West Yorkshire Adult COPD Guidelines: Guidelines for the Diagnosis & Management of Chronic Obstructive Pulmonary Disease

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Adapted with permission from the Leeds COPD - Full Guidelines for the Diagnosis & Management of Chronic Obstructive Pulmonary Disease.

Contents

1. Definition

Chronic Obstructive Pulmonary Disease (COPD) is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnoea, cough, sputum production and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction.[1]

The main environmental exposures leading to COPD are tobacco smoking and the inhalation of toxic particles and gases from household and outdoor air pollution, but other environmental and host factors (including abnormal lung development and accelerated lung aging) can also contribute.

2. Population at Risk

Clinicians should consider COPD as a potential cause of respiratory symptoms in order to begin early management. Failure to recognise COPD as early as possible can result in delay in interventions with potential to modify the course of disease, development of disability earlier in life, shortening of life expectancy, inadequate local planning of health care delivery, increased overall cost for the community as a whole.

2.1. Noxious agents

- Smoking (tobacco/cannabis/heroin/crack cocaine)
- Industrial pollution (sulphur dioxide)
- Mining (coal, silica, gold)
- Smoke from biomass fuel
- Car exhaust pollution
- Other substances:
    - Cadmium dust and fumes
    - Grain and flour dust
    - Welding fumes

2.2 Susceptible individuals

- Alpha-1-antitrypsin deficiency
- Bronchial hyper-reactivity
- Low birth weight (premature baby)
- Reduced lung function in childhood
- Atopy

2.3 COPD defining symptoms

- Exertional breathlessness with activity limitation
- Chronic cough with or without sputum production
- Wheeze
- Exacerbations – periods of worsening symptoms requiring treatment

2.4 Population eligible for diagnostic test

The diagnosis of COPD should be considered in the following groups of individuals:

1. Individuals presenting to health professionals with:
- age over 35 years
- exposure to noxious agents and/or known as susceptible
- at least one of the COPD defining symptoms

2. Patients identified through the systematic audit of GP records (case finding) as having a medical history that suggests the possibility of COPD (recurrent respiratory infections or use of inhalers in smokers and ex-smokers aged over 35 years)

Individuals who fall in either of the above groups should be offered a diagnostic test - **quality assured spirometry**.

3. Diagnosis

3.1. Confirm diagnosis of COPD

COPD is confirmed by demonstrating airflow obstruction by post-bronchodilator spirometry in patients over 35 years of age with COPD defining symptoms and exposure to risk factors:

- Airflow obstruction is defined as reduced FEV1/FVC ratio (< 0.7)
- It is no longer necessary to have an FEV1 < 80% predicted for definition of airflow obstruction
- If FEV1 is ≥ 80% predicted, a diagnosis of COPD should only be made in the presence of respiratory symptoms, for example breathlessness or cough

3.2. Exclude alternative diagnosis

3.2.1. Asthma

Clinical features differentiating COPD & Asthma		
	COPD	Asthma
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under age 35 years	Rare	Common
Chronic productive cough	Common	Uncommon
Breathlessness	Persistent and progressive	Variable
Night-time waking with Breathlessness and/or Wheeze	Uncommon	Common
Significant diurnal or day-to-day variability of symptoms	Uncommon	Common

Consider asthma if:

- Night-time waking with breathlessness or wheeze.
- there is a > 400ml response to bronchodilators
- serial peak flow measurements show significant diurnal (>20%) or day-to-day variability
- there is a > 400ml response to 30mg prednisolone daily for 2 weeks

NB diagnosis of COPD should only be made in lifelong non-smokers after very careful consideration of alternatives.

3.2.2. Other conditions

Other common conditions that may present with symptoms similar to COPD are:

- Bronchiectasis
- Congestive heart failure
- Carcinoma of the bronchus

Ask for:

- Weight loss
- Effort intolerance
- Ankle swelling
- Chest pain
- Haemoptysis
- Fatigue
- Occupational hazards

Check:

- Chest x-ray
- Full blood count
- Alpha-1-antitrypsin
- Body Mass Index

Refer to respiratory specialist if in doubt about the correct diagnosis.

People diagnosed with alpha-1-antitrypsin deficiency can be referred to local specialist COPD clinics.

- Leeds place: Leeds integrated COPD clinic
- Wakefield place: Referral through e-consultation or ERS referral system from primary care into secondary care
- For the rest of West Yorkshire follow your usual process to refer to secondary care

3.2.3 Referral to a member of the COPD team for specialist advice

Reason	Purpose
There is diagnostic uncertainty	Confirm diagnosis and optimise therapy
Suspected severe COPD	Confirm diagnosis and optimise therapy
The person with COPD requests a second opinion	Confirm diagnosis and optimise therapy
Onset of cor pulmonale	Confirm diagnosis and optimise therapy
Assessment for oxygen therapy	Optimise therapy and measure blood gases
Assessment for long-term nebuliser therapy	Optimise therapy and exclude inappropriate prescriptions
Assessment for oral corticosteroid therapy	Justify need for continued treatment or supervise withdrawal
Bullous lung disease	Identify candidates for lung volume reduction procedures
A rapid decline in FEV1	Encourage early intervention
Assessment for pulmonary rehabilitation	Identify candidates for pulmonary rehabilitation
Assessment for a lung volume reduction procedure	Identify candidates for surgical or bronchoscopic lung volume reduction
Assessment for lung transplantation	Identify candidates for surgery
Dysfunctional breathing	Confirm diagnosis, optimise pharmacotherapy and access other therapists
Onset of symptoms under 40 years or a family history of alpha-1 antitrypsin deficiency	Identify alpha-1 antitrypsin deficiency, consider therapy and screen family
Symptoms disproportionate to lung function deficit	Look for other explanations including cardiac impairment, pulmonary hypertension, depression and hyperventilation
Frequent infections	Exclude bronchiectasis, consider Azithromycin treatment
Haemoptysis	Do NOT refer to Integrated COPD service, this requires a 2WW fast track lung cancer clinic referral

4. Disease Register

4.1. Introduction

Patients with confirmed diagnosis of COPD should be entered in a disease register for COPD. This is a system of collection, storage, retrieval and transmission of all data relevant to the lifelong management of a patient with COPD.

The essential elements of a disease register for COPD are:

1. Record of evidence confirming the diagnosis (spirometry result, symptoms etc.)
2. Assessment of severity including all data used for this.
3. All data used to define indications for each of the available treatment interventions.
4. Personalised care plan.
5. All data needed for audit of the service (QOF, NICE Outcomes Standards, Patient Reported Outcomes etc.)

4.2. Record of evidence confirming the diagnosis

The diagnosis of COPD is confirmed on the basis of demonstration of irreversible or only partially reversible airway obstruction on spirometry in patients aged over 35 years exposed to risk factors and having at least one of the COPD defining symptoms. The data needed for this include:

- Age
- Post-bronchodilator FEV1%
- Post-bronchodilator FEV1/FVC
- Exacerbations
- Chronic cough
- Regular sputum
- Exertional breathlessness
- Wheeze
- Smoking status
- Occupational exposure

4.3. Assessment of severity

Severity of disease should be assessed and recorded at each care planning consultation.

All patients should have a record of the following:

1. Post bronchodilator FEV1 as percentage of predicted - FEV1%
2. Breathlessness level according to MRC Dyspnoea Scale.
3. A patient reported outcome score - COPD Assessment Test (CAT)
4. Number of exacerbations in 12 months.
5. Number of hospital admission with acute exacerbation of COPD in 12 months.

The main measures of severity of disease recommended by NICE NG115 are airflow obstruction, symptoms and exacerbations history:

4.3.1 Gradation of severity of airflow obstruction[2]

Post-bronchodilator FEV1/FVC	Post-bronchodilator FEV1%	Severity of airflow obstruction.
< 0.7	>80 %	Stage 1 - Mild*
< 0.7	50 - 79 %	Stage 2 - Moderate
< 0.7	30 - 49 %	Stage 3 - Severe
< 0.7	<30 %	Stage 4 - Very Severe**

*Symptoms should be present to diagnose COPD in people with mild airflow obstruction.
** Or FEV1%<50% with respiratory failure.

4.3.2. **Medical research council dyspnoea scale[1,2]:**
One of the primary symptoms of COPD is breathlessness. The severity of breathlessness according to the level of exertion required to elicit it can be graded using the Medical Research Council (MRC) dyspnoea scale.

Although NHS clinical systems continue to use the MRC dyspnoea scale, clinical trials and international COPD guidelines, such as the GOLD strategy,[2] use the modified MRC (mMRC) dyspnoea scale. The MRC and mMRC scales use the same description of activities, but the grades are numbered from 1 to 5 and 0-4 respectively. To avoid confusion, the West Yorkshire guidelines use the MRC scale throughout as this reflects NHS clinical systems currently in use.
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MRC Dyspnoea Scale	**Modified MRC (mMRC) Dyspnoea Scale**	**Degree of breathlessness related to activities**
Grade 1	Grade 0	Not troubled by breathlessness except on strenuous exercise
Grade 2	Grade 1	Short of breath when hurrying or walking up a slight hill
Grade 3	Grade 2	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
Grade 4	Grade 3	Stops for breath after walking about 100m or after a few minutes on level ground
Grade 5	Grade 4	Too breathless to leave the house, or breathless when dressing or undressing

4.3.3. COPD Assessment Test (CAT)

COPD affects patients beyond breathlessness, and so multidimensional questionnaires are recommended to assess overall COPD health status.

The COPD Assessment Test (CAT) questionnaire (https://www.catestonline.org/) is a validated 8-item questionnaire (available in over 60 languages), which measures the impact of COPD on a person's life, and how this changes over time. The results correlate closely with health-related quality of life questionnaires (e.g. the St George's Respiratory Questionnaire (SGRQ)).

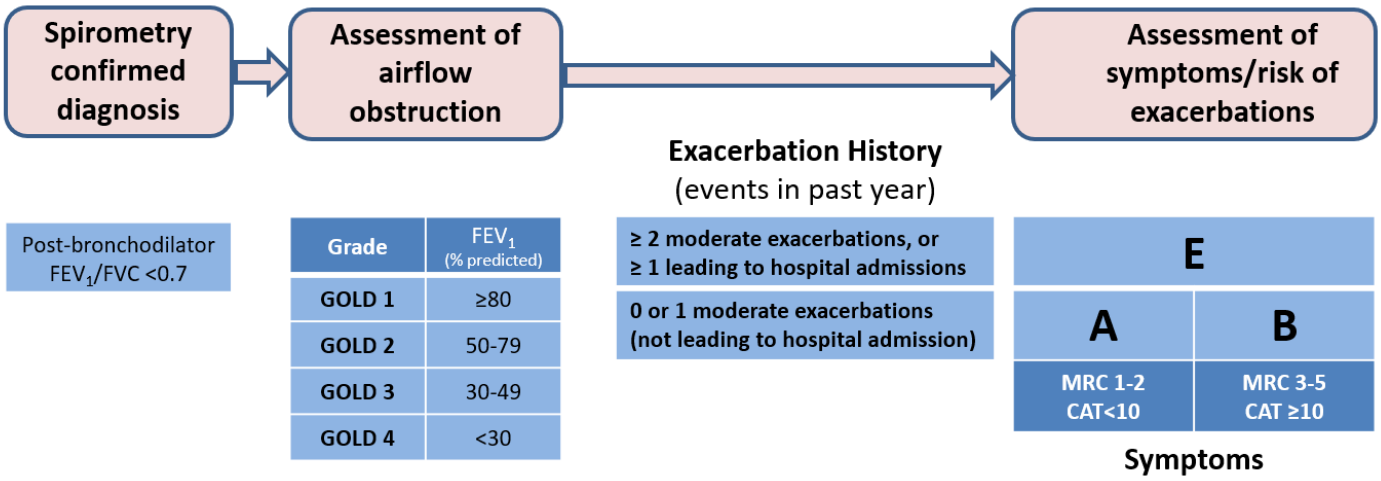
The results of the CAT questionnaire allow patients and healthcare professionals to understand the impact of COPD, and identify where COPD has the greatest effect on each patient's health and daily life. This can assist discussions and decisions about managing COPD.

Patients can be given the CAT questionnaire to complete immediately prior to their appointment (this may be whilst they are waiting to be seen), and may be repeated every 2 to 3 months to detect changes and trends in CAT score.

The CAT questionnaire has a scoring range of 0-40. A change of 2 or more in the score suggests a clinically significant change in health status.

CAT score	**Impact of COPD on a person's life**	**Management options**
<10	Low	• Smoking cessation advice. • Annual flu vaccination. • Advice to avoid exposure to exacerbation risk factors. • Prescription of SABA inhalers on a PRN basis.
10-20	Medium. Significant symptoms on most days, including breathlessness, wheeze, cough and/or sputum.	• Optimising COPD inhaled therapy. • Referral for pulmonary rehabilitation. • Ensuring best approaches to minimising and managing exacerbations. • Reviewing aggravating factors – is the patient still smoking?
21-40	High to very high. COPD may stop people doing most things that they want to do.	• Referral to specialist care. • Ensuring that COPD inhaled management is optimised, and using additional pharmacological treatments where indicated. • Referral for pulmonary rehabilitation. • Ensuring best approaches to minimising and managing exacerbations.

