



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

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

## 12 **Current practice**

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

17 Lung cancer has 2 main types:

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

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

24 Since 2011, when the NICE lung cancer guideline was last updated, there  
25 have been changes in the way that lung cancer is diagnosed and treated. The  
26 [2016 national lung cancer audit](#) identified that only 72% of people have  
27 pathological confirmation of their lung cancer. Generic versions of some  
28 systemic anti-cancer therapies have become available since 2011, and this  
29 may affect the cost effectiveness of treatment. For SCLC, there is evidence

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

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

### 9 **Policy, legislation, regulation and commissioning**

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

12 In [Five Year Forward View](#), NHS England identified prevention and earlier  
13 diagnosis of cancer as key strategic priorities. There are plans for a new  
14 tobacco control plan to be published in 2017, a campaign to increase  
15 awareness of lung cancer ([Be Clear On Cancer](#)) is still running, and the  
16 evidence for lung cancer screening is being reviewed by the National  
17 Screening Committee.

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

## 21 **2 Who the guideline is for**

22 This guideline is for:

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

25

26 It may also be relevant for:

- 27 • social care practitioners and commissioners
- 28 • voluntary organisations and patient support groups

29

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

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

### 7 ***Equality considerations***

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

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

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

## 14 **3 What the updated guideline will cover**

### 15 **3.1 Who is the focus?**

#### 16 **Groups that will be covered**

- 17 • Adults (18 years and older) with newly diagnosed non-small-cell lung  
18 cancer (NSCLC).
- 19 • Adults with newly diagnosed small-cell lung cancer (SCLC).
- 20 • Adults with relapsed NSCLC.
- 21 • Adults with relapsed SCLC.

22  
23 No specific subgroups of people have been identified as needing specific  
24 consideration.

#### 25 **Groups that will not be covered**

- 26 • Adults with mesothelioma.
- 27 • Adults with lung metastases caused by primary cancers outside the lung.

- 1 • Children (younger than 18) with lung cancer.
- 2 • Adults with rare lung tumours (for example, pulmonary blastoma).
- 3 • Adults with benign lung tumours (for example, bronchial adenoma).

4

## 5 **3.2 Settings**

### 6 **Settings that will be covered**

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

## 8 **3.3 Activities, services or aspects of care**

### 9 **Key areas that will be covered in this update**

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

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

18

#### 19 **1 Diagnosis and staging**

- 20 – Endobronchial ultrasound-guided transbronchial needle aspiration  
21 (EBUS-guided TBNA), endoscopic ultrasound-guided fine-needle  
22 aspiration (EUS-guided FNA), or non-ultrasound-guided TBNA as the  
23 first test for people with an intermediate risk of mediastinal malignancy
- 24 – EBUS-guided TBNA and EUS-guided FNA (alone or in combination)  
25 as an alternative to surgical staging for the initial staging of the  
26 mediastinum

#### 27 **2 Testing to inform treatment decisions**

- 28 – Phenotypic and molecular tests to inform treatment choices (cross  
29 referral to relevant NICE Technology Appraisal and Diagnostic  
30 guidance)

- 1 3 Treatment
- 2 – First-line treatment of limited-stage small-cell lung cancer (SCLC)
- 3 – First-line treatment for extensive-stage disease SCLC
- 4 – Radiotherapy for early-stage non-small-cell lung cancer (NSCLC)
- 5 – Systemic anti-cancer therapies for advanced NSCLC
- 6 – Targeted therapies for NSCLC (cross-refer to relevant NICE
- 7 Technology Appraisal guidance)
- 8 4 Palliative interventions and supportive and palliative care
- 9 – Cranial irradiation for brain metastases associated with NSCLC

### 10 Proposed outline for the guideline

11 The table below outlines all the areas that will be included in the guideline. It

12 sets out what NICE plans to do for each area.

13

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

14

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

• Targeted therapies for NSCLC	To incorporate relevant NICE technology appraisal guidance unchanged into the update.
1.5 Palliative interventions and supportive and palliative care	
• Managing brain metastases	Review evidence on cranial irradiation for brain metastases associated with NSCLC: update existing recommendations as needed
<ul style="list-style-type: none"> <li>• Providing palliative care</li> <li>• Palliative radiotherapy</li> <li>• Managing endobronchial obstruction</li> <li>• Other palliative treatments</li> <li>• Hypercalcaemia, bone pain and pathological fractures</li> <li>• Managing other symptoms: weight loss, loss of appetite, difficulty swallowing, fatigue and depression</li> </ul>	No evidence review: retain recommendations from existing guideline.
1.6 Follow-up and patient perspectives	
• Follow-up and patient perspectives	No evidence review: retain recommendations from existing guideline.
Testing to inform treatment decisions	
• Using phenotypic and molecular testing to inform treatment decisions	No evidence review: cross-refer to relevant NICE technology appraisals and diagnostics guidance

