DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Chronic Obstructive Pulmonary Disease (COPD) Management

- Update of COPD guidance based on NICE NG115 (Dec2018). This replaces NICE CG101.

- Diagnosis of COPD should be considered in patients over the age of 35 who have a risk factor (generally smoking or a history of smoking) presenting with exertional breathlessness, chronic cough, regular sputum production, frequent winter 'bronchitis' or wheeze.

- The fundamentals of COPD care listed below should be offered before commencing pharmacological treatment and reviewed at each patient contact.
  - Offering support and treatment to stop smoking
  - Offering once-only pneumococcal vaccination and an annual flu vaccination
  - Offer pulmonary rehabilitation
  - Co-develop a personalised self-management plan (respiratory action plan)
  - Optimise treatment for co-morbidities

- NICE recommends commencing inhaled therapies only if all the above interventions have been offered (if appropriate) and inhaled therapies are needed to relieve breathlessness or exercise limitation or the patient has had exacerbations.

- Before stepping up treatment to the next stage in the therapeutic management of COPD, the patient's inhaler technique, compliance with administration instructions and tolerance of the current device should be checked.

- Combination inhaled therapy with LABA/LAMA is recommended for patients who remain breathless or have exacerbations despite treatment and present with no asthmatic features or features suggestive of steroid responsiveness. (See algorithm p8 for further details).

- LABA/ICS combination inhalers are recommended for patients with asthmatic features or features suggestive of steroid responsiveness.

- NICE consider triple therapy (as a single inhaler) to be a cost-effective strategy compared to LABA/LAMA and LABA/ICS in patients who continue to exacerbate or remain breathless on dual therapies.

- Conduct a clinical review before commencing triple inhaled therapy to ensure that all non-pharmacological COPD interventions have been optimised and that acute episodes of worsening symptoms are caused by COPD exacerbations and not by other physical or mental health conditions.

- Features from the history and examinations should be used to differentiate COPD from asthma whenever possible.

- NHS Derby and Derbyshire ICB/System partners support the prescribing of inhalers with a reduced carbon footprint such as dry powder inhalers (DPIs) and Soft Mist inhalers (SMIs), wherever clinically appropriate and acceptable to the patient. See Greener Inhaler Prescribing Guidance

Contents

Key	
COPD	Chronic obstructive pulmonary disease
SABA	Short-acting beta2 agonist
SAMA	Short-acting muscarinic antagonist
LABA	Long-acting beta2 agonist
LAMA	Long-acting muscarinic antagonist
ICS	Inhaled corticosteroid
FEV1	Forced expiratory volume in 1 second
FVC	Forced vital capacity
BMI	Body Mass Index

Document update	**Date**
Add Appendix 4 – nebuliser for COPD patients (incorporate info from nebuliser guideline)	January 2023
Fostair removed	March 2023
Contact numbers for the community respiratory service in North Derbyshire is no longer in operation - removed	February 2024
remove reference to NACSYS brand acetylcysteine	March 2024

Bibecfo added as alternative preferred choice for patients requiring MDI; Luforbec price updated	April 2024

Definition

Chronic obstructive pulmonary disease (COPD) is a chronic slowly progressive disorder, characterised by airflow obstruction, which does not change markedly over several months. The impairment in lung function is largely fixed but may be partially reversible by bronchodilators or other therapy. Most cases are caused by tobacco smoking, though lifelong non-smokers may develop COPD probably related to occupation.