4.3.4. Combined COPD Assessment[1]



4.4. Data Suggesting Indications for Treatment Interventions

4.4.1 Smoking cessation
- Smoking status

4.4.2 Pharmacological management
- Breathlessness level according to MRC Dyspnoea Scale
- FEV1%
- Number of exacerbations in 12 months
- Patient reported outcome score - COPD Assessment Test (CAT)
- Regular sputum production
- Assessment of inhaler technique
- Eosinophil count

4.4.3 Pulmonary rehabilitation
- Breathlessness level according to MRC Dyspnoea Scale

4.4.4 Home oxygen therapy
- Sat O2 on air at rest.

4.4.5. Nutritional support
- BMI

4.4.6. Vaccinations
- Record of Influenza immunisation.
- Record of Pneumococcus vaccination
- Record of COVID 19 vaccinations

4.4.7. Personalised Care Plan

This is a list of interventions prescribed to the individual patient which includes any combination of the following:

- Smoking cessation intervention
- Inhaler therapy
- Nebuliser therapy
- Oral medication
- Pulmonary Rehabilitation
- Home Oxygen Therapy
- Vaccinations
- Nutritional support
- Palliative care
- Breathlessness management

4.5. QOF 2023 [3]

- COPD015: The contractor establishes and maintains a register of:
    - Patients with a clinical diagnosis of COPD before 1 April 2023 and Patients with a clinical diagnosis of COPD on or after 1 April 2023 whose diagnosis has been confirmed by a quality assured post bronchodilator spirometry FEV_1/FVC ratio below 0.7 between 3 months before and 6 months after diagnosis (or if newly registered at the practice in the preceding 12 months a record of an FEV_1/FVC ratio below 0.7 recorded within 6 months of registration); and
    - Patients with a clinical diagnosis of COPD on or after 1 April 2023 who are unable to undertake spirometry.

- COPD014. The percentage of patients with COPD and Medical Research Council (MRC) dyspnoea scale ≥3 at any time in the preceding 12 months, with a subsequent record of referral to a pulmonary rehabilitation programme (excluding those who have previously attended a pulmonary rehabilitation programme)

- COPD010. The percentage of patients with COPD on the register, who have had a review in the preceding 12 months, including a record of the number of exacerbations and an assessment of breathlessness using the Medical Research Council dyspnoea scale.

- SMOK002. The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses whose notes record smoking status in the preceding 12 months

- SMOK005. The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses who are recorded as current smokers who have a record of an offer of support and treatment within the preceding 12 months

4.6. NICE Quality Standards for COPD [4]

4.6.1. Statement 1. People aged over 35 years who present with a risk factor and one or more symptoms of chronic obstructive pulmonary disease (COPD) have post-bronchodilator spirometry. [2011, updated 2016]

4.6.2. Statement 2. People with COPD who are prescribed an inhaler have their inhaler technique assessed when starting or changing treatment and then at least annually during treatment. [2011, updated 2023]

4.6.3. Statement 3. People with stable COPD and a persistent resting stable oxygen saturation level of 92% or less have their arterial blood gases measured to assess whether they need long-term oxygen therapy. [2011, updated 2016]

4.6.4. Statement 4. People with stable COPD and a score of 3 or above on the Medical Research Council (MRC) dyspnoea scale are referred to a pulmonary rehabilitation programme. [2011, updated 2023]

4.6.5. Statement 5. This statement has been removed and pulmonary rehabilitation after an acute exacerbation is now covered in statement 8

4.6.6. Statement 6. People receiving emergency oxygen for an acute exacerbation of COPD have oxygen saturation levels maintained between 88% and 92%. [new 2016]

4.6.7. Statement 7. People with an acute exacerbation of COPD and persistent acidotic hypercapnic ventilatory failure that is not improving after 1 hour of optimal medical therapy have non-invasive ventilation. [2011, updated 2016]

4.6.8. Statement 8. People discharged from hospital after an acute exacerbation of COPD receive a hospital discharge care bundle. [new 2023]

Quality measures within this include understanding of medication and inhaler use; provision of a self-management plan, referral to smoking cessation behavioural change; assessment for pulmonary rehabilitation suitability; provision of follow-up within 72 hours.

Measures to assess compliance with each quality standard are available on the NICE website - https://www.nice.org.uk/guidance/qs10

5. Care Planning Consultation

Patients with COPD should have initial care planning consultation at the time of diagnosis and then review and care planning consultations at regular intervals of time depending on the severity of their illness:

1. Mild, moderate, or severe disease - every 12 months.
2. Very severe disease - every 6 months.
3. Additional review if change in symptoms, exacerbation or start of new treatment.

The essential elements of a care planning consultation are:

1. Assessment of severity.
2. Education of the patient.
3. Setting goals.
4. Personalised care plan.

Summary of a care planning consultation as recommended by NICE[2]

	Mild / moderate / Severe (stage 1 to 3)	**Very severe (stage 4)**
Frequency	**At least annual**	**At least twice per year**
Clinical assessment	• Smoking status and motivation to quit • Adequacy of symptom control: – breathlessness – exercise tolerance – estimated exacerbation frequency • Need for pulmonary rehabilitation • Presence of complications • Effects of each drug treatment • Inhaler technique • Need for referral to specialist and therapy services	• Smoking status and motivation to quit • Adequacy of symptom control: – breathlessness – exercise tolerance – estimated exacerbation frequency • Presence of Cor pulmonale • Need for long-term oxygen therapy • Nutritional state • Presence of depression • Effects of each drug treatment • Inhaler technique • Need for social services and occupational therapy input • Need for referral to specialist and therapy services • Need for pulmonary rehabilitation
Measurements to make	• FEV1 and FVC • calculate BMI • MRC dyspnoea score	• FEV1 and FVC • calculate BMI • MRC dyspnoea score • SaO2

5.1. Assessment of Severity

All patients should have a record of the following:

1. Post bronchodilator FEV1 as percentage of predicted - FEV1%

2. Breathlessness level according to MRC Dyspnoea Scale.
3. COPD Assessment Test (CAT) score.
4. Number of exacerbations in the last 12 months.
5. Number of hospital admissions in the last 12 months.

5.2. Patient Education

Education of the patients should be continuous during their life with COPD. It is important that it starts at the point of communication of the diagnosis.

Patients with new diagnosis of COPD should have an initial consultation at which the clinician should communicate the diagnosis to the patient and any supporting persons. This should take place face-to-face in an appropriate setting using the patient's first language, this may involve using an interpreting service, and they should be given time to ask questions regarding their diagnosis.

The patient should be given appropriate information including:
- Test results.
- Severity assessment.
- Identified co-morbidity.

Patients should receive education regarding the nature of COPD including the chronic course: Education should also include:

- How and when to access medical help
- Local information sources, including libraries and voluntary organisations such as the British Lung Foundation.
- Information about local care and support groups, including carers organisations and third-party organisations such as Breath Easy Groups.

The educational intervention should be repeated at each regular clinical review.

5.3. Setting Goals

Patient's preferences and priorities should be explored to agree on realistic goals to be achieved in collaboration between the clinician and the patient. These should be recorded preferably in patient's own words and should be considered in the personalised care plan.

5.4. Personalised Care Plan

At the Care Planning Consultation the Health Care Professional and the patient should agree a personalised care plan containing a list of all interventions recommended at the time. This plan should be updated at regular clinical review and care planning consultations at least every 12 months or at shorter intervals for patients with severe and very severe disease.

The essential intervention to be considered in the personalised care plan are:
- Smoking cessation intervention
- Inhaler therapy
- Nebuliser therapy
- Oral medication
- Pulmonary Rehabilitation

- Home Oxygen Therapy
- Vaccinations
- Nutritional support
- Management of co-morbidities
- Palliative care
- Breathlessness management

6. Smoking Cessation

Smoking remains the biggest preventable cause of death and disease in the UK, accounting for approximately 50% of the health inequalities between socio-economic groups. 1 in 2 smokers die prematurely due to smoking related disease and of the 80,000 deaths per year attributed to smoking approximately 50% are caused by respiratory diseases. Surveys indicate that two thirds of smokers would like to quit.[5]

Stopping smoking is one of the most cost-effective interventions that can be made in COPD, will slow disease progression, and will have health benefits for other conditions.[6]

Smoking cessation intervention should be applied at each contact of a patient with a health professional, by providing very brief advice (30 seconds). 'Ask, Advise and Act' will give them the best chance to successfully stop smoking:

- **ASK** and record their smoking status, and whether they live with a smoker.
- **ADVISE** patient of the health benefits of quitting, and inform them that the best way to quit is with a combination of trained support and treatments from a trained stop-smoking advisor.
- **ACT** on patient's response and refer smokers who want to quit to local NHS stop smoking service.

A combination of behavioural support counselling and pharmacotherapy is the most effective smoking cessation treatment for patients.[1,6]

Offer nicotine replacement therapy (NRT) according to local formulary guidelines.

Offer referral to local NHS Stop Smoking Services:

- Leeds Stop Smoking Services
- Calderdale Stop Smoking Services
- Wakefield Stop Smoking Services
- Kirklees Stop Smoking Services
- Bradford Living Well Stop Smoking Service

6.1. Nicotine Replacement Therapy (NRT)

NRT is available in different formulations, although not all products may be stocked in hospitals. Formulations include gum, inhalator, lozenge, microtab, mouth spray, nasal spray, or patch (applied for 16 hours or 24 hours).[2] There is no evidence that any formulation is more effective than the others, and most side effects from NRT are mild.

Combining the NRT patch with fast-acting NRT products (e.g. gum, inhalator, mouth spray) has been shown to increase success with quitting.[6]

The starting dose depends on the degree of nicotine addiction (e.g. the number of cigarettes smoked and "Time to the first cigarette" (TTFC) in the morning. A TTFC of less than 30 minutes suggests a maximal dose of NRT.[7]

The duration of NRT is typically 8–12 weeks, and the dose is reduced gradually throughout the course. Some individuals may continue with the full dose for extended periods of time, and this is a safe practice.

The benefits of NRT outweigh any risks with treatment but should be used with caution in patients with

- Unstable cardiovascular or cerebrovascular disease (e.g. individuals hospitalised with myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe dysrhythmia or CVA, or uncontrolled hypertension).
- Untreated peptic ulcer disease.
- Diabetes mellitus (monitor blood sugar levels closely)
- Moderate to severe hepatic impairment
- Severe renal impairment

Acidic beverages like coffee, juices and soft drinks interfere with the absorption of nicotine.

6.2. Electronic Cigarettes 'Vaping'

Public Health England, the Royal College of Physicians, London and NICE guidance all recommend regulated electronic cigarettes (also know as vapes) as a smoking cessation tool, as stated in the BTS position statement on smoking and tobacco, 2021.[5]

Smokers who have tried other methods of quitting without success may elect to try e-cigarettes (EC) to stop smoking and stop smoking services should support smokers using EC to quit by offering behavioural support.[6]

E-cigarettes are not licensed medicines but are regulated by the Tobacco and Related Products Regulations (2016).[6,8] Some NHS Trusts may not allow the use of e-cigarettes on hospital premises.

Current NICE guidance[6] recommends that advice on the use of e-cigarettes should include that there is not enough evidence to know whether there are long-term harms from e-cigarette use but is likely to be substantially less harmful than smoking.[11] Individuals using e-cigarettes should stop smoking tobacco completely.

The British Thoracic Society were due to publish a clinical statement on the medical management of tobacco dependency for hospital clinicians in October 2023, but as of January 2024 has not yet been published.[8] The draft consultation document advises clinicians on providing accurate and consistent information on vaping:

- Vaping delivers high dose short-acting nicotine
- Vaping is an effective treatment for tobacco dependency
- Vaping can be used to treat tobacco dependency when there is a clear focus on helping individuals to stop smoking completely
- When people use vapes to stop smoking, they should switch completely to vaping from smoking
- Vaping can be used with long-acting nicotine products (patches) as combination nicotine replacement therapy

- Vaping should be used to quit smoking with support from an expert trained to help with tobacco dependence
- Vaping is not risk-free. Smokers who use vaping as a tool to quit smoking should be supported to end their use of vapes at the appropriate time
- Vapes should not be used by any individual under 18 years of age. There is a need for clear education to highlight the potential risk vapes pose for this age group
- People who do not smoke, should not vape
- Inform people who want to use vapes to quit smoking that vaping products are regulated under Tobacco and Related Product Regulations 2016 (TRPR), that vape products need to be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) and comply with certain standards, and that vaping products should only be purchased from reputable sources to avoid illicit vaping products

6.3 Varenicline (Champix®)

Varenicline may be offered in line with NICE TA1234 as part of a programme of behavioural support.[9] However as of June 2021, it has not been available as a licensed medicine due to nitrosamine impurities.[10]

Varenicline is contraindicated in people aged under 18 years, pregnant and breastfeeding women, and in end-stage renal failure. It should be used with caution in severe renal disease and severe psychiatric disorders.

6.4 Bupropion (Zyban®)

Bupropion may be offered in line with NICE NG209[6] as part of a programme of behavioural support, but may be less effective than varenicline or long-acting NRT used in combination with short-acting NRT.

Bupropion is contraindicated in pregnancy and breastfeeding, people aged under 18 years, history of seizures, alcohol or sedative withdrawal, CNS tumour, people with a history of bulimia or anorexia nervosa, history of bipolar disorder, or in people taking use irreversible monoamine oxidase inhibitors. It should be used with caution in people with renal or hepatic impairment.

Bupropion was unavailable in the UK between December 2022 to December 2023 due to the potential for the presence of nitrosamine impurities. Supplies are now available again from 2024.[12]

6.5 Behavioural Support

A combination of behavioural support counselling and pharmacotherapy is the most effective smoking cessation treatment for patients.[1,6]

This is typically provided by specialists in smoking cessation counselling within local stop smoking services. Behavioural support interventions include written materials containing advice on quitting, multisession group therapy programmes or individual counselling sessions in person or by telephone.[36]

7. Pharmacological Management of COPD

7.1 General Principles of Management

Individuals who have asthma and COPD should be managed according to the West Yorkshire Adult Asthma Guidelines initially. Where appropriate, further COPD treatments may be added in, such as the addition of Long-Acting Muscarinic Antagonist (LAMA) inhalers in symptomatic patients.