1

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

### 5 **Related NICE guidance**

- 6 • [Lung cancer \(non-small cell, advanced, inoperable\) - liposomal cisplatin](#)  
7 [\(with chemotherapy\)](#) (publication date to be confirmed) NICE technology  
8 appraisal guidance  
9 • [Nivolumab for small-cell lung cancer after platinum-based chemotherapy](#)  
10 (publication expected July 2018) NICE technology appraisal guidance



- 1 • [Anamorelin for treating anorexia and cachexia associated with non-small](#)  
2 [cell lung cancer](#) (publication expected October 2017) NICE technology  
3 appraisal guidance
- 4 • [Pemetrexed maintenance treatment for non-squamous non-small-cell lung](#)  
5 [cancer after pemetrexed and cisplatin](#) (2016) NICE technology appraisal  
6 guidance 402
- 7 • [Suspected cancer](#) (2016) NICE quality standard 124
- 8 • [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12
- 9 • [Irreversible electroporation for treating primary lung cancer and metastases](#)  
10 [in the lung](#) (2013) NICE interventional procedure guidance 441
- 11 • [Microwave ablation for treating primary lung cancer and metastases in the](#)  
12 [lung](#) (2013) NICE interventional procedure guidance 469
- 13 • [Denosumab for the prevention of skeletal-related events in adults with bone](#)  
14 [metastases from solid tumours](#) (2012) NICE technology appraisal guidance  
15 265
- 16 • [Lung cancer in adults](#) (2012) NICE quality standard 17
- 17 • [The PleurX peritoneal catheter drainage system for vacuum-assisted](#)  
18 [drainage of treatment-resistant, recurrent malignant ascites](#) (2012) NICE  
19 medical technologies guidance 9
- 20 • [Endobronchial ultrasound-guided transbronchial biopsy for peripheral lung](#)  
21 [lesions](#) (2010) NICE interventional procedure guidance 337
- 22 • [Percutaneous radiofrequency ablation for primary or secondary lung](#)  
23 [cancers](#) (2010) NICE interventional procedure guidance 372
- 24 • [Topotecan for the treatment of relapsed small-cell lung cancer](#) (2009) NICE  
25 technology appraisal guidance 184
- 26 • [Endobronchial ultrasound-guided transbronchial needle aspiration for](#)  
27 [mediastinal masses](#) (2008) NICE interventional procedure guidance 254
- 28 • [Pemetrexed for the treatment of malignant pleural mesothelioma](#) (2008)  
29 NICE technology appraisal guidance 135
- 30 • [Pemetrexed for the treatment of non-small-cell lung cancer](#) (2007) NICE  
31 technology appraisal guidance 124
- 32 • [Cryotherapy for malignant endobronchial obstruction](#) (2005) NICE  
33 interventional procedure guidance 142

- 1 • [Photodynamic therapy for localised inoperable endobronchial cancer](#)  
2 (2005) NICE interventional procedure guidance 137
- 3 • [Photodynamic therapy for advanced bronchial carcinoma](#) (2004) NICE  
4 interventional procedure guidance 87
- 5 • [Stent placement for vena caval obstruction](#) (2004) NICE interventional  
6 procedure guidance 79

7 ***NICE guidance that will be updated by this guideline***

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

9 ***NICE guidance that will be incorporated unchanged in this guideline***

- 10 • [Erlotinib monotherapy for maintenance treatment of non-small-cell lung](#)  
11 [cancer](#) (2011) NICE technology appraisal guidance 227
- 12 • [Pemetrexed for the maintenance treatment of non-small-cell lung cancer](#)  
13 (2010) NICE technology appraisal guidance 190
- 14 • [Pemetrexed for the first-line treatment of non-small-cell lung cancer](#) (2009)  
15 NICE technology appraisal guidance 181

16 **NICE guidance that will be incorporated subject to approval following a**  
17 **review proposal**

- 18 • [Dabrafenib with trametinib for treating advanced, metastatic BRAF V600E](#)  
19 [mutation-positive non-small-cell lung cancer](#) (publication date to be  
20 confirmed) NICE technology appraisal guidance
- 21 • [Lung cancer \(non-small-cell, non-squamous, metastatic, after treatment\) -](#)  
22 [nivolumab](#) (publication date to be confirmed) NICE technology appraisal  
23 guidance
- 24 • [Lung cancer \(non-small-cell, squamous, metastatic\) - nivolumab \(after](#)  
25 [chemotherapy\)](#) (publication date to be confirmed) NICE technology  
26 appraisal guidance
- 27 • [Ceritinib for untreated anaplastic lymphoma kinase positive non-small-cell](#)  
28 [lung cancer](#) (publication expected April 2018) NICE technology appraisal  
29 guidance
- 30 • [Crizotinib for non-small cell lung cancer](#) (publication expected April 2018)  
31 NICE technology appraisal guidance

