

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Guideline scope

### Chronic obstructive pulmonary disease in over 16s: diagnosis and management (update)

This guideline will update the NICE guideline on [chronic obstructive pulmonary disease in over 16s](#) (CG101).

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 COPD in adults (NICE quality standard 10).

#### **1 Why the update is needed**

New evidence that could affect 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](#).

#### ***Why the guideline is needed***

##### **Key facts and figures**

Chronic obstructive pulmonary disease (COPD) is a long-term and progressive respiratory condition that causes breathlessness and makes it difficult to do everyday activities. The term 'COPD' includes chronic bronchitis, emphysema and chronic obstructive airways disease.

There are approximately 1 million people in the UK with diagnosed COPD and approximately 2 million with undiagnosed COPD. Smoking is the biggest cause of COPD, and according to the [2014 national COPD audit](#) 37% of people with COPD are tobacco dependent. The audit also showed that COPD

1 is the second most common cause of emergency admissions, and that COPD  
2 emergency admissions increased by 13% between 2008 and 2014. COPD is  
3 the fifth most common cause of mortality in the UK, and causes nearly 30,000  
4 deaths every year in England. It is much more common in areas of high  
5 deprivation. People living in these areas have a lower life expectancy than the  
6 general population, and COPD is responsible for 8% of this difference in men  
7 and 12% in women. Managing COPD costs the NHS over £800 million a year.

## 8 **Current practice**

9 New evidence has emerged and practice has changed in a number of areas  
10 since 2010, when the last version of the NICE guideline on COPD was  
11 published. This evidence and the changes in how care is delivered may have  
12 a significant impact on resource use, for example by increasing the focus on:

- 13 • treating tobacco dependence
- 14 • providing pulmonary rehabilitation
- 15 • commissioning and providing integrated respiratory care pathways
- 16 • changing the way multidimensional assessment tools and inhaled therapies  
17 are used.

18 The costs of some inhaled therapies have also reduced, as they are now off-  
19 patent and generic versions are available. However, the range and complexity  
20 of the inhaled therapies available (drugs and devices) has also increased  
21 enormously. This has led to changes in clinical practice, which means that  
22 large parts of the current guideline are out of date.

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

24 The Department of Health published [an outcomes strategy for people with](#)  
25 [chronic obstructive pulmonary disease \(COPD\) and asthma in England](#) in  
26 2011, and a [companion document](#) for the NHS in 2012. These documents  
27 make recommendations on reducing the impact of COPD by minimising  
28 progression, enhancing recovery and promoting independence. They have a  
29 specific focus on reducing premature death and improving quality of life for  
30 people with COPD. The documents highlight the following areas in particular:

- 1 • earlier and more accurate diagnosis (including risk profiling tools)
- 2 • support to stop smoking (including treating tobacco dependence)
- 3 • behaviour change, and having multidisciplinary teams provide training and
- 4 interventions for self-efficacy skills
- 5 • working with people with COPD and their families to help them manage
- 6 their condition more effectively
- 7 • managing exacerbations
- 8 • multimorbidity
- 9 • organising care to provide effective follow-up and treatment review.

10 In their [Five Year Forward View](#), NHS England recommended improvements  
11 to reduce premature mortality in people with COPD, including:

- 12 • earlier and accurate diagnosis
- 13 • effective treatment of tobacco dependence for all people who smoke
- 14 • oxygen therapy.

15

## 16 **2 Who the guideline is for**

17 People using COPD services, their families and carers and the public will be  
18 able to use the guideline to find out more about what NICE recommends, and  
19 help them make decisions.

20 This guideline is for:

- 21 • healthcare professionals in the NHS
- 22 • commissioners and providers of COPD services.

23 It may also be relevant for:

- 24 • social care practitioners and commissioners
- 25 • voluntary organisations and patient support groups.

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

## 1 ***Equality considerations***

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

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

6 The guideline will look at inequalities people may face because of  
7 socioeconomic status, difficulties speaking or reading English, homelessness,  
8 serious mental illness, dementia, or learning disabilities.