Diagnosis

The diagnosis of COPD depends on thinking of it as a cause of breathlessness or cough. The diagnosis is suspected on the basis of symptoms and signs and is supported by spirometry.
Diagnosis of COPD should be considered for patients aged over 35 years with a risk factor (e.g. tobacco smoking, occupational exposure, air pollution) and one or more of the following symptoms:

- Exertional breathlessness
- Chronic cough
- Regular sputum production
- Frequent winter 'bronchitis'
- wheeze

Spirometry

Spirometry is one of the essential lung function investigations in the diagnosis, severity assessment and monitoring of disease progression of COPD. It should be performed to a high standard, quality assured and only performed and interpreted by professionals assessed as competent against ARTP standards. Once certified healthcare professionals should record their qualification on National Register of certified professionals and operators.. See appendix 2

Further investigations for all patients at initial diagnostic evaluation

Chest radiograph to exclude other pathologies
FBC - to identify anaemia or polycythaemia
BMI calculated
Eosinophilia

Reversibility testing

NICE suggests routine spirometric reversibility testing is not necessary as part of the diagnostic process, as untreated COPD and asthma are frequently distinguishable on the basis of history in people presenting for the first time. Features from the history and examinations should be used to differentiate COPD from asthma whenever possible, however, when diagnostic uncertainly remains, or both COPD and asthma are present, reversibility testing may be helpful.

Clinical features differentiating COPD and asthma

	COPD	Asthma
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under age 35	Rare	Often
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

To help resolve cases where diagnostic uncertainty remains, or both COPD and asthma are present use the following findings to help identify asthma:

- a large (over 400ml) response to bronchodilators
- a large (over 400ml) response to 30mg oral prednisolone daily for 2 weeks
- serial peak flow measurements showing 20% or greater diurnal or day-to-day variability

Clinically significant COPD is not present if the FEV1 and FEV1/FVC ratio return to normal with drug therapy**.**

Symptoms

Breathlessness

One of the primary symptoms of COPD is breathlessness. Evaluation of breathlessness is undertaken using MRC dyspnoea scale.

Grade	Degree of breathlessness related to activity
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower that contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
4	Stops for breath after walking about 100 m or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

Adapted from Fletcher C.M, Elmes P.C., Fairbairn M.B. et al (1959). The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population British Medical Journal 2: 257-66

Airflow Obstruction

The severity of airflow obstruction is assessed according to the reduction in FEV_1 as per table below

Gradation of severity of airflow obstruction		Severity of airflow obstruction (NICE & GOLD, 2008)
Post-bronchodilator FEV_1/FVC	**FEV_1 % predicted**	**Post-bronchodilator**
<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

Effective COPD interventions

The following COPD interventions should be optimised before commencing pharmacological treatment and reviewed at each patient contact.

Smoking cessation (treatment of tobacco addiction)

Smoking cessation is the single most effective intervention for reducing the risk of developing COPD and slowing its progression. For all patients with COPD

- Record an up-to-date smoking history, including pack-years smoked
- Encourage patients who smoke to stop and offer evidence based treatment for tobacco addiction (e.g. very brief advice, nicotine replacement therapy- see NICE NG209) and refer on to specialist support with local services.

Live life better Derbyshire (helpline number 0800 085 2299)
Live well derby (helpline number 01332 641 254).

Vaccinations

Pneumococcal vaccination and annual influenza vaccination should be offered to all patients with COPD. These reduce the rates of hospital admissions and risk of death from pneumonia and influenza. People with COPD are currently included as a priority group in COVID-19 vaccination programme

Pulmonary rehabilitation

Pulmonary rehabilitation should be made available for all patients with COPD (patients who consider themselves functionally disabled by COPD, usually MRC 3, 4 and 5 but may include patients with MRC 2) including those with recent hospitalisation for acute exacerbation, who are considered a priority to access pulmonary rehabilitation due to its impact on reducing readmission to hospital. For referral to local pulmonary rehabilitation services see contacts below.

Note: If patients have excessive sputum and struggling to clear, and/or symptoms of breathlessness limiting functional activities despite on optimum inhaled medication, consider referral to respiratory physiotherapist via local respiratory teams (contact details below).

Respiratory action plans (RAP)

Individualised Respiratory action plans (RAP) allow patients to adapt their lifestyles and acquire skills to successfully identify the first signs of an exacerbation and respond appropriately.

NICE recommends that patients who are at risk of exacerbation should be given a RAP that encourages them to respond promptly to the symptoms of an exacerbation. (For further details regarding management of exacerbations see p12.)