- 1 • [Atezolizumab for treating non-small-cell lung cancer after platinum-based](#)  
2 [chemotherapy](#) (publication expected October 2017) NICE technology  
3 appraisal guidance
- 4 • [Pembrolizumab for untreated PD-L1 positive metastatic non-small-cell lung](#)  
5 [cancer](#) (2017) NICE technology appraisal guidance 447
- 6 • [Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after](#)  
7 [chemotherapy](#) (2017) NICE technology appraisal guidance 428
- 8 • [Crizotinib for previously treated anaplastic lymphoma kinase-positive](#)  
9 [advanced non-small-cell lung cancer](#) (2016) NICE technology appraisal  
10 guidance 422
- 11 • [Osimertinib for treating locally advanced or metastatic EGFR T790M](#)  
12 [mutation-positive non-small-cell lung cancer](#) (2016) NICE technology  
13 appraisal guidance 416
- 14 • [Necitumumab for untreated advanced or metastatic squamous non-small-](#)  
15 [cell lung cancer](#) (2016) NICE technology appraisal guidance 411
- 16 • [Crizotinib for untreated anaplastic lymphoma kinase-positive advanced](#)  
17 [non-small-cell lung cancer](#) (2016) NICE technology appraisal guidance 406
- 18 • [Ramucirumab for previously treated locally advanced or metastatic non-](#)  
19 [small-cell lung cancer](#) (2016) NICE technology appraisal guidance 403
- 20 • [Ceritinib for previously treated anaplastic lymphoma kinase positive non-](#)  
21 [small-cell lung cancer](#) (2016) NICE technology appraisal guidance 395
- 22 • [Erlotinib and gefitinib for treating non-small-cell lung cancer that has](#)  
23 [progressed after prior chemotherapy](#) (2015) NICE technology appraisal  
24 guidance 374
- 25 • [Nintedanib for previously treated locally advanced, metastatic, or locally](#)  
26 [recurrent non-small-cell lung cancer](#) (2015) NICE technology appraisal  
27 guidance 347
- 28 • [Afatinib for treating epidermal growth factor receptor mutation-positive](#)  
29 [locally advanced or metastatic non-small-cell lung cancer](#) (2014) NICE  
30 technology appraisal guidance 310
- 31 • [Erlotinib for the first-line treatment of locally advanced or metastatic EGFR-](#)  
32 [TK mutation-positive non-small-cell lung cancer](#) (2012) NICE technology  
33 appraisal guidance 258

- 1 • [Gefitinib for the first-line treatment of locally advanced or metastatic non-](#)  
2 [small-cell lung cancer](#) (2010) NICE technology appraisal guidance 192  
3

#### 4 **NICE guidance about the experience of people using NHS services**

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

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

### 13 **3.4 Economic aspects**

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

### 21 **3.5 Key issues and questions**

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

- 24 1 Diagnosis and staging  
25 1.1 What is the clinical and cost effectiveness of using non-ultrasound-  
26 guided TBNA, EBUS-TBNA or EUS-FNA as the first test for people  
27 with an intermediate probability of mediastinal malignancy?  
28 1.2 What is the clinical and cost-effectiveness of EBUS-TBNA alone,  
29 EUS-FNA alone or EBUS-TBNA and EUS-FNA in combination

1 compared with surgical staging to diagnose and/or stage lung  
2 cancer?

3 2 Testing to inform treatment decisions

4 2.1 Cross-refer to relevant NICE Technology Appraisal and Diagnostic  
5 guidance.

6 3 Treatment

7 3.1 What is the clinical and cost effectiveness of different radiotherapy  
8 regimens with curative intent for NSCLC (stage T1a–2b N0 M0)?

9 3.2 What is the clinical and cost effectiveness of the following systemic  
10 anti-cancer therapy regimens for treating NSCLC:

- 11 • platinum combinations compared with non-platinum combinations in  
12 people with advanced NSCLC (stage III or IV)
- 13 • non-platinum monotherapy compared with non-platinum  
14 combinations in people with advanced NSCLC (stage III or IV) who  
15 cannot tolerate platinum combinations
- 16 • docetaxel monotherapy compared with docetaxel doublet therapy in  
17 second-line treatment of NSCLC.

18 3.3 What is the most clinically and cost-effective regimen of  
19 chemoradiotherapy for people with limited-stage SCLC?

20 3.4 When is first-line thoracic radiotherapy clinically and cost effective in  
21 people with extensive-stage SCLC who have had first-line treatment with  
22 systemic anti-cancer therapies?

23 3.5 What is the clinical and cost effectiveness of cranial irradiation for  
24 brain metastases in people with NSCLC?

25

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

### 28 **3.6 Main outcomes**

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

31 1 Mortality



## 1 **5 Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 29 June to 13 July 2017.

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.

2