

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

July 2017

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](#).

September 2018 update

Following consultation on the draft updated guideline in August 2018, two additional areas were identified where an evidence review is needed:

- inhaled triple therapy for stable COPD
- duration of systemic corticosteroid treatment for managing exacerbations.

Review questions 2.9 and 3.2 have been added to this scope. These questions will be addressed and developed in an additional update.

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

Current practice

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

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

The costs of some inhaled therapies have also reduced, as they are now off-patent and generic versions are available. However, the range and complexity of the inhaled therapies available (drugs and devices) has also increased

enormously. This has led to changes in clinical practice, which means that large parts of the current guideline are out of date.

Policy, legislation, regulation and commissioning

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

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

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

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

2 Who the guideline is for

People using COPD services, 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.

This guideline is for:

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

It may also be relevant for:

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

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.

3 What the updated guideline will cover

3.1 Who is the focus?

Groups that will be covered

- Adults (over 16 years) who have COPD (including chronic bronchitis, emphysema, and chronic airflow limitation or obstruction).
- Adults (over 16 years) who have COPD with asthma, COPD with bronchopulmonary dysplasia, or COPD with bronchiectasis.

No subgroups of people have been identified as needing specific consideration in addition to those listed in the [equality impact assessment document](#).

Groups that will not be covered

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

3.2 Settings

Settings that will be covered

- All settings where NHS care is delivered.

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. This is because new evidence and expert advice suggests these are the areas of the guideline that need updating. Further details outlining the specific aspects of the key areas that will be covered and how they will be dealt with, are in the table later on in this section.

- 1 Diagnosing and classifying the severity of COPD
 - further investigations for initial assessment (for example, imaging and biomarkers) to confirm the diagnosis
 - assessing severity and prognostic factors (for example multidimensional severity assessment tools)
- 2 Managing stable COPD and preventing disease progression
 - inhaled therapy
 - prophylactic oral antibiotics
 - long-term oxygen therapy: who should have treatment (indications for its use) and effectiveness in those indicated
 - oxygen therapy: for people with stable COPD who are mildly hypoxaemic or non-hypoxaemic at rest
 - managing complications of COPD: pulmonary hypertension and cor pulmonale

- referral criteria for lung surgery (including intact fissures)
 - education, self-management and home telehealth monitoring
- 3 Managing exacerbations of COPD
- Systemic corticosteroids
 - Investigating what may cause exacerbations of COPD (for example viral infection).

Note that guideline recommendations for all 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 people.

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 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 review of the evidence: retain the recommendations from the existing guideline.
Further investigations for initial assessment (for example, imaging and biomarkers) Assessing severity and prognostic factors (for example multidimensional assessment indices)	Review the evidence: update the existing recommendations as needed.

2. Management of stable COPD	
Smoking cessation	<p>Review the evidence for oxygen for people with stable COPD who are mildly hypoxaemic or non-hypoxaemic at rest.</p> <p>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.</p> <p>For smoking cessation, a cross-reference to NICE guidance on smoking, will be added to the guideline.</p> <p>For PDE-4 inhibitors, a cross-reference to the NICE technology appraisal Roflumilast for the management of severe chronic obstructive pulmonary disease will be added to the guideline.</p> <p>For all other areas in this section there will not be a review of the evidence: the recommendations from the existing guideline will be retained.</p>
Inhaled therapy	
<ul style="list-style-type: none"> • delivery systems 	
Oral therapy	
<ul style="list-style-type: none"> • oral corticosteroids • oral theophylline • phosphodiesterase-4 (PDE-4) inhibitors • oral mucolytic therapy • oral anti-oxidant therapy • anti-tussive therapy 	
Combined oral and inhaled therapy	
Oxygen	
<ul style="list-style-type: none"> • long-term oxygen therapy • ambulatory oxygen therapy • short-burst oxygen therapy 	
Non-invasive ventilation	
Management: pulmonary hypertension and cor pulmonale	
<ul style="list-style-type: none"> • diagnosis of pulmonary hypertension and cor pulmonale 	
Pulmonary rehabilitation	
Vaccination and anti-viral therapy	
Lung surgery	
<ul style="list-style-type: none"> • role of surgery • fitness for surgery • operation of choice (bullectomy, lung volume reduction or transplantation) 	
Alpha-1 antitrypsin replacement therapy	