The read codes for primary care use, for the RAPs are as follows:

Description	SystmOne	EMIS
COPD self-management plan given	XalUt	66YI
COPD self-management plan reviewed	XaYZO	661N3

See relevant resources on RAP here including Health Professional Guidelines

The local respiratory teams educate and support patient's knowledge and understanding of their respiratory condition through provision of self-management strategies and action planning. Details of the teams are included below:

Contacts for local services

North Derbyshire

Respiratory & Pulmonary therapy Service
https://dchs.nhs.uk/our-services-and-locations/a-z-list-of-services/community-respiratory-pulmonary-therapy
Walton Hospital, Chesterfield, S40 3HW
Phone: 01246 253 067 Email: dchst.respiratory@nhs.net
Referral forms available through DCHS website.

South Derbyshire

ImpACT+ integrated respiratory care team https://www.uhdb.nhs.uk/service-impact
Florence Nightingale Community Hospital, London Road, Derby, DE1 2QY
Telephone: 01332 788225 Email: dhft.impact-plus@nhs.net
Pulmonary rehabilitation https://www.uhdb.nhs.uk/service-pulmonary-rehabilitation
Referral form is available here or via e-Referral https://www.uhdb.nhs.uk/e-referrals

Follow-up for COPD patients in primary care

Listed in the table below is the good practice follow-up suggested by NICE for COPD patients in primary care. Practices should have robust systems in place to ensure that people with COPD are reviewed appropriately.

	Mild/Moderate/severe (stages 1 to 3)	Very Severe (stage 4)
Frequency	At least annual	At least twice per year

Clinical assessment	• Smoking status
	• 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.
	• Presence of depression & anxiety
	• Address co-morbidities including osteoporosis, other respiratory diseases and CVD.
		• Smoking status
		• Adequacy of symptom control
		  ○ Breathlessness
		  ○ Exercise tolerance
		  ○ Estimated exacerbation frequency
		• Presence of cor pulmonale
		• Need for long-term oxygen therapy
		• Person with COPD nutritional state
		• Presence of depression & anxiety
		• Effect 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
		• Consider palliative care and end-of life requirements

Measurements to make	• FEV_1 and FVC • Calculate BMI • MRC dyspnoea score • CAT score to assess changes in symptoms and response to treatment	• FEV_1 and FVC • Calculate BMI • MRC dyspnoea score • CAT score to assess changes in symptoms and response to treatment • SpO_2

Management of stable COPD

Confirm diagnosis of COPD

Fundamentals of COPD care

- Offer treatment and support to stop smoking
- Offer pneumococcal and influenza vaccinations
- Offer pulmonary rehabilitation if indicated
- Co-develop a respiratory action plan
- Optimise treatment for co-morbidities

Check inhaler technique and compliance with particular device using In-check DIAL at annual review. If a patient is unable to use a particular device satisfactorily, then an alternative device should be sought.
Use COPD assessment tool (CAT) to assess the clinical response at baseline and when changing treatment. These treatments and plans should be revisited at every review

Start inhaled therapy only if:

- All the above interventions have been offered (if appropriate) and
- Inhaled therapies are needed to relieve breathlessness or exercise limitation.
- People have been trained to use inhalers and can demonstrate satisfactory technique

If exacerbations continue review as per protocol for frequent exacerbators (p9).

South – discuss patient at virtual MDT clinic or refer to ImpACT service

North – refer to the community teams

Offer SABA or **SAMA (to use if needed)**
SABA should continue through all stages of symptoms
(Salamol MDI 100mcg 2 puffs PRN = £1.46/device)
(Ipratropium MDI 20mcg 2 puffs PRN or QDS = £5.56/device)

Patient is limited by symptoms or has exacerbations despite treatment

No asthmatic features or features suggesting steroid responsiveness [a]

Asthmatic features or features suggesting steroid responsiveness [a]