The management of stable COPD should be based on the assessment of symptoms and exacerbation history, and treatment prescribed to reduce symptoms, the future risk and severity of exacerbations, improve health status, and in some cases improve survival.

The initial inhaler therapy should be based on an assessment of severity using GOLD 2023 ABE Assessment Tool[1] (Figure 2), whilst stepping up treatment is based on a stepwise progression based on treatable traits of dyspnoea and occurrence of exacerbations.

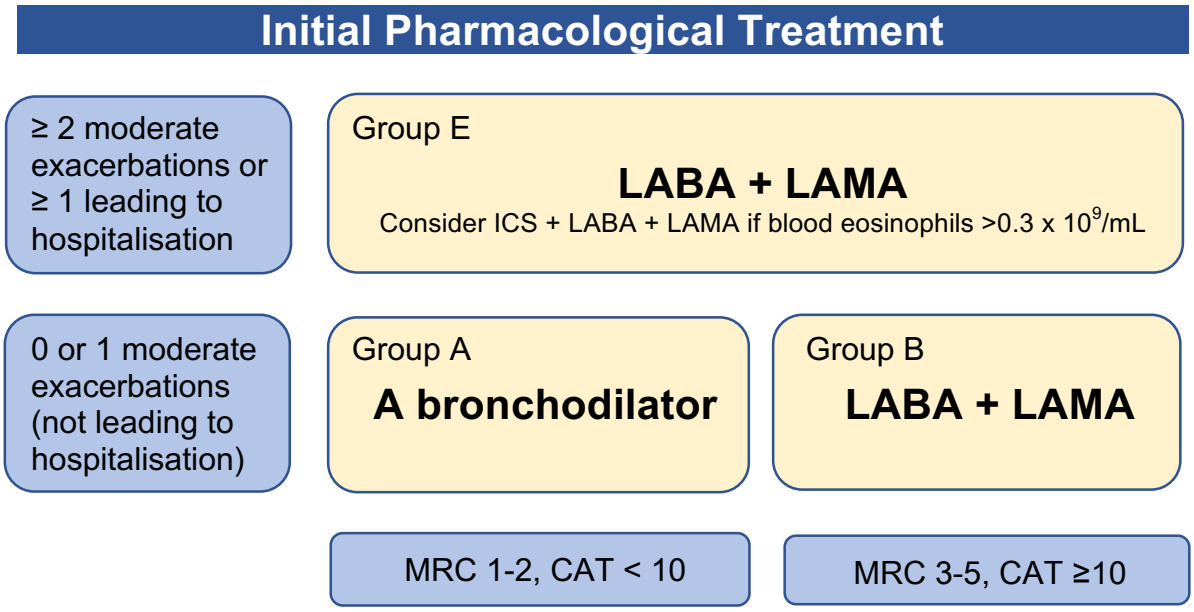


Figure 2. GOLD 2023 ABE Assessment[1]

Definition of abbreviations: MRC: Medical Research Council dyspnoea questionnaire; CAT: COPD Assessment Test, LABA: Long-Acting Beta-2 Agonist; LAMA: Long-Acting Muscarinic Antagonist; ICS: Inhaled Corticosteroid

Throughout the West Yorkshire COPD guideline, combination inhalers are the preferred choice rather than multiple single inhalers.

Inhalers should be prescribed using Brand names and not generic names, and changing inhaler therapy in stable patients should be only with patient consent.

ICS/LABA are no longer routinely recommended for the management of COPD in the West Yorkshire COPD Guidelines. Where an ICS is recommended, this should usually be as a 3-drug combination ICS/LABA/LAMA inhaler, as these have been shown to be superior to ICS/LABA.

ICS has no role in the management of mild COPD and/or where there is no evidence of steroid-responsive disease (e.g. any previous secure diagnosis of asthma or atopy, a higher blood eosinophil count, substantial variation in FEV_1 over time (at least 400 ml) or substantial diurnal

variation in peak expiratory flow (at least 20%)). There is a small but significant increased risk of pneumonia in people with COPD using ICS, which appears to be a class effect.[2]

Data modelling studies have demonstrated that there is a continuous relationship between blood eosinophil count and the efficacy of ICS in COPD. At low blood eosinophil counts $<0.1 \times 10^9$/mL, ICS provides little or no benefit on COPD outcomes, whilst high blood eosinophil count $>0.3 \times 10^9$/mL identifies individuals with the greatest likelihood of achieving benefit from ICS treatment.[1]

People at higher risk of pneumonia include those who are current smokers, aged ≥ 55 years, have previous pneumonia, body mass index (BMI) $<25 kg/m^2$, poor dyspnoea grades and more severe airflow obstruction.[1]

Consequently, ICS should be reserved for severe COPD with high risk of exacerbations and high blood eosinophil counts.

7.2 Device Selection

Inhalers should only be prescribed after patients have received training on the device and had their technique checked. This can be supported by signposting to the Asthma + Lung UK videos. Always involve the patient when choosing the device. Take into account individual preference, the ease with which the device can be used, and prior success or failure with different preparations.

Ensure continuity of the device for individual patients so that only one inhaler technique is required. Whenever possible do not mix pressurised Metered Dose Inhalers (pMDIs) and Dry Powder Inhalers (DPIs) as they require radically different inhaler techniques (slow and steady vs. quick and deep respectively). Many patients are prescribed a pMDI SABA reliever despite being on a DPI preventer.

The majority of adults with COPD are able to inhale at the optimal inspiratory flow rates required to use dry powder inhalers, particularly those with high airflow resistances, such as the Easyhaler device.[14] Studies have also demonstrated that adults with COPD admitted to hospital are more likely to be able to inhale at the optimal inspiratory flow rates using high resistance dry powder inhaler devices than with pMDIs.[15]

- A clinician-aimed video describing the benefits and principles of device resistance is available on You Tube

The internal resistance of dry powder inhalers is important to their function, as de-aggregation of the powdered dose occurs through the creation of turbulent pressure when patients inhale through the DPI, such that pressure is proportional to inspiratory flow and internal device resistance. Consequently, low resistance DPIs require a faster inspiratory flow to achieve an effective turbulent pressure than high resistance devices. As device resistance increases, the difference in drug delivery to the lung is smaller when comparing adults with healthy lungs to those with COPD or children. Consequently, people with a reduced inspiratory flow (i.e. those with COPD) will do better with high resistance DPIs than low resistance DPIs, because these high resistance devices are less flow dependent.

pMDI devices are commonly used incorrectly, with many people inhaling too fast to use the device, or have poor coordination for inhaling slowly as the devices is actuated. Most people who use pMDI devices should be offered a spacer device to improve drug delivery (see section 7.3). In particular, the use of a pMDI with a spacer may be best device for patients that require help with administration, such as residents in care homes where co-ordination needs support.

If a new inhaler device is needed, prescribing decisions should be individualised, and an appropriate device chosen for everyone. The Assess, Choose, and Train (ACT) decision tool (see Figure 1)[16] can be used to structure the review to ensure shared decision-making:

1. **A**ssess: Patients should be assessed on their inspiratory flow in order to determine whether they are physically able to inhale through DPIs, or through pMDI / breath-actuated pMDI (Autohaler/Easi-Breathe) / Soft Mist Inhaler devices in an effective manner;
2. **C**hoose: An appropriate device should be chosen, which may depend on the local formulary, cost, and environmental considerations;
3. **T**rain: the patient should be taught how to use the device using the seven steps required for good inhaler technique.

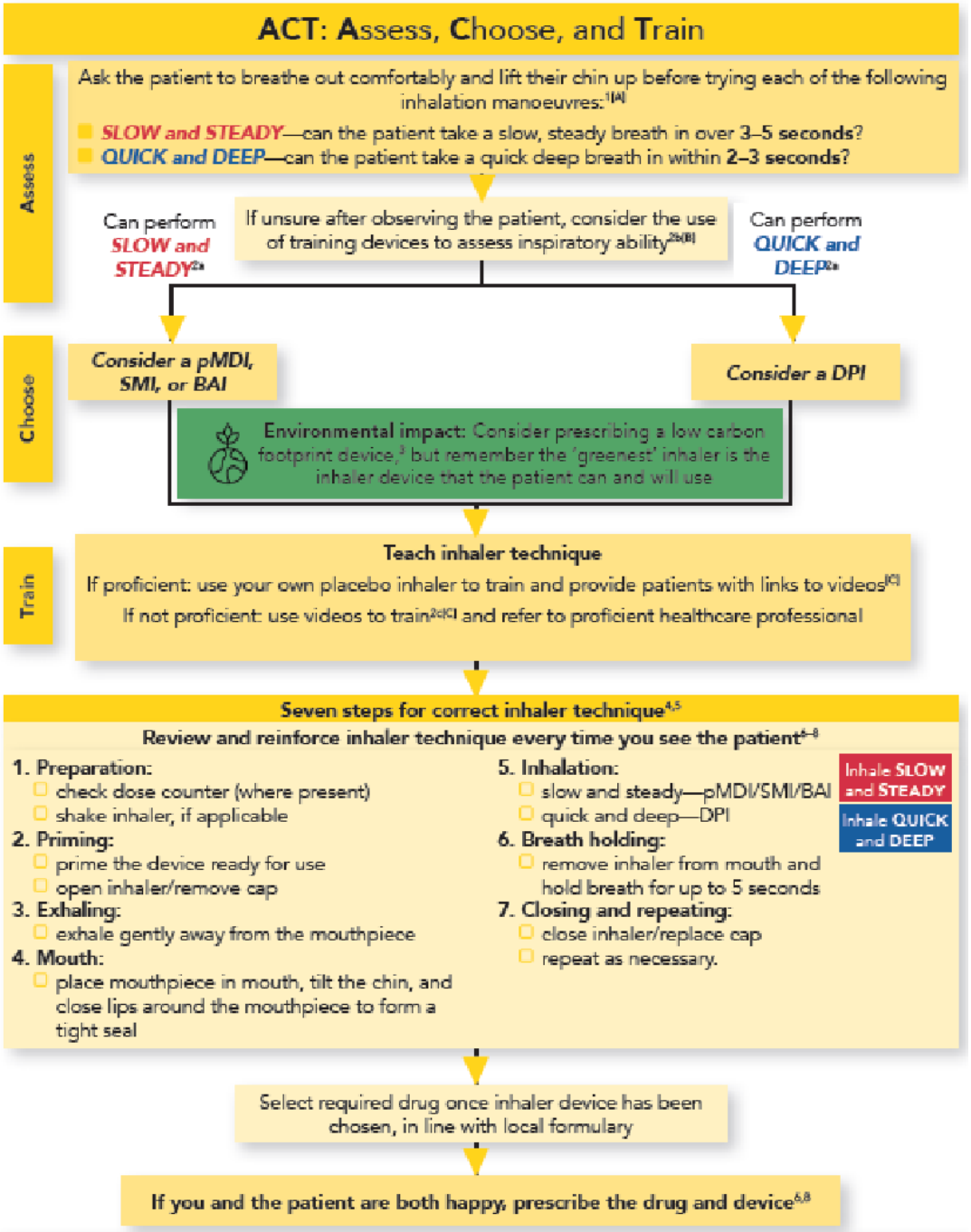


Figure 1: Assess, Choose, Train (ACT) decision tool for inhaler selection[16]

7.3 Spacers

To optimise drug delivery, a spacer should be prescribed with all pMDI devices. The *AeroChamber Plus Flow-Vu* spacer is the first-line spacer for both adults and children in West Yorkshire.

We recommend using spacers with a mouthpiece, rather than a mask, for all adults, unless they are unable to achieve a tight seal with their lips around the mouthpiece.

The AeroChamber Plus Flow-Vu spacer is available in a range of sizes depending on patient age and needs. Most adults should be prescribed the blue *AeroChamber Plus Flow-Vu Anti-static VHC with Mouthpiece*.

Colour	Name of Spacer
Orange	AeroChamber Plus Flow-Vu Anti-static VHC with Small Mask for Infants (0-18 months)
Yellow	AeroChamber Plus Flow-Vu Anti-static VHC with Medium Mask for Children (1-5 years)
Green	AeroChamber Plus Flow-Vu Anti-static VHC Youth Mouthpiece (5+ years)
Blue	AeroChamber Plus Flow-Vu Anti-static VHC with Mouthpiece
Purple	AeroChamber Plus Flow-Vu Anti-static VHC with Small Adult Mask
Blue	AeroChamber Plus Flow-Vu Anti-static VHC with Large Adult Mask

7.4 Environmental impact of inhalers

Metered dose inhalers have a higher carbon footprint than dry powder devices and British Thoracic Society (BTS) recommend that inhalers with low global-warming potential should be used when they are likely to be equally effective.[17] pMDIs currently contribute an estimated 4% of the carbon footprint of the NHS. If patients are able to inhale effectively (i.e. inhale quickly and deeply) to use a DPI, then these devices should be the default option for prescribing *with the patient's agreement*. However, if patients are only able to use pMDI devices (e.g. inhales slowly and steadily), or has a better technique with pMDIs, or prefers to use pMDI devices, then these should be prescribed.

Addressing the overuse of SABA inhalers will have a significant impact on the overall carbon footprint from inhaled therapy prescribed by the NHS. There may also be some patients who can be prescribed a DPI SABA but may need an pMDI with a spacer for emergency treatment. Ventolin® (salbutamol) Evohaler has been omitted from the guidelines as it is an pMDI with a very high carbon footprint (>25 kg CO2e per inhaler). Salamol® pMDI in comparison has a lower carbon footprint (<10 kg CO2e per inhaler) although is still classed as having a high global warming potential in comparison to DPIs.