## 9 **3 What the updated guideline will cover**

### 10 **3.1 *Who is the focus?***

#### 11 **Groups that will be covered**

- 12 • Adults (over 16 years) with COPD (including chronic bronchitis,  
13 emphysema, and chronic airflow limitation or obstruction)
- 14 • Adults (over 16 years) with COPD and asthma, bronchopulmonary  
15 dysplasia, or bronchiectasis

16 No specific subgroups of people have been identified as needing specific  
17 consideration.

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

- 19 • People who have asthma, bronchopulmonary dysplasia or bronchiectasis,  
20 but do not have COPD.

### 21 **3.2 *Settings***

#### 22 **Settings that will be covered**

- 23 • All settings where NHS care is delivered

### 1 **3.3 Activities, services or aspects of care**

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

3 We will look at evidence in the areas below when developing this update. We  
4 will consider making new recommendations or updating existing  
5 recommendations in these areas only. This is because new evidence and  
6 expert advice suggests these are the areas of the guideline that need  
7 updating.

#### 8 1 Diagnosing and classifying the severity of COPD

- 9 – further investigations for initial assessment (for example, imaging and
- 10 biomarkers) to confirm the diagnosis
- 11 – assessing severity and prognostic factors (for example
- 12 multidimensional severity assessment tools)

#### 14 2 Managing stable COPD and preventing disease progression

- 15 – inhaled therapy
  - 16 ○ long-acting muscarinic antagonists (LAMA) and long-acting beta<sub>2</sub>
  - 17 antagonists (LABA)
  - 18
  - 19 ○ long-acting anticholinergics: which is the most effective, and who
  - 20 should have treatment
- 21 – prophylactic oral antibiotics
- 22 – long-term oxygen therapy: who should have treatment (indications for
- 23 its use) and effectiveness in those indicated
- 24 – managing complications of COPD: pulmonary hypertension and
- 25 cor pulmonale
- 26 – referral criteria for lung surgery (including intact fissures)
- 27 – education and self-management (including telehealth monitoring)

#### 28 3 Investigating what may cause exacerbations of COPD (for example viral

29 infection).

30 Note that guideline recommendations for all medicines will normally fall within  
31 licensed indications; exceptionally, and only if clearly supported by evidence,

1 use outside a licensed indication may be recommended. The guideline will  
 2 assume that prescribers will use a medicine's summary of product  
 3 characteristics to inform decisions made with individual people.

#### 4 **Proposed outline for the guideline**

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

Area in the guideline	What NICE plans to do
1. Diagnosing and classifying the severity of COPD	
Symptoms  Signs  Spirometry  Differential diagnosis  Reversibility testing  Assessment and classification of severity of airflow obstruction  Identification of early disease  Referral for specialist advice	No evidence review: retain recommendations from existing guideline
Further investigations for initial assessment (for example, imaging and biomarkers)  Assessing severity and prognostic factors (for example multidimensional assessment indices)	Review evidence: update existing recommendations as needed

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2. Management of stable COPD	
Smoking cessation	No evidence review: retain recommendations from existing guideline.
Oral therapy <ul style="list-style-type: none"> <li>• oral corticosteroids</li> <li>• oral theophylline</li> <li>• phosphodiesterase-4 inhibitors</li> <li>• oral mucolytic therapy</li> <li>• oral anti-oxidant therapy</li> <li>• anti-tussive therapy</li> </ul>	
Combined oral and inhaled therapy	For smoking cessation, a cross-reference to the <a href="#">NICE guideline on smoking cessation</a> (publication expected November 2017) will be added
Oxygen <ul style="list-style-type: none"> <li>• long-term oxygen therapy*</li> <li>• ambulatory oxygen therapy</li> <li>• short-burst oxygen therapy</li> </ul>	
Non-invasive ventilation	*For long-term oxygen therapy, the recommendations on assessment, delivery and review will not be updated. However the recommendations on who should have treatment (indications) will be updated.
Management: pulmonary hypertension and cor pulmonale <ul style="list-style-type: none"> <li>• diagnosis of pulmonary hypertension and cor pulmonale</li> </ul>	
Pulmonary rehabilitation	
Vaccination and anti-viral therapy	
Lung surgery <ul style="list-style-type: none"> <li>• role of surgery</li> <li>• fitness for surgery</li> <li>• operation of choice (bullectomy, lung volume reduction or transplantation)</li> </ul>	
Alpha-1 antitrypsin replacement therapy	