See appendix 4: Cost comparison table for further detail for each drug

Offer LABA + LAMA (£390/pa)
Spiolto Respimat (softmist), Duaklir Genuair (DPI), Ultibro Breezhaler (DPI), Anoro Ellipta (DPI), Bevespi Aerosphere (MDI)
Choice of combination preparation should be driven by patient choice and device acceptability. (stop SAMA if prescribed) **DPI preferred if clinically appropriate**

Consider LABA + ICS[b]

Fobumix DPI
(budesonide /formoterol) (1st line) **(£258/pa)**
Or
Luforbec MDI / Bibecfo MDI (1st line MDIs)
(beclometasone/ formoterol 100/6) **(£168/pa)**

Patient still limited by symptoms

Patient has 1 severe or 2 moderate exacerbations within a year

Patient still limited by symptoms or has 1 severe or 2 moderate exacerbations within a year

Consider 3-month trial of **LAMA + LABA + ICS [b.c]**
In a combination inhaler

If no improvement, revert to LABA+LAMA

Consider

Offer

LAMA + LABA + ICS [b,c] (as a combination inhaler) Options include:

- **Trimbow NEXThaler DPI (Beclometasone 88mcg, Formoterol 5mcg, Glycopyrronium 9mcg) (£534/pa)**
- **Trelegy DPI (**Fluticasone furoate 92 mcg, Vilanterol 22 mcg, Umeclidinium 65 mcg) **(£534/pa)**
- **Trimbow MDI (**Beclometasone 87mcg, Formoterol 5mcg, glycopyrronium 9 mcg) **(£534/pa)**
- **Trixeo aerosphere MDI** (Budesonide 160mcg/ formoterol 5mcg/ glycopyrronium 7.2 mcg) **(£534/pa)**

Explore further options if still limited by breathlessness or subject to frequent exacerbations[d] - review diagnosis and consider referring to local COPD clinic.

[a] asthmatic features/features suggesting steroid responsiveness in this context include any previous secure diagnosis of asthma or atopy, a higher blood eosinophil count, substantial variation in FEV1 over time (at least 400ml) or substantial diurnal variation in peak expiratory flow (at least 20%). **Local expert opinion suggests a plasma eosinophil >0.3 x 10^9/l is suggestive of asthmatic features**

[b] Be aware of an increased risk of side effects (including pneumonia) in people who take ICS.

[C] document in clinical records the reason for continuing ICS treatment

d roflumilast may be an option as per NICE TA461following specialist initiation and 3 months stabilisation.

NICE recommends for patients using long-acting bronchodilators outside of the current recommendations and whose symptoms are under control, have the option to continue treatment until both, they and their clinician/ healthcare professional agree it is appropriate to change.

Key messages for prescribers

Is the treatment working?
1. Has your treatment made a difference to you?
2. Is your breathing easier?
3. Is the inhaler device appropriate for the patient?

If there is no benefit from a new treatment – it should be stopped after an adequate trial period.
If the treatment is not working after **checking adherence, compliance and inhaler technique** - Review the diagnosis.

The effectiveness of bronchodilator therapy should not be assessed by lung function alone but should include a variety of other measures such as improvement in symptoms, activities of daily living, exercise capacity, and rapidity of symptom relief.

COPD assessment test (CAT)
Use COPD assessment tool (CAT) to assess the clinical response at baseline and when changing treatment.

Frequent exacerbators
An exacerbation is a sustained worsening of the patient's symptoms from their usual stable state, which is beyond normal day-to-day variations, and is acute in onset.

Review "fundamentals of COPD care" which include:
- Check for co-morbidities
  - e.g. anxiety/depression
  - cardiac failure / ischaemic heart disease; consider beta blockers in this case as they reduce death rates by 30% in COPD
- Vaccination status
- Referral for pulmonary rehabilitation
- Chest X-ray (CXR) – to exclude other diagnosis e.g. lung cancer. If patients continue to exacerbate and the CXR is clear and no "red flag signs" refer to specialist as per COPD management pathway and NOT through the 2ww pathway.