Patients should also be encouraged to

- use any locally available inhaler recycling and recovery schemes, where available
- to return empty or unwanted inhalers to their community pharmacy for safe disposal. (This involves thermal treatment which destroys remaining propellant greenhouse gases. Inhalers should not be disposed of in household waste as this is likely to become landfill which is harmful to the environment both in material waste and in greenhouse gas emissions as the residual gas from canisters is subsequently released into the atmosphere).

Full instructions on the inhaler technique for specific devices can be found on the RightBreathe app or Asthma + Lung UK website, www.asthma.org.uk/advice/inhaler-videos.

All inhalers should also be prescribed by the brand to ensure familiarity for the patient and prevent the wrong inhaler device from being inadvertently dispensed by the pharmacy.

7.5 Inhalers and the Tobacco Industry

Philip Morris International (PMI) is one of the world's largest tobacco companies. PMI bought Vectura, a company that specialises in inhaled medication technology, in September 2021. Several pharmaceutical companies that make medicines used by people with COPD, asthma, and other lung diseases worked with Vectura in the past before it was taken over by PMI. This meant that Vectura received money based on sales of its products. Now that Vectura is owned by PMI, sales of these products results in income going to the tobacco industry.

We recommend that patients are made aware of these links so that they are able to make informed decisions about their treatment. Patient information leaflets on this are available from Asthma + Lung UK at https://www.asthmaandlung.org.uk/vectura-patient-information,[18] and reproduced in Appendix 1.

It is important that patients are not switched without checking the inhaler technique and agreeing for a change in device. Patients who are stable on their current inhalers may wish to stay on their usual inhaler device.

Affected inhalers that are licensed for asthma or COPD include:

Product	**Manufacturer(s)/Partners***
Flutiform® pMDI	MundiPharma
Enerzair® Breezhaler	Novartis
AirFluSal® Forspiro	Sandoz
WockAIR® Forspiro	Wockhardt
Relvar® Ellipta	GSK

7.6 Stepping-Up Therapy

It is important to check and address factors known to be associated with poor control at every opportunity including when considering a step up in treatment. The following factors should be considered:

- Inhaler technique
- Adherence to COPD medication. Good adherence (>75%) to treatment and adequate inhaler technique should be ensured before changing treatment.
    - This can be checked by an open conversation with the patient.
    - It is important to be non-judgemental and explore barriers to adherence with medication (e.g. dislike of device, side effects, chaotic lifestyle).
    - The prescription 'fill rate' should be reviewed (i.e. the actual number of maintenance inhalers prescribed in a 12-month period compared with the number that should have been prescribed). This is a surrogate measure of adherence and can prompt a conversation with a patient, particularly where fewer inhalers are collected than expected.
- Smoking status and referral to smoking cessation services
- Co-morbid conditions – e.g. weight management, obstructive sleep apnoea, heart failure

7.7 STEP 1: MILD COPD

At the point of diagnosis of COPD, these are individuals who fit into Group A of the GOLD ABE assessment tool. These are people with only mild occasional symptoms (MRC 1-2 and CAT score <10) and infrequent exacerbations (0 or 1 moderate exacerbations and no hospitalisations).

People with COPD with mild intermittent symptoms of dyspnoea should be commenced on a SABA inhaler (e.g. salbutamol or terbutaline). The choice of inhaler device is dependent on an assessment of inhaler technique, and in most cases, a dry powder inhaler is more likely to be used correctly (in terms of inhaler technique and inspiratory flow) and is preferred for environmental reasons.

Salbutamol and terbutaline should be prescribed to be used on an as required basis only for relief of symptoms and for the management of COPD exacerbations. Individuals with stable COPD should not use SABA inhalers on a regular basis.

Stepping up treatment

If individuals find that they are needing to use SABA inhalers on a regular basis, then treatment should be escalated to Step 2 (LABA+LAMA).

7.8 STEP 2: Group 1 - Moderate-Severe COPD with NO Steroid Responsive Features and LOW risk of exacerbations

At the point of diagnosis of COPD, these are individuals who fit into Group B of the GOLD ABE assessment tool. These are people with more severe symptoms (MRC 3-5 and/or CAT score ≥10) but with infrequent exacerbations (0 or 1 moderate exacerbations and no hospitalisations).

People with COPD with moderate symptoms of dyspnoea and infrequent exacerbations should be commenced on long-acting bronchodilators. Combination LABA+LAMA dual long-acting bronchodilators are preferred over single long-acting bronchodilators (either a LABA or a LAMA) as they provided added benefit in terms of lung function, symptom control,[19] exercise tolerance,[20] and exacerbations.[21]

Compared to ICS/LABA inhalers, LABA+LAMA combination inhalers produce greater improvements in lung function and quality of life, and achieve greater reductions in exacerbations with a lower risk of pneumonia.[22]

Whilst there are no studies available to determine the effect of using combination LABA/LAMA inhalers on adherence or patient preference in comparison to using separate LABA and LAMA inhalers, the cost of these are lower, thus making them an attractive option for patients requiring dual long-acting bronchodilator therapy.

As of July 2023, there are currently five different LABA/LAMA combination inhalers available in the UK. The choice of product and inhale device is dependent on an assessment of inhaler technique, and in most cases, a dry powder inhaler is more likely to be used correctly (in terms of inhaler technique and inspiratory flow) and is preferred for environmental reasons.

	Anoro® 55/22 Ellipta	**Duaklir® 340/12 Genuari**	**Spiolto® 2.5/2.5 Respimat**	**Bevespi® 7.2/5 Aerosphere pMDI**	**Ultibro® 85/43 Breezhaler**
Carbon Footprint	Low	Low	Low	High	Low
Dose	1 dose OD	1 dose BD	2 doses OD	2 doses BD	1 dose OD
LABA	Vilanterol	Formoterol	Olodaterol	Formoterol	Indacaterol
LAMA	Umeclidinium	Aclidinium	Tiotropium	Glycopyrronium	Glycopyrronium

OD: once daily; BD: twice daily

A SABA inhaler (e.g. salbutamol or terbutaline) should be prescribed as rescue therapy for relief of breakthrough symptoms and for exacerbations. It is important that patients who are using a dry powder LABA/LAMA inhaler device are prescribed a dry powder SABA reliever inhaler

Stepping up treatment

Before stepping up treatment, an assessment should be made of contributing factors, including assessing adherence, inhaler technique, and other causes or co-morbidities.

Dyspnoea

If individuals find that they are experiencing more severe symptoms of dyspnoea resulting in more regular use of SABA rescue inhalers despite good adherence to LABA/LAMA, then an alternative inhaler device or drug molecule within this class should be trialled before escalating treatment.

Exacerbations

If individuals continue to experience frequent exacerbations despite LABA/LAMA, then consideration should be made to escalate treatment further. The choice of add-on therapy may depend on individual treatable traits:

- **Blood eosinophil count >0.3 x 10^9/mL**: strong recommendation to escalate to ICS/LABA/LAMA
- **Blood eosinophil count 0.1-0.3 x 10^9/mL**: consider the addition of an ICS. A beneficial response may be achieved with the addition of an ICS above a count of 0.1 x 10^9/mL, with a greater magnitude of response with higher blood eosinophil counts.
- **Blood eosinophil count <0.1 x 10^9/mL**: the addition of an ICS is less likely to have a significant impact on exacerbations. Alternative strategies include the addition of roflumilast or azithromycin (see later sections).

7.9. STEP 2: Group 2 - Moderate-Severe COPD with NO Steroid Responsive Features and HIGH risk of exacerbations with LOW eosinophils

At the point of diagnosis of COPD, these are individuals who fit into Group E of the GOLD ABE assessment tool. These are people with more severe symptoms (MRC 3-5 and/or CAT score ≥10), and with frequent exacerbations (≥2 moderate exacerbations or ≥1 leading to hospitalisation). These patients also have low eosinophil counts (<0.1 x 10^9/mL), suggesting no steroid responsive disease.

Most people with COPD with severe symptoms of dyspnoea and frequent exacerbations should be commenced on dual long-acting bronchodilators (LABA/LAMA), as these are more effective in preventing exacerbations compared to single long-acting bronchodilators (LABA or LAMA) and to ICS/LABA combination inhalers.[21] Individuals who have a low eosinophil count (<0.1 x 10^9/mL), are less likely to achieve any clinical benefit from the inclusion of an ICS,[23,24] and may be at higher risk of pneumonia.

A SABA inhaler (e.g. salbutamol or terbutaline) should be prescribed as rescue therapy for relief of breakthrough symptoms and for exacerbations. It is important that patients who are using a dry powder LABA/LAMA inhaler device are prescribed a dry powder SABA reliever inhaler

Stepping up treatment

Before stepping up treatment, an assessment should be made of contributing factors, including assessing adherence, inhaler technique, and other causes or co-morbidities.

Dyspnoea

If individuals find that they are experiencing more severe symptoms of dyspnoea resulting in more regular use of SABA rescue inhalers despite good adherence to LABA/LAMA, then an alternative inhaler device or drug molecule within this class should be trialled before escalating treatment.

Exacerbations

If individuals continue to experience frequent exacerbations despite LABA/LAMA, then consideration should be made to escalate treatment further. The addition of an ICS is less likely to have a significant impact on exacerbations in people with low eosinophil counts. Alternative strategies include the addition of roflumilast or azithromycin (see later sections).

7.10 STEP 3: Moderate-Severe COPD with Steroid Responsive Features and HIGH risk of exacerbations with HIGH eosinophils

At the point of diagnosis of COPD, these are individuals who fit into Group E of the GOLD ABE assessment tool. These are people with more severe symptoms (MRC 3-5 and/or CAT score ≥10), and with frequent exacerbations (≥2 moderate exacerbations or ≥1 leading to hospitalisation). These patients also have high eosinophil counts (>0.3 x 10^9/mL), suggesting steroid responsive disease.

People with COPD and a high eosinophil count with severe symptoms of dyspnoea and frequent exacerbations should be commenced on triple combination inhalers of ICS+LABA+LAMA. This is a strong recommendation for individuals with a high eosinophil count (>0.3 x 10^9/mL), as this correlates with the greatest potential for benefit from the inclusion of an inhaled corticosteroid.[23,24]

Triple ICS/LABA/LAMA inhalers produce significant reductions in exacerbation rate compared to ICS/LABA and LABA/LAMA inhalers,[24-26], particularly in those with high eosinophil counts.[23,24]

Similar to LABA/LAMA combination inhalers, there are no studies assessing the effect of using combination ICS/LABA/LAMA inhalers on adherence or patient preference in comparison to using separate inhalers. However, the cost of combination inhalers is lower than using separate inhalers, allowing the possibility of financial savings whilst simplifying treatment for patients.

As of July 2023, there are currently four different ICS/LABA/LAMA combination inhalers available in the UK. The choice of product and inhale device is dependent on an assessment of inhaler technique, and in most cases, a dry powder inhaler is more likely to be used correctly (in terms of inhaler technique and inspiratory flow) and is preferred for environmental reasons.

	Trelegy® 92/55/22 Ellipta	**Trimbow® 88/5/9 NEXThaler**	**Trimbow® 87/5/9 pMDI**	**Trixeo® 5/7.2/160 Aerosphere pMDI**
Carbon Footprint	Low	Low	High	High
Dose	1 dose OD	2 doses BD	2 doses BD	2 doses BD
ICS	Fluticasone furoate	Beclomethasone	Beclomethasone	Budesonide
LABA	Vilanterol	Formoterol	Formoterol	Formoterol
LAMA	umeclidinium	Glycopyrronium	Glycopyrronium	Glycopyrronium

A SABA inhaler (e.g. salbutamol or terbutaline) should be prescribed as rescue therapy for relief of breakthrough symptoms and for exacerbations. It is important that patients who are using a dry powder ICS/LABA/LAMA inhaler device are prescribed a dry powder SABA reliever inhaler

Stepping up treatment

Before stepping up treatment, an assessment should be made of contributing factors, including assessing adherence, inhaler technique, and other causes or co-morbidities.

Dyspnoea

If individuals find that they are experiencing more severe symptoms of dyspnoea resulting in more regular use of SABA rescue inhalers despite good adherence to ICS/LABA/LAMA, then an alternative inhaler device or drug molecule within this class should be trialled before escalating treatment.

Exacerbations

If individuals continue to experience frequent exacerbations despite ICS/LABA/LAMA, then consideration should be made to escalate treatment further. Alternative strategies include the addition of roflumilast or azithromycin (see later sections).

7.11 Withdrawing Inhaled Corticosteroids

This guidance is only for people with COPD who have NO features of asthma.

ICS-containing regimens should only be prescribed for COPD patients at high risk of exacerbations with high eosinophil counts, and/or with features of asthma.

There is increasing evidence that ICS-containing inhalers provide limited clinical benefit when used in addition to bronchodilators in patients with COPD at low risk of exacerbations and low blood eosinophil counts. Regular treatment with ICS is not without risks. Evidence shows that there is an increased risk of pneumonia, and other side effects such as oral candidiasis, hoarse voice, and skin bruising.

This guidance aims to help healthcare professionals to evaluate the appropriateness of ICS therapy in COPD patients and identify those patients where ICS may be withdrawn.

STAGE 1: Evaluating the Appropriateness of ICS therapy

- **Asthma**: Continue ICS where there are signs or symptoms that may suggest a history of asthma, e.g.:
    - More than one of the following: variable wheeze, breathlessness, cough, and chest tightness
    - Variable lung function (e.g. an increase of >12% and 400mL in post-bronchodilator FEV1)
    - History of atopic disorder
    - Family history of asthma
    - Absence of a significant smoking history
- **Blood eosinophils**: High counts may suggest a greater response to ICS (particularly those with counts >0.3 x 10^9/mL).
- **Assess exacerbation history**: Continue ICS-containing regimen in patients with a high risk of COPD exacerbations:
    - At least 2 exacerbations, or one hospital admission in the past 12 months despite good (>75%) adherence to treatment.
        - Patient remains at high risk of COPD exacerbations.
        - Consider reviewing the current treatment regimen, check the inhaler technique, and consider referral to secondary care specialist clinics.
    - 0 or 1 exacerbations and no hospital admissions in the past 12 months, but were exacerbating prior to commencing treatment despite good (>75%) adherence to treatment.
        - This suggests a positive response to an appropriate treatment.