<p>Multidisciplinary management</p> <ul style="list-style-type: none"><li>• respiratory nurse specialists</li><li>• physiotherapy</li><li>• identifying and managing anxiety and depression</li><li>• nutritional factors</li><li>• palliative care</li><li>• assessment for occupational therapy</li><li>• social services</li><li>• advice on travel</li><li>• advice on diving</li></ul> <p>Fitness for general surgery</p> <p>Follow-up of patients with COPD</p>	<p>No evidence review: retain recommendations from existing guideline.</p>
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<p>Inhaled therapy</p> <ul style="list-style-type: none"> <li>• LAMA plus LABA compared with LAMA alone</li> <li>• LAMA plus LABA compared with LABA plus ICS</li> <li>• long-acting anticholinergics: identifying which is the most effective and who should have treatment</li> </ul> <p>Oral therapy</p> <ul style="list-style-type: none"> <li>• oral prophylactic antibiotic therapy</li> </ul> <p>Oxygen therapy</p> <ul style="list-style-type: none"> <li>• long-term oxygen therapy: who should have treatment (indications for its use) and effectiveness in those indicated</li> </ul> <p>Management of: pulmonary hypertension and cor pulmonale</p> <ul style="list-style-type: none"> <li>• treatment of pulmonary hypertension and cor pulmonale</li> </ul> <p>Lung surgery</p> <ul style="list-style-type: none"> <li>• referral criteria for lung surgery (including intact fissures)</li> </ul> <p>Multidisciplinary management</p> <ul style="list-style-type: none"> <li>• education</li> <li>• self-management (including telehealth monitoring)</li> </ul>	<p>Review evidence: update existing recommendations as needed.</p>
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<p>Inhaled therapy</p> <ul style="list-style-type: none"> <li>• monotherapy with SABA, LABA, or ICS</li> <li>• dual therapy with SABA plus SAMA, LAMA plus ICS, or LABA plus ICS (excluding LAMA + LABA)</li> <li>• triple therapy with LAMA plus LABA plus ICS</li> <li>• delivery systems</li> </ul>	<p>No evidence review: amend recommendations if needed to fit with other parts of the update.</p> <p>There is no new evidence for monotherapy, dual therapy, triple therapy, or delivery systems. However, updates to other inhaled therapy recommendations may mean these recommendations need to be amended as well, to fit within the inhaled therapy pathway.</p> <p>In addition, footnotes highlighting safety considerations will be added to the recommendations on ICS monotherapy and delivery systems. This is because of Drug Safety Updates published:</p> <ul style="list-style-type: none"> <li>– in <a href="#">2010</a>, covering psychological and behavioural side effects associated with inhaled corticosteroids</li> <li>– in <a href="#">2015</a>, covering the risk for people with certain cardiac conditions when taking tiotropium delivered via Respimat or Handihaler.</li> </ul>
<p>3. Management of exacerbations of COPD</p>	
<p>Definition of an exacerbation</p> <p>Consequences of having an exacerbation</p> <p>Symptoms of an exacerbation</p> <p>Differential diagnosis of an exacerbation</p> <p>Assessment of the severity of an exacerbation</p> <p>Assessment of need for hospital treatment</p> <p>Investigation of an exacerbation</p>	<p>No evidence review: retain recommendations from existing guideline.</p>

Hospital-at-home and assisted discharge schemes	No evidence review: retain recommendations from existing guideline.
Pharmacological management	
Oxygen therapy during exacerbations of COPD	
Non-invasive ventilation and COPD exacerbations	
Invasive ventilation and intensive care	
Respiratory physiotherapy and exacerbations	
Monitoring recovery from an exacerbation	
Discharge planning	
Causes of an exacerbation (including viral infection)	Review evidence: update existing recommendations as needed.
4. Audit criteria	
Audit criteria	Remove: no longer current practice. Audit criteria are no longer covered by NICE guidelines.