Consider unusual organism:
- Check sputum for Acid-Fast Bacillius (AFB), Pseudomonas

Consider wrong diagnosis?
- FEV1 / FVC <70%
- Bronchiectasis
- Cardiac failure
- CXR – to exclude other diagnosis e.g. lung cancer

COPD is a progressive disease with usual decline 40ml/year.

Inhaled therapies

1. SABA or SAMA
Short acting bronchodilators may be used when required as the initial empirical treatment to relieve breathlessness and exercise limitation.

2. LABA + LAMA combinations
The evidence (NICE NG115) shows that, compared with other dual therapy combinations and with monotherapy, the combinations LABA/LAMA:
- provides the greatest benefit to overall quality of life
- is better than other inhaled treatments for many individual outcomes (such as reducing the risk of moderate to severe exacerbations)
- is the most cost-effective option

NICE do not recommend a particular LAMA because they were not convinced that the evidence showed meaningful difference in effectiveness between the drugs in the class. There is no difference in cost for the current four available LABA/LAMA combinations, therefore choice between LABA/LAMA combination inhaler should be based on patient ability to tolerate and use the inhaler device. LAMA monotherapy is no longer recommended first line in the management of COPD. When initiating a LABA/LAMA combination inhaler, take care to ensure the SAMA is stopped.

Note – tiotropium and glycopyrronium are associated with raised plasma concentrations with reduced renal function. Manufacturers advise use only if the potential benefits outweigh the risks. See SPC for tiotropium and glycopyrronium for further details.

Tiotropium: risk of cardiovascular side effects
MHRA, 2015 - When using tiotropium (via Respimat or Handihaler) for COPD:
Take the risk of CV side effects into account for patients with conditions that may be affected by the anticholinergic action of tiotropium, including:

- myocardial infarction in the last 6 months
- unstable or life threatening cardiac arrhythmia
- cardiac arrhythmia requiring intervention or a change in drug therapy in the past year
- hospitalisation for heart failure (NYHA Class III or IV) within the past year

Prescribers are reminded to tell these patients to report any worsening of cardiac symptoms after starting tiotropium. Also remind patients not to exceed the recommended once daily dose.

3. LABA + ICS combinations

Most trials specifically excluded people with COPD and asthma, so there was no direct evidence for this group. NICE recommended LABA/ICS based on their clinical experience and knowledge of the likely benefit of ICS in certain specific COPD phenotypes.

NICE recommends not using oral corticosteroid reversibility tests to identify patients who should be prescribed inhaled corticosteroids, because it does not predict a response to inhaled corticosteroid therapy.

Prescribers are reminded to be vigilant of potential adverse effects with ICS, these include:

- Pneumonia
- Anxiety
- Sleep disorders
- Behavioural changes, including psychomotor hyperactivity and irritability (predominantly in children)
- Depression,
- Aggression

Long-term use with ICS is associated with a significant risk of pneumonia and systematic side-effects. Patients should be informed of the potential risks with ICS. (See appendix 1 for further details regarding side effects with ICS)

Consider stepping down treatment with an ICS - see local guidance for further details.

4. LABA + LAMA + ICS

There is stronger evidence from a greater number of studies that triple therapy benefits people taking LABA/ICS, compared with people taking LABA/LAMA.

For people currently taking LABA/ICS, the evidence showed that LABA/LAMA/ICS reduced the rate of severe exacerbations, improved FEV1 and did not increase the risk of pneumonia or other serious adverse effects.

For people currently taking LABA/LAMA, the evidence showed that LABA/LAMA/ICS reduced the rate of serious exacerbations and provides some quality of life improvement. However, these improvements were smaller than the ones for people who are taking LABA/ICS before they started triple therapy. In addition, people who switched from LABA/LAMA to triple therapy were more likely to get pneumonia.

Conduct a clinical review before commencing triple inhaled therapy to ensure that all non-pharmacological COPD interventions have been optimised and that acute episodes of worsening symptoms are caused by COPD exacerbations and not by other physical or mental health conditions.