STAGE 2: Withdrawal of ICS in COPD

- Consider withdrawal of ICS for patients at low risk of COPD exacerbation, a low blood eosinophil count (particularly those with counts <0.1 x 10^9/mL), and no history of asthma.
- At each step, check inhaler technique, and obtain verbal consent to change treatment.
- Review patient four weeks after reducing ICS dose, and/or stopping ICS:
    - Check adherence
    - Ensure patient remains stable
    - Consider repeating spirometry
- Patients should be advised to contact GP practice if any worsening symptoms.
- Reassess need for ICS if:
    - Any COPD exacerbation requiring oral corticosteroids and/or hospital admission
    - Significant worsening of airflow limitation (FEV_1 decrease ≥100mL)

- **Patients on *high* dose ICS (e.g. Seretide 500 Accuhaler)**: reduce ICS dose:
    - Month 1: Prescribe LABA/LAMA plus additional medium dose ICS inhaler (e.g. Easyhaler budesonide 200micrograms 2 puffs BD)
    - Month 2: If stable, stop ICS and continue LABA/LAMA

- **Patients on *medium* dose ICS (e.g. Trelegy Ellipta, Trimbow pMDI, Relvar 92/22 Ellipta, Fostair 100/6 pMDI)**: stop ICS:
    - Prescribe LABA/LAMA

7.12 Theophylline

Theophylline has a modest bronchodilatory effect compared to placebo in stable COPD, and have a small additive effect on lung function and dyspnoea to LABA.[1] Theophylline has a limited role in COPD, as has an inferior safety and efficacy compared to inhaled bronchodilators.

NICE recommend that theophylline should only be used after a trial of short-acting bronchodilators and long-acting bronchodilators, or in patients who are unable to use inhaled therapy, as there is a need to monitor plasma levels and interactions.[2] The effectiveness of the treatment with theophylline should be assessed by improvements in symptoms, activities of daily living, exercise capacity, and lung function.

Theophylline has a narrow therapeutic index and cautious dose increases should be made to avoid large increases in the level of theophylline in the blood and toxicity. Theophylline should always be prescribed by brand (e.g. Uniphyllin Continus).

Particular caution needs to be taken with the use of theophylline in older people because of differences in pharmacokinetics, the increased likelihood of comorbidities, and the use of other medications which may interact.

Therapeutic drug monitoring should be undertaken in all patients prescribed theophylline, with serum levels taken at least 3 days after dose adjustments and at least 5 days after starting treatment. Levels should be repeated every 6-12 months.[27] Routine 12-monthly monitoring may be adequate in some adults, but more frequent monitoring (every 6 months) is recommended in adults with other co-morbidities such as heart failure or hepatic impairment, and in older people. If there are concerns about theophylline toxicity, serum levels should be taken immediately. Further advice is available on the Specialist Pharmacy Service Theophylline Monitoring webpage.

What level should theophylline be?[27]

- 10–20mg/L is usually required for satisfactory bronchodilation
- ≥5mg/L may give effective bronchodilation
- Symptoms of toxicity can occur within the 10-20mg/L range
- The severity of symptoms of toxicity increases at levels ≥20mg/L

Levels should be taken for ongoing treatment in the following instances:

- If the patient has side-effects suggestive of toxicity
- If the patient has stopped or started smoking for >7 days
- If a macrolide or a CYP1A2 enzyme-inhibiting drug is prescribed (raises plasma levels) or if a CYP1A2 enzyme-inducing drug (lower plasma levels) is prescribed.
    - Examples of CYP1A2 inhibiting drugs include ethinyl-oestradiol present in several oral contraceptive pills/hormone replacement therapy, cimetidine, and ciprofloxacin.
        - Omit evening theophylline dose for the duration of treatment of short-course antibiotics.
- If an enzyme-inducing drug, likely to interact with theophylline, is prescribed (reduces levels).
    - Examples of CYP1A2-inducing drugs include barbiturates, carbamazepine (e.g. Tegretol) and rifampicin
    - Consider checking levels after one week of starting an enzyme-inducing drug, and repeating if a loss of effect is experienced.
- Pregnancy. Since protein binding decreases in pregnancy, resulting in increased free drug levels, a lower therapeutic range (5-12mg/L) is probably appropriate.[28-29] Levels should be checked throughout pregnancy, with the frequency dependent on previous levels (e.g. repeat

sooner where levels are higher [>12mg/L], disease control, and possible side effects of theophylline).

Additional monitoring may be recommended for patients with congestive heart failure, chronic alcoholism, liver dysfunction, or viral infections as these conditions can affect theophylline levels

7.13 Roflumilast

Roflumilast is recommended by NICE as an option that should be started by a specialist in respiratory medicine.[30]

It is recommended as an add-on to bronchodilator therapy as an option for treating severe COPD in adults with chronic bronchitis, only if:

- the disease is severe, defined as a forced expiratory volume in 1 second (FEV_1) after a bronchodilator of less than 50% of predicted normal, and
- the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a LAMA, a LABA and an ICS.

Protocol:

- Treatment should be initiated by a respiratory specialist, and continued when stable by the GP
- All patients should be issued a standard information leaflet.
- Patients should monitor their weight every 2 weeks.
- Review at 4 weeks by a respiratory specialist to assess tolerance.
- Review at 6 and 12 months by a respiratory specialist to assess benefits.

Dose:

- Starting dose: 250 micrograms once daily for 28 days
- Maintenance dose: 500 micrograms once daily

Contraindications:

- Moderate to severe liver impairment (Child-Pugh B or C).
- Congestive heart failure (NYHA grades 3 and 4).
- Severe immunological diseases or immunosuppressive therapies.
- Severe acute infections.
- Cancers.
- History of depression associated with suicidal ideation or behaviour.
- Use with caution in people with a history of psychiatric disorders

7.14 Azithromycin

Azithromycin is recommended by NICE[2] as an option for individuals with COPD who:

- Do not smoke
- Have optimised non-pharmacological (smoking cessation, optimised inhaler technique, optimised self-management plan, and airway clearance techniques) and inhaled treatments, vaccinations and where appropriate have been referred for pulmonary rehabilitation.
- Continue to meet at least one of the following criteria:[2]
    - frequent (typically 4 or more per year) exacerbations with sputum production
    - prolonged exacerbations with sputum production
    - exacerbations resulting in hospitalisation

The British Thoracic Society recommends azithromycin for patients with COPD with more than three acute exacerbations requiring steroid therapy and at least one exacerbation requiring hospital admission per year to reduce exacerbation rate.[31]

Dose:

- 250mg three times a week (Monday, Wednesday, Friday)
- Patients should be warned about potential side effects including gastrointestinal upset, hearing and balance disturbance, cardiac effects (QTc prolongation), and microbiological resistance.

Assessment of response:

- Long-term macrolide therapy could be considered for a minimum of 6 months and up to 12 months to assess the impact on the exacerbation rate.
- Objective measures of response: exacerbation rate, CAT score, quality of life (e.g. SGRQ).

Contraindications

- Prolonged QTc at baseline (>450 ms for men and >470 ms for women)
- Non-tuberculous mycobacterial (NTM) infection
- Severe liver disease
- Myasthenia gravis

Monitoring:

- Baseline tests required before starting treatment:
    - ECG
    - Liver function tests
    - Microbiological assessment of sputum, including NTM to rule out other possible causes of persistent or recurrent infection that may need specific treatment.
- Liver function tests: repeat after 1 month, and then every 6 months.
- ECG: repeat after 1 month

7.15 Mucolytics

In people with COPD, mucolytic therapy with carbocisteine or n-acetylcysteine may reduce exacerbations and modestly improve health status.[1]

NICE recommends the use of mucolytic therapy in people with COPD with chronic cough productive of sputum.[2] This should only be continued if there is a symptomatic improvement (e.g. reduction in the frequency of cough and sputum production).

Mucolytics should not be routinely used to prevent exacerbations in people with stable COPD.[2]

There are two mucolytic therapies currently available: acetylcysteine and carbocisteine. The recommended formulations in the West Yorkshire guidelines and doses are:

- Acetylcysteine 600mg effervescent tablets once daily.
- Carbocisteine capsules 750mg three times a day for 2 weeks, then 750mg twice a day.
    - Carbocisteine is also available in 250mg/5mL oral liquid and 750mg/10ml oral liquid sachets. However, the liquid preparations are currently significantly more expensive than the capsule preparations.

Contraindications:

- Active peptic ulceration
- Carbocisteine only: People with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption.
- Acetylcysteine only: Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome.

7.16 Oral Corticosteroids

Long term oral corticosteroid treatment is not usually recommended in COPD, but we recognise that there is a cohort of patients with end stage COPD who may benefit from low dose oral corticosteroids (Prednisolone 5-10mg once a day) to control intractable symptoms of breathlessness and fatigue. This is viewed as a palliative measure and should only be used in end stage disease.

The appropriate patients are likely to have severe or very severe airflow obstruction on spirometry: FEV1 <50% predicted, be on the Gold Standard Framework, have less than a year's life expectancy and be otherwise medically optimised from COPD point of view.

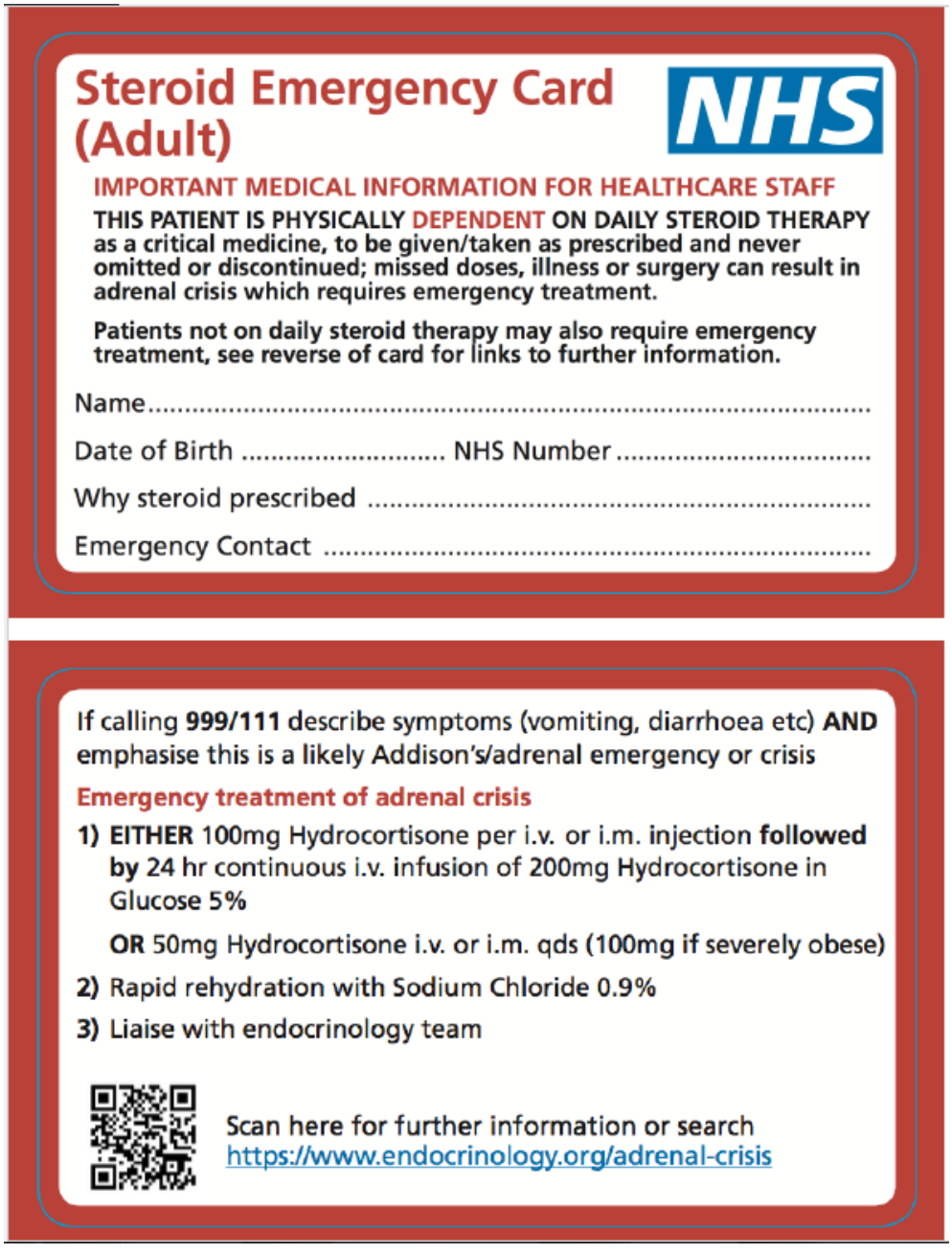
NICE also support the use of oral corticosteroids for 'advanced COPD', stating: Maintenance use of oral corticosteroid therapy in COPD is not normally recommended. However, some people with advanced COPD may require maintenance oral corticosteroids when these cannot be withdrawn after an exacerbation. In these cases, the dose of oral corticosteroids should be kept as low as possible.[2]

8. National Steroid Treatment Cards

A National Steroid Treatment Card should be given to all patients taking inhaled beclomethasone >1000 mcg/day or fluticasone propionate >500 mcg/day, or continuous oral corticosteroids (for more than 4 weeks), as they are at risk of adrenal insufficiency due to hypothalamic-pituitary axis suppression and should be issued with an NHS Steroid Emergency Card.