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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 • [Indoor air pollution](#) (publication expected February 2019) NICE guideline
- 7 • [Smoking cessation interventions and services](#) (publication expected  
8 November 2017) NICE guideline
- 9 • [Asthma management](#) (publication expected June 2017) NICE guideline
- 10 • [Asthma – diagnosis and monitoring](#) (publication date not confirmed) NICE  
11 guideline
- 12 • [Air pollution – outdoor air quality and health](#) (publication expected June  
13 2017) NICE guideline

- 1 • [Workplace health: support for employees with disabilities and long term](#)
- 2 [conditions](#) (publication date not confirmed) NICE guideline
- 3 • [Antimicrobial stewardship: changing risk-related behaviours in the general](#)
- 4 [population](#) (2017) NICE guideline NG63
- 5 • [Multimorbidity: clinical assessment and management](#) (2016) NICE
- 6 guideline NG56
- 7 • [Extracorporeal carbon dioxide removal for acute respiratory failure](#) (2016)
- 8 NICE interventional procedure guidance 564
- 9 • [Depression in adults: recognition and management](#) (2009; updated 2016)
- 10 NICE guideline CG90
- 11 • [Care of dying adults in the last days of life](#) (2015) NICE guideline NG31
- 12 • [Older people with social care needs and multiple long-term conditions](#)
- 13 (2015) NICE guideline NG22
- 14 • [Antimicrobial stewardship: systems and processes for effective](#)
- 15 [antimicrobial medicine use](#) (2015) NICE guideline NG15
- 16 • [Insertion of endobronchial nitinol coils to improve lung function in](#)
- 17 [emphysema](#) (2015) NICE interventional procedure guidance 517
- 18 • [Pneumonia in adults: diagnosis and management](#) (2014) NICE guideline
- 19 CG191
- 20 • [Behaviour change: individual approaches](#) (2014) NICE guideline PH49
- 21 • [Smoking: acute, maternity and mental health services](#) (2013) NICE
- 22 guideline PH48
- 23 • [Smoking: harm reduction](#) (2013) NICE guideline PH45
- 24 • [Stop smoking services](#) (2008; updated 2013) NICE guideline PH10
- 25 • [Insertion of endobronchial valves for lung volume reduction in emphysema](#)
- 26 (2013) NICE interventional procedure guidance 465
- 27 • [Extracorporeal membrane oxygenation for severe acute respiratory failure](#)
- 28 [in adults](#) (2011) NICE interventional procedure guidance 391
- 29 • [Smoking: stopping in pregnancy and after childbirth](#) (2010) NICE guideline
- 30 PH26
- 31 • [Respiratory tract infections \(self-limiting\): prescribing antibiotics](#) (2008)
- 32 NICE guideline CG69
- 33 • [Smoking: workplace interventions](#) (2007) NICE guideline PH5

- 1 • [Living-donor lung transplantation for end-stage lung disease](#) (2006) NICE  
2 interventional procedure guidance 170
- 3 • [Smoking: brief interventions and referrals](#) (2006) NICE guideline PH1
- 4 • [Lung volume reduction surgery for advanced emphysema](#) (2005) NICE  
5 interventional procedure guidance 114

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### 7 ***NICE guidance that will be incorporated unchanged in this guideline***

- 8 • [Roflumilast for the management of severe chronic obstructive pulmonary](#)  
9 [disease](#) (2012) NICE technology appraisal guidance 244. [Currently being](#)  
10 [updated](#) (publication expected June 2017)
- 11 • [Amantadine, oseltamivir and zanamivir for the treatment of influenza](#) (2009)  
12 NICE technology appraisal guidance 168
- 13 • [Oseltamivir, amantadine \(review\) and zanamivir for the prophylaxis of](#)  
14 [influenza](#) (2008) NICE technology appraisal guidance 158
- 15 • [Varenicline for smoking cessation](#) (2007) NICE technology appraisal  
16 guidance 123

17

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

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

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

### 27 **3.4 Economic aspects**

28 We will take economic aspects into account when making recommendations.  
29 For each review question (or key area in the scope) for which the evidence is  
30 being reviewed, we will develop an economic plan that states whether

1 economic considerations are relevant, and if so whether this is an area that  
2 should be prioritised for economic modelling and analysis. We will review the  
3 economic evidence and carry out economic analyses, using an NHS and  
4 personal social services (PSS) perspective, as appropriate.