<p>Multidisciplinary management</p> <ul style="list-style-type: none"> • respiratory nurse specialists • physiotherapy • identifying and managing anxiety and depression • nutritional factors • palliative care • assessment for occupational therapy • social services • advice on travel • advice on diving <p>Fitness for general surgery</p> <p>Follow-up of patients with COPD</p>	<p>No review of the evidence: retain the recommendations from the existing guideline.</p> <p>For palliative care, a cross-reference to the NICE guideline on care of dying adults in the last days of life will be added to the guideline.</p>
<p>Inhaled therapy</p> <ul style="list-style-type: none"> • long acting muscarinic antagonist (LAMA) plus long acting beta₂ agonist (LABA) compared with LAMA alone • LAMA plus LABA compared with LABA alone • LAMA plus LABA compared with LABA plus inhaled corticosteroid (ICS) • LAMA: identifying which is the most effective and who should have treatment 	<p>Review the evidence: update the existing recommendations as needed.</p>

<p>Inhaled therapy</p> <ul style="list-style-type: none"> • monotherapy with short acting beta₂ agonist (SABA), LABA, ICS, or LAMA (excluding LAMA vs. LAMA) • dual therapy with SABA plus short acting muscarinic antagonist (SAMA), LAMA plus ICS, or LABA plus ICS (excluding LAMA plus LABA) • triple therapy with LAMA plus LABA plus ICS 	<p>Review the evidence for triple therapy: update the existing recommendations as needed.</p> <p>No review of the evidence for any other area in this section: amend the recommendations if needed to fit with other parts of the update.</p> <p>There is no new evidence for these particular monotherapy and dual therapy regimes or for 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"> – in 2010, covering psychological and behavioural side effects associated with inhaled corticosteroids – in 2015, covering the risk for people with certain cardiac conditions when taking tiotropium delivered via Respimat or Handihaler.
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<p>Oral therapy</p> <ul style="list-style-type: none"> oral prophylactic antibiotic therapy <p>Oxygen therapy</p> <ul style="list-style-type: none"> long-term oxygen therapy: who should have treatment (indications for its use) and effectiveness in those indicated <p>Management of pulmonary hypertension and cor pulmonale</p> <ul style="list-style-type: none"> treatment of pulmonary hypertension and cor pulmonale <p>Lung surgery</p> <ul style="list-style-type: none"> referral criteria for lung surgery (including intact fissures) <p>Multidisciplinary management</p> <ul style="list-style-type: none"> education self-management home telehealth monitoring 	<p>Review the evidence: update the existing recommendations as needed.</p>
<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 review of the evidence: retain the recommendations from the existing guideline.</p>

Hospital-at-home and assisted discharge schemes	Review the evidence for systemic corticosteroids: update the existing recommendations as needed. No review of the evidence for any other area in this section: retain the recommendations from the 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 the evidence: update the existing recommendations as needed.
4. Audit criteria	
Audit criteria	Remove: this is no longer current practice. Audit criteria are no longer covered by NICE guidelines.

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

- [Indoor air pollution](#) (publication expected February 2019) NICE guideline
- [Asthma – diagnosis and monitoring](#) (publication expected October 2017) NICE guideline
- [Asthma management](#) (publication expected October 2017) NICE guideline
- [Air pollution – outdoor air quality and health](#) (publication expected June 2017) NICE guideline
- [Multimorbidity: clinical assessment and management](#) (2016) NICE guideline NG56