In addition, steroid cards should be considered for people using other glucocorticoids (including potent/very potent topical glucocorticoids, intra-articular injection, and regular nasal glucocorticoids) alongside medium-dose inhaled steroids.

Further information on steroid treatment cards can be found in the National Patient Safety Alert Reference No. NatPSA/2020/005/NHSPS (13th August 2020).[32]



9. Home Nebuliser Therapy

Most people with COPD do not routinely require nebulised therapy, as inhaler devices are more cost-effective, and there is no significant difference in improvement in lung function when bronchodilators are given via pMDI (with or without a spacer) or via a nebuliser.[1]

Nebulised bronchodilators may be considered in people who are unable to use inhaler devices include dry powder inhalers, soft mist inhalers or pMDIs (with or without spacers).[1]

Home nebuliser therapy may also be considered for patients with distressing or disabling breathlessness despite maximal therapy using inhalers should be considered for nebuliser therapy.[2]

Nebuliser therapy should not be prescribed without an assessment of the patient's and/or carer's ability to use it, and should only be continued after assessment of response, confirming that one or more of the following occurs:

- A reduction in symptoms.
- An increase in the ability to undertake activities of daily living.
- An increase in exercise capacity.
- An improvement in lung function.

Administration

- An air-driven nebuliser should be used, rather than an oxygen-driven nebuliser to reduce the risk of increasing $PaCO_2$.
- A mouthpiece is preferred over a facemask when administering nebuliser therapy (particularly for antimuscarinic and corticosteroid drugs), but it is good practice to offer patients a choice between a facemask and a mouthpiece to administer their nebulised therapy

10. Pulmonary Rehabilitation

People with stable chronic obstructive pulmonary disease (COPD) and a score of 3 or above on the Medical Research Council (MRC) dyspnoea scale are referred to a pulmonary rehabilitation programme. [NICE Quality Standards for COPD 2011, updated 2023][4]

People admitted to hospital for an acute exacerbation of COPD assessed for pulmonary rehabilitation suitability. [NICE Quality Standards for COPD 2011, updated 2023].[4]

For Leeds the current agreement is that patients admitted to hospital with Acute Exacerbation of COPD should be assessed for suitability and offered referral for pulmonary rehabilitation at a later stage as part of a COPD Care Bundle.

- All patients with confirmed diagnosis of COPD should be encouraged to do exercise at mild breathlessness pace for at least 30 minutes 5 days a week.

- Patients who feel functionally disabled by COPD (MRC dyspnoea grade 3 or more) or who have recent hospitalisation because of acute exacerbation should be considered for pulmonary rehabilitation.

- Check motivation for pulmonary rehabilitation?

- Check for co-morbidity preventing pulmonary rehabilitation:
    - Unstable IHD,
    - MI or surgery last 6 weeks,
    - AAA ≥5cm,
    - Musculo-skeletal problems preventing ability to exercise

Refer for a course of Pulmonary Rehabilitation to local services, e.g.:

- Leeds Integrated COPD Service
- Calderdale (telephone 01422 317084)
- Wakefield: referral through SystmOne
- Airedale and Craven: through the Gateway on SystmOne
- For other areas of West Yorkshire, refer to the respiratory team in secondary care.

For those not able or willing to attend a standard course - refer to **the community respiratory physiotherapists** who may be able to arrange a home visit for housebound patients and consider a virtual pulmonary rehabilitation or a Home exercise programme.

- Leeds Integrated COPD Service
- For other areas of West Yorkshire, refer to the respiratory team in secondary care.

11. Home Oxygen Therapy

Oxygen will not be considered in patients with COPD who continue to smoke.

People with stable COPD and a persistent resting stable oxygen saturation level of 92% or less have their arterial blood gases measured to assess whether they need long-term oxygen therapy. [NICE Quality Standard for COPD 2011, updated 2016][4]

- Home Oxygen Therapy should be considered in patients with quality assured diagnosis of COPD on optimal treatment who meet the following criteria:
    - Oxygen saturation less than 92% on air at rest when in stable condition (preferably six weeks after the last exacerbation).
    - Documented drop in oxygen saturation by 4% and below 90% at a standardised walking test.

- Patients meeting the above criteria should be referred for Home Oxygen Therapy assessment to Home Oxygen Service - Assessment & Review (HOS-AR) - refer to the **local services**:
    - Airedale and Craven: Refer to BOC, using the referral form on SystmOne
    - Wakefield: Refer to respiratory nursing team through SystmOne
    - Leeds: Leeds Integrated COPD Service

- Patients starting Home Oxygen Therapy should have a review at home by HOS-AR four weeks after starting home oxygen therapy.

- Regular follow up by home oxygen therapy specialist:
    - Every six months with check of oxygen saturation.
    - Every twelve months with check of arterial blood gases (ABG) / capillary blood gases (CBG).
    - Within four weeks after hospital admission or treatment at home for severe exacerbation of COPD.

- Patient not using the oxygen therapy as prescribed should be provided further education or change regimen.
- If patients cannot use oxygen therapy as prescribed and there is a perceive risk of harm to the patient of others the case should be discussed in the specialist COPD MDT, which is held weekly. In extreme cases, oxygen may need to be removed.
- Patients who no longer benefit from oxygen therapy should have this withdrawn according to agreed local protocol.

12. Home Non-Invasive Ventilation (NIV)

Among patients with persistent hypercapnia following acute exacerbation of COPD, adding home non-invasive ventilation to home oxygen therapy may prolong the time or death within 12 months.[33]

Recommendations:

- Patients admitted acutely with acute exacerbation of COPD and hypercapnic respiratory failure should have arterial blood gases checked before discharge.
- Patients with **PaCO2 greater than 7.0 kPa** should be referred to the appropriate COPD team for an arterial (capillary) blood gas to be performed 2 weeks post-discharge.

13. Lung Volume Reduction

Consider surgical or bronchoscopic lung volume reduction in patients with significant limitation of exercise capacity who are otherwise fit for a surgical intervention.

Eligible patients should have:

- Severe obstruction FEV_1 < 50% and MRC ≥3 post pulmonary rehab.
- Stopped smoking for more than 3 months.
- Completed a course of pulmonary rehabilitation.
- Good compliance with optimal conservative management plan.
- Motivation to undergo surgical or bronchoscopic intervention under general anaesthetic.

Eligible patients should be referred for assessment by a respiratory specialist, e.g.:

- Leeds Integrated COPD Service
- For other areas of West Yorkshire, refer to the respiratory team in secondary care.

14. Vaccinations

Pneumococcal vaccination and an annual influenza vaccination should be offered to all patients with COPD as recommended by the Chief Medical Officer, and as outlined in The Green Book.[34]

In addition, it is recommended that all patients with COPD have COVID 19 (coronavirus: SARS-CoV-2) booster vaccinations.

15. Comorbidities

In a significant proportion of patients COPD coexists with other long-term conditions (comorbidities) which can have major impact on prognosis and outcomes.

When dealing with a patient with COPD check also for:

1. Cardiovascular Disease (CVD)
   a) Ischemic Heart Disease (IHD)
   b) Heart Failure (HF)
   c) Atrial Fibrillation (AF)
   d) Hypertension
2. Osteoporosis
3. Anxiety and Depression
4. Lung Cancer
5. Metabolic Syndrome and Diabetes
6. Cachexia

15.1. Cardiovascular Disease

15.1.1. Ischemic Heart Disease (IHD)[1]

Incidence of IHD is increased in patients with COPD. IHD in patients with COPD should be treated according to the existing guidelines for management of IHD.

Treatment with a beta blocker may be indicated in some patients with IHD and COPD to treat angina or after myocardial infarction.

Treatment with beta blockers is considered safe and the benefits of prescribing cardioselective beta blockers when indicated to treat IHD are considerably larger than the potential risks associated with treatment, even in patients with severe COPD.

During and for the next 90 days after a COPD exacerbation there is an increased risk of cardiovascular events.

15.1.2. Heart Failure (HF)[1]

Coexistence of COPD and HF is common (incidence ranging from 20-70%) - approximately 30% of patients with COPD also have HF and 30% of HF patients also have COPD

Low FEV1 is a strong predictor of mortality in patients with HF.

Attention needs to be paid to the differential diagnosis between worsening HF and exacerbation of COPD because of common cardinal symptom - breathlessness.

HF in patients with COPD should be treated according to the existing guidelines for management of IHD.

Treatment with cardioselective beta-blockers has significant impact on survival in patients with HF. Treatment with beta-blockers is considered safe and the benefits of prescribing cardioselective beta-blockers when indicated to treat HF are considerably larger than the potential risks associated with treatment, even in patients with severe COPD.

15.1.3. Atrial Fibrillation (AF)[1]

There is increased incidence of atrial fibrillation in patients with COPD and is associated with lower FEV1. Breathlessness and disability can be result of the coexistence of COPD and atrial fibrillation.

AF in patients with COPD should be treated according to the existing guidelines for management of AF.

Treatment with beta blockers is considered safe and the benefits of prescribing cardioselective beta blockers when indicated to treat AF are considerably larger than the potential risks associated with treatment, even in patients with severe COPD.

High doses of beta2-agonists may make the control of heart rate difficult and should be prescribed with care.

15.1.4. Hypertension[1]

Hypertension is the most common comorbidity in COPD and has implications for the prognosis.

Cardio-selective beta blockers should be used if beta blockers are needed for the treatment of hypertension.

15.2. Osteoporosis [1]

Osteoporosis is a major comorbidity in patients with COPD and is associated with poor health status and prognosis.

In patients with COPD osteoporosis is most common in emphysema phenotype, low BMI and low fat-free mass.

Systemic corticosteroids significantly increase the risk of osteoporosis and frequent courses of systemic corticosteroids for exacerbations of COPD should be kept to a minimum.

Osteoporosis in patients with COPD should be treated according to the existing guidelines.

15.3. Anxiety and Depression [1]

Anxiety and depression are major comorbidities in patients with COPD and are associated with poor prognosis.

Risk factors for developing anxiety and depression in patients with COPD include: younger age, female sex, smoking, lower FEV1, cough, higher symptoms scores and a history of cardiovascular disease.

Anxiety and depression in patients with COPD should be treated according to the existing guidelines.

Pulmonary rehabilitation has the potential for positive impact through the beneficial effect of exercise on depression.

15.4. Lung Cancer [1]

Lung cancer is the leading cause of cancer deaths worldwide. It is the most common cause of death in patients with mild COPD.

Lung cancer in patients with COPD should be treated according to the existing cancer guidelines.

There does not appear to be a relationship between inhaled corticosteroids (ICS) use and lung cancer.

15.5. Metabolic Syndrome and Diabetes [1]

Metabolic syndrome and diabetes are common comorbidities in COPD and have implications for the prognosis.

Patients with COPD metabolic syndrome and diabetes should be treated according to the existing guidelines. It is not recommended to aim for BMI below 21 in patients with severe COPD

15.6 Gastroesophageal reflux disease (GORD) [1]

The presence of GORD in patients with COPD is an independent risk factor for exacerbations and is associated with worse health status.

It is recommended that treated with proton pump inhibitors, or alternatives, is offered to patients with GORD and COPD

15.7. Cachexia

Pulmonary cachexia syndrome is associated with an accelerated decline in functional status and is an independent predictor of mortality in patients with COPD.

- Optimise respiratory function - maximal bronchodilatation
- See Pharmacological Management
- Regular exercise as much as tolerated - see Pulmonary Rehabilitation
- Optimal oxygen therapy - see Home Oxygen Therapy
- Optimise heart function - see Comorbidities - Cardio-Vascular Disease
- Correct anaemia if present
- Control inflammation through adequate treatment with inhaled corticosteroids, careful use of systemic steroids where appropriate and control of infection - see Pharmacological Management
- Nutritional therapy for COPD - calories intake adequate to meet the basal energy expenditure through frequent small meals with nutrient dense foods and supplemental nutrition when appropriate.

16. Multidisciplinary Management of COPD

16.1. Respiratory Nurse Specialist [2]

COPD Nurse Specialists can be based both in primary and secondary care and may have the following roles:

- Education of patients and their carers/supporting individuals.
- Support and education of other health professionals caring for COPD patients.
- Coordination of care - main point of contact for the patients and their families and link to the multidisciplinary team.
- Assessment and monitoring of stable COPD patients.
- Psychological and emotional support for the patients and their families.
- Nurse prescribing.
- Provision of home care.
- Home oxygen assessment.
- Monitoring patients on home ventilation.
- Supporting hospital at home.

16.2. Respiratory Physiotherapist [2]

Respiratory physiotherapy is a specialised area of care with the aim of:

- helping to reduce the work of breathing associated with respiratory disease
- teaching sputum clearance techniques
- to help restore patients' maximal function
- to help improve peripheral and respiratory muscle

16.3. Occupational Therapist [2]

Patients should be regularly asked about their ability to undertake activities of daily living and how breathless they become when doing these.

Clinicians involved in the care of people with COPD should assess their need for occupational therapy using validated tools.

16.4. Social Services [2]

Patients disabled by COPD should be considered for signposting for assessment by a social services department.

Patients and their carers may be entitled to claim benefits including benefits for people who cannot work and benefits for the extra costs of disability.

Website: Department for Work and Pensions (www.gov.uk)

16.5. Nutritional Support [1,2]

Measure BMI in all patients with COPD. If you are concerned about malnutrition, screen patients using the Malnutrition Universal Screening Tool (MUST)

A higher BMI >20 is recommended in patients with COPD due to risk factors associated with reduced weight (where normal BMI is considered 18.5 to <25 kg/m^2.