### 5 **3.5 Key issues and questions**

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

#### 8 1 Diagnosis

9 1.1 In people with stable COPD, does routine assessment using a  
10 multidimensional severity assessment index (such as BODE [BMI,  
11 airflow obstruction, dyspnoea and exercise capacity]) better predict  
12 outcomes than forced expiratory volume in 1 second (FEV<sub>1</sub>) alone?

13 1.2 In people with suspected COPD, what is the most accurate and  
14 appropriate test (for example imaging or biomarkers) to confirm the  
15 diagnosis?

16 1.3 In people with suspected COPD, which tests (for example imaging or  
17 biomarkers) are the most accurate to identify whether they are at risk of  
18 poor outcomes and whether they will develop mild, moderate or severe  
19 COPD?

20

#### 21 2 Management of stable COPD

22 2.1 In people with stable COPD, what is the clinical and cost  
23 effectiveness of a long-acting muscarinic antagonist (LAMA) alone  
24 compared with:

- 25 - a long-acting beta<sub>2</sub> agonist (LABA) alone
- 26 - a short-acting muscarinic antagonist (SAMA) alone

27 2.2 In people with stable COPD, what is the clinical and cost  
28 effectiveness of a LAMA plus a LABA compared with:

- 29 - a LAMA alone
- 30 - a LABA plus an inhaled corticosteroid (ICS)

31 2.3 In people with stable COPD, what is the clinical and cost  
32 effectiveness of a LAMA plus an ICS compared with:

1           - a LAMA alone

2           - a LABA alone

3           2.4 In people with stable COPD, what is the clinical and cost  
4 effectiveness of a LABA plus an ICS compared with:

5           - a LAMA alone

6           - a LABA alone

7           2.5 In people with stable COPD, what is the clinical and cost  
8 effectiveness of a LAMA plus a LABA plus an ICS compared with:

9           - a LAMA alone

10          - a LABA plus a LAMA

11          - a LABA plus an ICS

12          2.6 Which is the most clinically and cost-effective long-acting  
13 anticholinergic for managing stable COPD, and which subgroups of  
14 people should receive treatment with it?

15          2.7 What is the clinical and cost effectiveness of prophylactic oral  
16 antibiotics for preventing exacerbations in people with stable COPD?

17          2.8 What are the most clinically and cost-effective therapies for  
18 managing complications (pulmonary hypertension and cor pulmonale) in  
19 people with stable COPD?

20          2.9 What is the clinical and cost effectiveness of self-management  
21 interventions (including telehealth monitoring) and education for  
22 improving outcomes and adherence to treatment in people with stable  
23 COPD?

24          2.10 In which subgroups of people is long-term oxygen therapy  
25 indicated, and is it a clinically and cost effective option for managing  
26 stable COPD in these subgroups?

27          2.11 In people with stable COPD, what are the referral criteria (for  
28 example intact fissures) for lung surgery?

29

30    3    Management of exacerbations of COPD

31          3.1 In people with COPD, what factors (for example, viral infection) may  
32 cause an exacerbation?

33

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

### 3 **3.6 Main outcomes**

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

- 6 1 Mortality
- 7 2 Hospital admissions and readmissions
- 8 3 Exacerbations
- 9 4 Gas transfer (carbon monoxide diffusion capacity and arterial oxygen  
10 partial pressure)
- 11 5 Change in FEV<sub>1</sub>
- 12 6 Symptoms (including breathlessness)
- 13 7 Adverse events
- 14 8 Quality of life

15

## 16 **4 NICE quality standards and NICE Pathways**

### 17 **4.1 NICE quality standards**

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

- 20 • [Chronic obstructive pulmonary disease in adults](#) (2016) NICE quality  
21 standard 10

### 22 **4.2 NICE Pathways**

23 When this guideline is published, we will update the existing NICE pathway on  
24 [Chronic obstructive pulmonary disease](#). NICE Pathways bring together  
25 everything NICE has said on a topic in an interactive flow chart.



## 1 **5 Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 11 January to 25 January 2017.

The guideline is expected to be published in November 2018.

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

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

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