- [Extracorporeal carbon dioxide removal for acute respiratory failure](#) (2016)
NICE interventional procedure guidance 564
- [Depression in adults: recognition and management](#) (2009; updated 2016)
NICE guideline CG90
- [Older people with social care needs and multiple long-term conditions](#)
(2015) NICE guideline NG22
- [Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use](#) (2015) NICE guideline NG15
- [Pneumonia in adults: diagnosis and management](#) (2014) NICE guideline CG191
- [Respiratory tract infections \(self-limiting\): prescribing antibiotics](#) (2008)
NICE guideline CG69
- [Amantadine, oseltamivir and zanamivir for the treatment of influenza](#) (2009)
NICE technology appraisal guidance 168
- [Oseltamivir, amantadine \(review\) and zanamivir for the prophylaxis of influenza](#) (2008) NICE technology appraisal guidance 158
- [Varenicline for smoking cessation](#) (2007) NICE technology appraisal guidance 123
- [Behaviour change: individual approaches](#) (2014) NICE guideline PH49
- [Smoking: acute, maternity and mental health services](#) (2013) NICE guideline PH48
- [Smoking: harm reduction](#) (2013) NICE guideline PH45
- [Smoking: stopping in pregnancy and after childbirth](#) (2010) NICE guideline PH26
- [Smoking: workplace interventions](#) (2007) NICE guideline PH5
- [Insertion of endobronchial valves for lung volume reduction in emphysema](#) (2013) NICE interventional procedure guidance 465
- [Insertion of endobronchial nitinol coils to improve lung function in emphysema](#) (2015) NICE interventional procedure guidance 517
- [Extracorporeal membrane oxygenation for severe acute respiratory failure in adults](#) (2011) NICE interventional procedure guidance 391
- [Living-donor lung transplantation for end-stage lung disease](#) (2006) NICE interventional procedure guidance 170

- [Lung volume reduction surgery for advanced emphysema](#) (2005) NICE interventional procedure guidance 114

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

- [Smoking cessation interventions and services](#) (publication tbc) NICE guideline
- [Care of dying adults in the last days of life](#) (2015) NICE guideline NG31
- [Roflumilast for the management of severe chronic obstructive pulmonary disease](#) (2012) NICE technology appraisal guidance 244. [Currently being updated](#) (publication expected June 2017)

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 COPD:

- [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 questions

While writing the scope for this updated guideline, we have identified the following key issues and draft review questions related to them. The draft questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

- 1 Diagnosis
 - 1.1 In people with stable COPD, does routine assessment using a multidimensional severity assessment index (such as BODE [BMI, airflow obstruction, dyspnoea and exercise capacity] and GOLD ABCD) better predict outcomes than forced expiratory volume in 1 second (FEV₁) alone?
 - 1.2 In people with suspected COPD, what is the most accurate and appropriate test (for example imaging or biomarkers) to confirm the diagnosis?
 - 1.3 In people with suspected COPD, which tests (for example imaging or biomarkers) are the most accurate to identify whether they are at risk of poor outcomes and whether they will develop mild, moderate or severe COPD?

- 2 Management of stable COPD
 - 2.1 In people with stable COPD, what is the clinical and cost effectiveness of a LAMA plus a LABA compared with:
 - a LAMA alone
 - a LABA alone
 - a LABA plus an inhaled corticosteroid (ICS)
 - 2.2 Which is the most clinically and cost-effective LAMA for managing stable COPD, and which subgroups of people should receive treatment with it?
 - 2.3 What is the clinical and cost effectiveness of prophylactic oral antibiotics for preventing exacerbations in people with stable COPD?
 - 2.4 What are the most clinically and cost-effective therapies for managing complications (pulmonary hypertension and cor pulmonale) in people with stable COPD?

2.5 What is the clinical and cost effectiveness of self-management interventions, education, and home telehealth monitoring for improving outcomes and adherence to treatment in people with stable COPD?

2.6 What is the effectiveness of oxygen therapy in people with stable COPD who are mildly hypoxaemic or non-hypoxaemic at rest?

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

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

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

- a LABA plus an ICS
- a LAMA plus a LABA? (**New question September 2018**)

3 Management of exacerbations of COPD

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

3.2 Are shorter durations (7 or fewer days) of corticosteroid treatment effective at treating acute exacerbations in people with COPD, compared with longer durations (over 7 days)? (**New question September 2018**)

3.6 *Main outcomes*

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

- 1 Mortality
- 2 Hospital admissions and readmissions
- 3 Exacerbations
- 4 Gas transfer (carbon monoxide diffusion capacity and arterial oxygen partial pressure)
- 5 Change in FEV₁

- 6 Symptoms (including breathlessness)
- 7 Adverse events
- 8 Quality of life

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

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

4.2 NICE Pathways

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

5 Further information

July 2017: This is the final scope, incorporating comments from registered stakeholders during consultation.

The guideline is expected to be published in December 2018.

September 2018 update: the two additional review questions identified at consultation will be covered in an additional update, expected to publish in June 2019.

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

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