Interventions should follow local malnutrition guidelines and NICE guidelines on nutrition support for adults.[37] Offer 'food first' dietary advice (including patient information leaflets), set food first goals and undertake a 4-weekly review. Explain and encourage the daily 1-2-3 advice:

1. pint of fortified milk (add 4 tablespoons of dried milk powder to 1 pint whole milk, use in drinks, on cereal, sauces, milk based soups) AND
2. high energy snacks AND
3. fortified meals i.e. breakfast, lunch, evening meal (eg using cream, cheese, butter and choosing full fat products)

Oral Nutritional Supplements (ONS) should only be provided to patients who are classed as malnourished or at risk of malnutrition, where dietary intervention alone has not led to an improvement in nutritional status or is highly unlikely to do so.

For people with a low BMI, give nutritional supplements to increase their total calorific intake and encourage them to exercise to augment the effects of nutritional supplementation.

16.6. Psychological Support [1,2]

NICE guidelines CG91 on the treatment and management of depression and adults with a chronic physical health problem (October 2009) updates the recommendations on treatment of depression in patients with COPD. This guidance notices the importance of offering psychological and psycho-social interventions before considering anti-depressant drugs.

16.7. Palliative Care [2]

Patients with end stage COPD and their family and carers should have access to the full range of services provided by a multidisciplinary palliative care teams, including admission to hospices.

Refer to local palliative care services.

In Leeds there is a monthly Respiratory Palliative Care MDT: for more information regarding this or to suggest patients for discussion please email: leedsth-tr.respiratorypalliativemdt@nhs.net

17. Exacerbations

An exacerbation is a sustained worsening of patient's symptoms from his or her usual stable state that is beyond the normal day-to-day variations, and is acute in onset.

Symptoms associated with acute exacerbation of COPD:

- Increased dyspnoea
- Increased sputum purulence
- Increased sputum volume
- Increased cough
- Upper airways symptoms (e.g. colds and sore throats)
- Increased wheeze
- Chest tightness
- Reduced exercise tolerance
- Fluid retention
- Increased fatigue
- Acute confusion

Other causes of similar symptoms:

- Pneumonia
- Pneumothorax
- Left ventricular failure/ pulmonary oedema
- Pulmonary embolus
- Lung cancer
- Upper airway obstruction
- Pleural effusion
- Recurrent aspiration

Prescribe pharmacological treatment for acute exacerbation of COPD:

- Bronchodilators
  - Increase doses and/or frequency of short acting bronchodilators
  - High-resistance DPI devices (e.g. Easyhaler) are suitable for many people with COPD.
    - These devices are less flow-dependent than low-resistance DPIs and many people with COPD can achieve adequate and effective inspiratory effort to use these devices.
  - Consider use of pMDI via spacers or air driven nebulisers for very severe exacerbations
- Steroids: Prednisolone 30 - 40 mg od for 5-7 days
- Antibiotics when signs of bacterial infection – please see trust antimicrobial guidelines. A 5-day course of antibiotics is sufficient for most people with COPD.
  - Short-course antibiotics (for less than 6 days) were not significantly different from long-course antibiotics (for 7 days or more of the same antibiotic) in resolution of exacerbation symptoms after completing treatment, in people with an acute exacerbation of COPD.[38]
  - Antibiotics are not always required. Repeated use may increase the risk of antibiotic resistance.
- Rescue packs should not usually be on repeat prescription. Repeated requests (more than 2 per year) should monitored to ensure appropriate use.

Decide about most appropriate place of treatment - home vs hospital management

17.1. Home or Hospital Treatment

Factor	Treat at home	Treat in hospital
Able to cope at home	Yes	No
Breathlessness	Mild/Moderate	Moderate/Severe
General condition	Good	Poor/ deteriorating
Level of activity	Good/reduced	Poor/ confined to bed
Cyanosis	No	Yes
Worsening peripheral oedema	Yes	Yes
Level of consciousness	Normal	Impaired
Already receiving LTOT	Yes	Yes
Social circumstances	Good/living alone	Living alone/ not coping
Acute confusion	No	Yes
Rapid rate of onset	No	Yes
Significant comorbidity (cardiac, insulin dependent diabetes)	Yes	Yes
Requiring acute oxygen therapy	No	Yes
Changes on chest radiograph	No	Present
Arterial pH level	>/= 7.35	< 7.35
Arterial pO2 level	>/= 7.0 kPa	< 7.0 kPa

17.2. Self-Management

Self-management interventions help people with COPD to acquire and practice the skills they need to carry out disease-specific medical regimens, guide changes in health behaviour and provide emotional support to enable them to control their disease.[35] Self-management plans maybe paper based or electronic.

Paper self-management plans
A paper-based COPD self-management plan is available to download from Asthma + Lung UK https://www.asthmaandlung.org.uk/conditions/copd-chronic-obstructive-pulmonary-disease/your-copd-self-management-plan, although other versions may be available from other sources.

Electronic self-management plans
The West Yorkshire Respiratory (Asthma & COPD) Self-Management Smart Phone Apps (July 2023) (known as **COPDhub (England)**) are available at: https://www.swyapc.org/respiratory-resources-clinicians/

- These apps have been developed with, and will continue to be updated by, experts in asthma & COPD and have been co-produced by patient representatives. They are freely available for patients across England.
- The purpose of the apps is to support patients and parents of children with the long-term management of their asthma or COPD to help them stay well. The apps provide advice, education, and support for staying well and spotting worsening symptoms early using a personalised asthma or COPD plan.
- There have been some significant positive outcomes where the apps have been introduced in Wales. Among ALL users of the respiratory apps 36% reduced their visits to the GP and 19% their admissions to A&E when they regularly used their app for six months or more.

Self management plans should include:[1]
- Instruction to recognise clinically significant change from baseline in COPD symptoms.
- Instruction to increase bronchodilator use to the maximum.
- Instruction to commence oral steroid - Prednisolone 30 - 40 mg od for 5-7 days.
- Instruction to start a course of broad spectrum antibiotic (as per local antibiotic guidelines).
- Instruction on recognising deterioration or failure to improve.
- Instruction on when and how to alert the usual clinician.
- Instruction on how to recognise features of an exacerbation which require urgent action - e.g. when to call an ambulance.
- Instruction on how to arrange review following exacerbation of COPD.

17.3. Treatment at Home

The risk of dying from an exacerbation of COPD is closely related to the development of respiratory acidosis, the presence of significant comorbidities, and the need for ventilatory support. Patients lacking these features are not at high risk of dying.[1]

- Patients with a history of exacerbations should have a rapid access to a consultation with their usual clinician.
- Ensure correct diagnosis and pharmacological management of AECOPD - see Exacerbations.
- Ensure the patient does not require hospital treatment - see home vs hospital management .
- Assess the patient regularly at an appropriate frequency.
    - Indications for changes in pharmacological management.
    - Indications for hospital treatment - see home vs hospital management .
    - Availability of services to support the patient in their own homes.
    - Safety of the patient throughout the period of AECOPD.
- Review following an acute exacerbation of COPD.

17.4. Respiratory Home Ward / Respiratory Virtual Ward

Respiratory Home / Virtual wards may be available in some areas of West Yorkshire

Patients admitted to hospital with acute exacerbation of COPD should be assessed for the possibility to continue their treatment at home supported by the Community Respiratory Team on the Respiratory Home Ward (RHW).

Criteria for eligibility for Hospital at Home (may vary depending on locality):

- Telephone at home.
- Patient is alert and orientated.
- The reason for admission is purely an exacerbation of COPD.
- The patient able to take own medication.
- The oxygen saturation is greater than 85% at rest, on air or on the usual home oxygen therapy.
- pH>7.35, PO2>7.3
- No, mild or improving leg oedema.
- Pulse rate ≤ 100 bpm.
- Respiratory rate ≤ 24 breath per minute.
- Systolic BP >100 mmHg.
- Blood sugar controlled (if diabetic).
- The patient/carer is able to cope at home with or without extra social support.
- Able to take diet and fluids satisfactorily.
- CXR reviewed in the last 24 hours by a SHO/ Registrar/Consultant.
- ECG performed and reviewed by a SHO/Registrar/Consultant.
- No untoward incidents - lone worker visit.

Eligible patients should be referred to the Community Respiratory Team.

Patients in the community can also be referred for treatment on the RHW with an acute exacerbation of COPD, identified by healthcare professionals including GPs, practice nurses, advanced care practitioners, community matrons, paramedics from Yorkshire ambulance service (YAS). With the aim of community care for admission avoidance.

17.5. Hospital Treatment

Ensure correct diagnosis of AECOPD
Record of deterioration from baseline of chronic COPD defining symptoms (chronic cough, volume and purulence of sputum, breathlessness, wheeze), exposure to risk factors (smoking), and result of CXR and ECG excluding alternative diagnosis.

Recognise hypoxia and prescribe correct oxygen **therapy**
Record of oxygen saturation and prescription of oxygen with target oxygen concentration of 88-92% for all patients with SatO2<92% on air within 30 min of arrival to hospital.

Recognise and respond to respiratory acidosis within 1 hour of arrival to hospital
ABG for all patients on oxygen or with SatO2<94% on air and documented action plan for those with pH<7.35 including:

1. Trial of nebulised bronchodilator and controlled oxygen for 1 hour.
2. Initiation of NIV of all patients with pH<7.35 after a trial of treatment within 3 hours of arrival to hospital.
3. Decision about escalation to ICU.
4. Decision about DNAR status with ReSPECT from completion

Prescribe correct medication for AECOPD

- Nebulised bronchodilator given within 1 hour of arrival to hospital.
- Prednisolone 30-40 mg and antibiotics (where appropriate according to local guidelines) given within 4 hours of arrival to hospital.

Review by respiratory team (nurse specialist, SpR or consultant) within 24 hours of arrival to hospital to apply a COPD Care Bundle.

17.5.1. COPD Care Bundle

This may vary in different hospitals. *Below is Leeds Trust's as an indicative bundle.*

Information for patients admitted to the Leeds teaching Hospitals NHS Trust:
All patients admitted to LTHT with primary diagnosis Acute Exacerbation of COPD should be treated along the following care bundle:

1. Review by a member of the Respiratory Team (Consultant, Specialist Registrar or Nurse Specialist) within 24 hours of admission (this is the time the patient is admitted to a hospital ward and not the time of arrival to the Emergency Department). The review should be chronologically recorded on PPM+ (electronic medical notes) via a clinical note/free text annotation or on a PPM+ e-Form, once such is implemented.

2. Confirmation of the diagnosis of COPD by checking spirometry result and relevant clinical information in the hospital and GP records. In case of uncertain diagnosis spirometry may be performed prior to discharge. The lung function laboratory will upload the results onto PPM+.

3. Review of COPD medication including inhaler therapy - inhalers should be prescribed according to the current guidelines, patients shout be able to demonstrate understanding of their inhaler therapy and ability to use their inhaler devices. This should be chronologically recorded in the medical notes.

4. Emergency oxygen prescription - if needed emergency oxygen should be appropriately prescribed and a target SatO2 range stipulated. Review of emergency oxygen prescription should be chronologically recorded in the medical notes.

5. Non-invasive ventilation Patients with persistent acidotic hypercapnic ventilatory failure that is not improving after 1 hour of optimal medical therapy should be offered non-invasive ventilation starting within 4 hours of arrival to hospital (or recognising deterioration for those who are already inpatients). This should be chronologically recorded in the medical notes. The record should include date and time of start of non-invasive ventilation as well as a reason for not having non-invasive ventilation if this is the case.

6. Smoking status should be recorded. Current smokers should be offered smoking cessation pharmacotherapy and referral to smoking cessation service. This should be chronologically recorded in the medical notes.

7. Assessment for suitability for pulmonary rehabilitation. This should be chronologically recorded in the medical notes.

8. Referral for follow up with the Integrated COPD Service. This should be chronologically recorded in the medical notes using a created for the purpose sticker or on a PPM e-Form, once such is implemented.

17.5.2. Treatment in Respiratory Support Unit (RSU)

These criteria may vary depending on admitting hospital. *Below is Leeds Trust's as an example.*

Consider Respiratory Support Unit (RSU) admission if:

- Respiratory acidosis - pH<7.35 and PaCO2>6.0 kPa.
- Severe dyspnoea with clinical signs suggestive of respiratory muscle fatigue, increasing work of breathing, or both, such as use of respiratory accessory muscles, paradoxical motion of the abdomen or retraction of the intercostal muscles.

- A ceiling of care decision that permits treatment on RSU
- Patient not for escalation above RSU: in patients with acute hypercapnic respiratory failure who are to be considered for mechanical ventilation, the best place of care for delivery is the intensive care unit, where escalation to intubation and invasive ventilation can be facilitated in a safe and timely manner in the event of failure of treatment with NIV.

Refer to RSU according to the local referral pathway.

Start non-invasive ventilation (NIV) according to the local protocol for NIV for hypercapnic acidotic respiratory failure within 3 hours of arrival to hospital or deterioration in an already admitted patient.

Discharge to a general ward when the patient no longer meets the criteria for treatment in RSU

17.5.3. Treatment in Intensive Care Unit (ICU)

These criteria may vary depending on admitting hospital. *Below is Leeds Trust's as an example.*

Consider ICU admission if patient is for escalation of care and has:

- Severe dyspnoea that responds inadequately to initial emergency treatment.
- Changes in mental status (confusion, lethargy, coma).
- Persistent or worsening hypoxaemia (PaO2<5.3 kPa) and/or severe/worsening respiratory acidosis (pH<7.25) despite supplemental oxygen and non-invasive ventilation.
- Need for invasive mechanical ventilation:
  - Unable to tolerate NIV or NIV failure.
  - Respiratory or cardiac arrest.
  - Respiratory pauses with loss of consciousness or gasping for air.
  - Diminished consciousness, psychomotor agitation inadequately controlled with sedation.
  - Massive aspiration.
  - Persistent inability to remove secretions.
  - Heart rate <50/min with loss of alertness.
  - Severe haemodynamic instability without response to fluids
  - Severe ventricular arrhythmias.
  - Life-threatening hypoxaemia in patients unable to tolerate NIV.
- Haemodynamic instability - need for vasopressors

17.5.4. Criteria for Discharge from Hospital

- Able to use long-acting bronchodilators, either beta2-agonists and/or anticholinergics with or without inhaled corticosteroids.

