#) (2011) NICE technology appraisal guidance 227
- [Pemetrexed for the maintenance treatment of non-small-cell lung cancer](#) (2010) NICE technology appraisal guidance 190
- [Pemetrexed for the first-line treatment of non-small-cell lung cancer](#) (2009) NICE technology appraisal guidance 181

NICE guidance that will be reviewed and may be incorporated unchanged in this guideline

- [Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy](#) (2017) NICE technology appraisal guidance 428

- [Crizotinib for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer](#) (2016) NICE technology appraisal guidance 422
- [Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer](#) (2016) NICE technology appraisal guidance 403
- [Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer](#) (2016) NICE technology appraisal guidance 395
- [Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy](#) (2015) NICE technology appraisal guidance 374
- [Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer](#) (2015) NICE technology appraisal guidance 347
- [Afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer](#) (2014) NICE technology appraisal guidance 310
- [Erlotinib for the first-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer](#) (2012) NICE technology appraisal guidance 258
- [Gefitinib for the first-line treatment of locally advanced or metastatic non-small-cell lung cancer](#) (2010) NICE technology appraisal guidance 192

NICE guidance that may be cross-referred to in this guideline

- [EGFR-TK mutation testing in adults with locally advanced or metastatic non-small-cell lung cancer](#) (2013) NICE diagnostics guidance 9
- [Dabrafenib with trametinib for treating advanced, metastatic BRAF V600E mutation-positive non-small-cell lung cancer](#) (publication date to be confirmed) NICE technology appraisal guidance
- [Nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer](#) (publication date to be confirmed) NICE technology appraisal guidance

- [Nivolumab for previously treated locally advanced or metastatic squamous non-small-cell lung cancer](#) (publication date to be confirmed) NICE technology appraisal guidance
- [Durvalumab with tremelimumab for untreated EGFR-positive, ALK-negative non-small-cell lung cancer](#) (publication expected January 2019) NICE technology appraisal guidance
- [Durvalumab for treating unresectable non-small-cell lung cancer after platinum-based chemoradiation](#) (publication expected January 2019) NICE technology appraisal guidance
- [Ceritinib for untreated anaplastic lymphoma kinase positive non-small-cell lung cancer](#) (publication expected April 2018) NICE technology appraisal guidance
- [Crizotinib for non-small cell lung cancer](#) (publication expected April 2018) NICE technology appraisal guidance
- [Atezolizumab for treating non-small-cell lung cancer after platinum-based chemotherapy](#) NICE technology appraisal guidance 492
- [Pembrolizumab for untreated PD-L1 positive metastatic non-small-cell lung cancer](#) (2017) NICE technology appraisal guidance 447
- [Osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer](#) (2016) NICE technology appraisal guidance 416
- [Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer](#) (2016) NICE technology appraisal guidance 406

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to lung cancer:

- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

3.4 Economic aspects

We will take economic aspects into account when making recommendations. For each review question (or key area in the scope) for which the evidence is being reviewed, we will develop an economic plan that states whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective, as appropriate.

3.5 Key issues and draft questions

While writing the scope for this updated guideline, we have identified the following key issues and draft questions related to them:

- 1 Diagnosis and staging
 - 1.1 What is the clinical and cost effectiveness of using non-ultrasound-guided TBNA, EBUS-TBNA or EUS-FNA as the first test for people with a risk of mediastinal malignancy?
 - 1.2 What is the clinical and cost-effectiveness of EBUS-TBNA alone, EUS-FNA alone or EBUS-TBNA and EUS-FNA in combination compared with surgical staging to diagnose and/or stage lung cancer?
 - 1.3 What is the clinical and cost-effectiveness of routine MRI or CT of the brain in the management of people with lung cancer prior to radical therapy with curative intent?

- 2 Testing to inform treatment decisions
(incorporate or cross refer to relevant NICE technology appraisal and diagnostics guidance)
- 3 Treatment
(incorporate or cross refer to relevant NICE technology appraisal guidance on systemic anti-cancer therapies for NSCLC unchanged into the guideline)
 - 3.1 What is the clinical and cost effectiveness of chemotherapy, radiotherapy or surgery (alone or in combination) for the treatment for N2 stage NSCLC?
 - 3.2 What is the clinical and cost effectiveness of different radiotherapy regimens with curative intent for NSCLC (stage T1a–2b N0 M0)?
 - 3.3 What is the most clinically and cost-effective regimen of chemoradiotherapy for people with limited-stage SCLC?
 - 3.4 In people with extensive-stage SCLC who have had first-line treatment with systemic anti-cancer therapies, when is first use of thoracic radiotherapy clinically and cost effective?
- 4 Palliative interventions and supportive and palliative care
(cross reference to the NICE guideline on brain tumours (primary and brain metastases in adults))
 - 4.1 What is the clinical and cost-effectiveness of prophylactic cranial irradiation to prevent brain metastases in people with SCLC?

The key questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

3.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

- 1 Mortality
 - cancer-related
 - treatment-related

- all-cause
- 2 Quality of life
 - Eastern Cooperative Oncology Group (ECOG) score and Karnofsky performance status scale
 - European Organisation for Research and Treatment of Cancer (EORTC) score
 - EQ-5D
- 3 Length of stay
 - hospital
 - ICU
- 4 Exercise tolerance
- 5 Adverse events
 - dyspnoea
 - hypoxia and need for home oxygen
 - stroke
 - cardiovascular disease
- 6 Treatment-related dropout rates

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- [Lung cancer in adults](#) (2012) NICE quality standard 17

4.2 NICE Pathways

When this guideline is published, we will update the existing NICE pathway on [lung cancer](#). NICE Pathways bring together everything NICE has said on a topic in an interactive flow chart.

5 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation.

The guideline is expected to be published in January 2019.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.