- Inhaled short acting beta2-agonist therapy is required no more frequently than every 4 hours.
- Patient, if previously ambulatory can walk appropriate distance required to manage at home.
- Patient is able to eat and sleep without frequent disturbance by dyspnoea.
- Patient has been clinically stable for 12 - 24 hours.
- Arterial blood gases have been stable for 12 - 24 hours.
- Patient (or home caregiver) fully understands correct use of medications.
- Follow-up and home care arrangements have been completed (e.g., visiting nurse, oxygen delivery, meals provision)
- Patient, family, physician and allied healthcare professionals are confident that the patient can manage successfully at home.

17.5.5. Follow Up Consultation After Acute Exacerbation and/or Hospital Admission

Patients recovering from acute exacerbation or discharged from hospital need to have follow up consultation after 2 weeks with assessment of the following items:

- Assess ability to cope in usual environment and capacity to do physical activity
- Complete CAT and MRC Dyspnoea Scale
- Ensure the patient is on optimal medical therapy - see Pharmacological Management.
- Reassess inhaler technique and understanding of recommended treatment regimen
- Discuss self management and consider emergency medicines pack.
- Offer smoking cessation intervention if appropriate.
- Refer to pulmonary rehabilitation if appropriate.
- Assess the need for long term oxygen therapy and/or home nebuliser
- Assess the status of comorbidities
- Return to usual regular care planning consultations schedule

Refer to local specialist COPD services.

17.5.6 Frequent Exacerbations. What to do?

There are sometimes concerns that people experiencing frequent and recurrent COPD exacerbations are no optimally managed and may have the highest mortality. A review of the diagnosis, causes and management should take place:

- Consider alternative diagnosis (a fifth of all people on COPD registers do not have a diagnosis of COPD).
- Check for other and optimise co-existing conditions, for example cardiac failure, bronchiectasis (consider HRCT chest), ischaemic heart disease, cor pulmonale, anxiety and depression.
- Check for other microbiological causes of infective exacerbations, such as repeat sputum cultures, 3 x AAFB for non-tuberculous mycobacterial disease and aspergillus IgG.
- Assess adherence to current COPD treatments: ask the patient and check prescription refill records.
- Check and optimise inhaler technique at every opportunity. Ensure patients are prescribed consistent inhaler devices - all dry powder inhalers, or all aerosol devices (e.g. pMDI. Respimat). Encourage a slow and steady inhalation with aerosol devices and quick and deep inhalation with DPIs.
- Optimise inhaled therapy and give general self-management advice.
- Consider referral to the specialist COPD clinics.
- Ensure vaccination status is up to date (pneumococcal vaccine once, annual influenza and covid vaccines).
- Refer for pulmonary rehabilitation.

18. Palliative and End of Life Care

An approach, independent of prognosis, is needed to address the large symptom burden and physical needs of people living with severe COPD. Palliative care aims to prevent and relieve suffering and to support the best quality of life for a patient and their family, regardless of stage of disease.[1]

18.1. Check for indicators of risk of deteriorating and dying:

- Unplanned hospital admissions
- Severe chronic lung disease with breathlessness at rest or on minimal exertion between exacerbations
- Patient on LTOT
- Has needed ventilation / non-invasive ventilation for respiratory failure
- Persistent symptoms despite optimal treatment of COPD
- Performance status poor or deteriorating with limited reversibility; (person in bed or chair for 50% or more of the day)
- Depends on others for care due to increasing physical and/or mental health problems and the person's carer needs more help and support
- Significant weight loss over the past 3-6 months and/ or a low BMI (<19).
- Comorbidities - particularly heart failure
- The person (or family) asks for palliative care; chooses to reduce, stop or not have treatment; or wishes to focus on quality of life

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18.2. Ensure physical, social and spiritual support for patients and their carers

- Routinely assess physical, psychological, social and spiritual needs for people with more severe disease (e.g. MRC Dyspnoea scores 4 or 5) enabling supportive care to be provided as needs evolve
- Assess and palliate physical symptoms.
- Look for and treat psychological distress: anxiety and depression are common.
- Offer to discuss the future. Patients may, or may not, want to discuss dying, but they may have practical concerns about the future that can be discussed openly.

18.3. Respiratory Palliative MDT

- COPD MDTs may be held by local COPD services:
    - Leeds:
        - For patients at home, the initial referral should be to the community respiratory team via Integrated COPD service leedsintegrated.copdservice@nhs.net or Long term conditions longtermconditions@nhs.net
        - For hospital inpatients, the initial referral should be to the LTHT Respiratory Nurse Specialists leedsth-tr.respiratorynurse@nhs.net
        - In both settings, the community respiratory team or LTH respiratory nurse specialists will facilitate discussion at the MDT as appropriate.
        - For further information, contact Respiratory Palliative care MDT: leedsth-tr.respiratorypalliativemdt@nhs.net

- Ask the GP to place patient on the Gold Standards Framework Register www.goldstandardsframework.org.uk

- Consider involvement of the specialist palliative care if symptoms or needs are complex and difficult to manage www.leedspalliativecare.co.uk/staff/resources/

18.4. Alleviate distressing symptoms:

Breathlessness:
- Palliative oxygen therapy if Sat O2<92% at rest and documented improvement of symptoms.
- Cool air to the face (from a fan).
- Breathing relaxation techniques.
- Oral morphine (immediate release) 2.5 to 5mg 4 hourly, titrate according to response This can be converted to a long acting morphine preparation
- Morphine sulphate modified release tablets 5mg BD (e.g. MST®) has the best evidence for breathlessness management, with higher doses not offering increased symptom benefit, but causing increased opiate side effects. If being used for additional pain relief higher doses may be used.

Anxiety +/- Breathlessness
- Lorazepam 0.5mg - 1mg SL may give rapid relief during panic attacks.
- Longer-term management oral diazepam 5mg once at night or twice daily

Cough
- Oral morphine 10mg/5mL liquid 5mg four hourly.

Excess secretions
- Hyoscine butlybromide sc 20mg 4-6 hourly.

Delirium
- Haloperidol 1-3mg 8 hourly

A Guide to Symptom Management in Palliative Care (leedspalliativecare.org.uk)

18.5. Advance Care Planning

Agree current and future care goals and care plan with the person and their family. Especially consider limitations of treatment, for example
- Non-invasive ventilation
- Intensive care admission
- Further admissions to hospital for treatment of exacerbations
- ReSPECT and DNACPR

Plan ahead if the person is at risk of loss of capacity for example preferred place of care and death.

Start such conversations early in a patient's journey.

Record, communicate and coordinate the care plan between primary and secondary care (complete a GP out of hours form, EPACS).

18.6. Help with social needs

- Refer for carer needs assessment if appropriate
- OT assessment for aids and adaptations which could support independent living.
- Physiotherapy input
- Give information about local support groups / day hospice
- Direct them to support for benefits:
    - Benefits - GOV.UK (www.gov.uk)
    - Benefits and financial support when you have a lung condition | Asthma + Lung UK (asthmaandlung.org.uk)

19. Audit

This guideline is a decision support tool. It recommends what is considered best practice. Each organisation using the guideline should define which elements of it represent mandatory quality standards for the service it provides requiring audit. Audit should be performed according to the clinical governance procedures operating in the relevant organisation. This includes designating the group with responsibility of reviewing audit results and monitoring the action plan.

The recommended quality standards to evaluate the care provided for patients with COPD are the NICE QS10 Chronic Obstructive Pulmonary Disease Quality Standard - https://www.nice.org.uk/guidance/qs10 .

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21. Development of the Guideline

The West Yorkshire COPD Management and Prescribing Guideline was developed by a working group of the West Yorkshire Respiratory Network with design support from the Institute of Clinical Science and Technology (https://wyh.icst.org.uk/). Draft versions of the guideline were sent for consultation amongst primary and secondary care healthcare professionals specialising in asthma management.

Members of the working group were:

- Dr Katherine Hickman, GP & Respiratory Lead for West Yorkshire
- Patrick Heaton, Kirklees place West Yorkshire Integrated Care Board (ICB) Medicines Optimisation Advisor & Practice Pharmacist
- Kevin Frost, Senior Clinical Pharmacist – Respiratory, Airedale NHS Foundation Trust
- Dr Toby Capstick, Consultant Pharmacist, Respiratory, Leeds Teaching Hospitals NHS Trust
- Dr Kirsty Hambleton, Consultant in Respiratory Medicine, Leeds Teaching Hospitals NHS Trust

Decisions on formulary choices and inhaler drug/device selection were achieved by consensus, based on objective and subjective factors including:

- Ease of use of inhaler device
- Presence of dose counter
- Carbon Impact of inhaler devices
- Range of low/medium/high ICS/LABA doses within product range
- Comparative
- Tobacco Industry Links

The pharmaceutical industry has had no role in the development of this guideline. The West Yorkshire Respiratory Network is unable to receive any representation from members of the pharmaceutical industry on this guideline, or subsequent versions.

22. Appendix 1. Patient information regarding inhaler links to the tobacco industry

Inhalers for asthma, COPD, and other lung conditions

Patient information regarding inhaler links to the tobacco industry

This document is endorsed by:

Asthma + Lung UK, British Thoracic Society, Primary Care Respiratory Society, the Royal Pharmaceutical Society, the UK Inhaler Group and the UK Clinical Pharmacy Association

British Thoracic Society

Endorsed by ROYAL PHARMACEUTICAL SOCIETY

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Inhalers for asthma, COPD, and other lung conditions – links to the tobacco industry

The aim of this leaflet is to provide information to people with asthma, COPD and other lung conditions who are taking inhaled medications and are concerned about the recent takeover of Vectura by Philip Morris International.

Whatever happens, your priority and that of your healthcare professional is to make sure that you have medication that is safe and works for you.

Do not stop taking the inhalers that you have been prescribed without speaking to a healthcare professional.

Background

Philip Morris International (PMI) is one of the world's largest tobacco companies. PMI bought Vectura, a company that specialises in inhaled medication technology, in September 2021. Tobacco products cause lung disease and make lung disease worse, so this takeover has been widely condemned both by healthcare professional bodies and by patient organisations.

Several pharmaceutical companies that make medicines used by people with COPD, asthma and other lung diseases worked with Vectura in the past before it was taken over by PMI. This meant that Vectura received money based on sales of their products. Now that Vectura is owned by PMI, sales of these products results in income going to the tobacco industry.

What if I am using one of these inhalers and want to change?

If you feel uncomfortable using a device/brand linked to the tobacco industry, you can ask to use an alternative product. There are now many inhalers available to treat asthma, COPD and other lung diseases. This means that for most people there are a range of alternatives which are just as effective and as safe as the medications above. Speak to your healthcare professional about this and they can advise about alternatives.

What should happen if I do change inhaler?

Whenever you start a new inhaler it is important to make sure that you are using it correctly. This makes it as effective as possible and reduces the risk of side-effects. Your doctor, nurse, physiotherapist or pharmacist can show you how to use your new device. Make sure that you have a look at the instruction leaflet.

There are also good inhaler technique videos https://www.asthma.org.uk/advice/inhaler-videos/ that you can watch online to check your technique.

For most people, changing inhalers will make little difference to their symptoms on a day-to-day basis. It may be worth keeping a diary of your symptoms for a few weeks to help keep an eye on this.

Some people may even notice an improvement, but if you feel that your symptoms have got worse after changing inhalers, let your health professional know. The options may be to try another alternative inhaler or to go back to what you were on before.

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What if I do not want to change my inhaler?

Some people feel safest staying with what they know. Sometimes it has taken some trial and error to find the inhaler that is best for an individual. The most important thing will always be that you are able to manage your lung condition safely and well.

Which inhalers have a link to Vectura?

Some of the inhalers on the list below are made by Vectura, and some have licensing links to Vectura relating to the ingredients within the inhaler. This means that sales of these devices results in income going to the tobacco industry.

Product	Manufacturer(s)/Partners*
Flutiform pMDI	MundiPharma
Flutiform K-haler	MundiPharma
Ultibro Breezhaler	Novartis
Seebri Breezhaler	Novartis
Enerzair Breezhaler	Novartis
AirFluSal Forspiro	Sandoz
WockAIR Forspiro	Wockhardt
Breelib nebuliser	Bayer
Incruse Ellipta	GSK
Anoro Ellipta	GSK
Relvar Ellipta	GSK
Trelegy Ellipta	GSK

Remember, the priority is always to ensure that you have the treatment you need to manage your condition.

This patient information has been developed and endorsed by:

Asthma + Lung UK

The British Thoracic Society

The Primary Care Respiratory Society

The Royal Pharmaceutical Society

The UK Inhaler Group

The UK Clinical Pharmacy Association

The advice reflects the Forum of International Respiratory Societies (FIRS) Joint statement on the implications of Philip Morris International's acquisition of Vectura Issued by: The European Respiratory Society, The American Thoracic Society, International Union Against Tuberculosis and Lung Diseases, Asian Pacific Society of Respirology, Asociación Latino Americana De Tórax, the Global Initiative for Asthma.

**this list of medications is based on information from Vectura prospectus and is accurate as of 1/12/21.*

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