NICE recommend for patients currently using

- ***LABA/ICS - offer triple inhaled therapy to patients with asthmatic features if:***
    - their day-to-day symptoms continue to adversely impact their quality of life or
    - they have a severe exacerbation (requiring hospitalisation) or
    - they have 2 moderate exacerbations within a year.

- ***LABA/LAMA - consider triple inhaled therapy to patients with no asthmatic features if:***
    - They have severe exacerbation (requiring hospitalisation) or
    - They have 2 moderate exacerbations within a year

- ***LABA/LAMA and whose day-to-day symptoms adversely impact their quality of life***
    - Consider a clinical review of breathless patients before moving to triple therapy
    - Consider a trial of triple therapy with caution, lasting for 3 months only
    - After 3 months, **conduct a clinical review, and if symptoms have not improved, stop LABA/LAMA/ICS and switch back to LABA/LAMA**
    - If symptoms have improved, continue with LABA/LAMA/ICS

Document the reason for continuing ICS use in clinical records and review at least annually.

Choice of drugs/inhalers

See appendix 4 for inhaler cost comparison
NICE recommend the choice of drugs and inhalers should be based on:

- how much the drug/inhaler improves symptoms
- the patient's preference and ability to use the inhaler
- the drug's potential to reduce exacerbations
- side effects
- cost

All formulary dry powder inhalers contain lactose and are contraindicated in patients with hypersensitivity to lactose or milk proteins. Refer to The SPC for full prescribing information.

Other therapies

Oral corticosteroids

Long-term oral corticosteroid therapy in COPD is not normally recommended. However, some patients with advanced COPD may need long-term oral corticosteroids on specialist recommendation, when these cannot be withdrawn following an exacerbation. In these circumstances the dose of oral corticosteroid should be kept as low as possible.

Osteoprotection
Patients on or commencing high dose corticosteroid long-term (≥7.5mg per day of prednisolone or its equivalent for 3 months or more) should be offered bone protection with bisphosphonate. Patients taking lower doses of oral corticosteroids long-term should be considered for risk fracture assessment. See osteoporosis guidance for details.

Theophylline

Offer only after inhaler therapy has been optimised, or for people who are unable to use inhaled therapy. (See SPS drug monitoring tool for theophylline monitoring).

Mucolytics

Do not routinely use mucolytic to prevent exacerbations in people with stable COPD.

Mucolytic drug therapy should be considered in patients with a chronic cough productive of sputum and continued only if there is symptomatic improvement (for example, reduction in frequency of cough and sputum production).

Consider trial of

Acetylcysteine 600mg effervescent tablets sugar free OD or
carbocisteine capsules /sachets 750mg TDS for 6-8 weeks then 750mg BD if improvement in sputum production and reduction in viscosity.

Mucolytic therapy should be stopped if there is no benefit after a 4 week trial.

Oral prophylactic antibiotic therapy

The respiratory specialist may initiate prophylactic antibiotic therapy azithromycin as per shared care guidance.

Azithromycin (usually 250 mg 3 times a week) (off-label) for COPD patients if they:

- do not smoke **and**
- have optimised non-pharmacological management and inhaled therapies, relevant vaccinations and (if appropriate) have been referred for pulmonary rehabilitation **and**
- continue to have 1 or more of the following, particularly if they have significant daily sputum production:
    - frequent (typically 4 or more per year) exacerbations with sputum production
    - prolonged exacerbations with sputum production
    - exacerbations resulting in hospitalisation

Roflumilast

Roflumilast (**GREY**- specialist initiation) is a phosphodiesterase type-4 inhibitor with anti-inflammatory properties. It is used as an add-on to bronchodilator therapy in adults with severe COPD with chronic bronchitis as per NICE TA461 if: (Treatment is initiated by consultants in respiratory medicine)

- the disease is severe, defined as FEV1 after a bronchodilator <50% of predicted normal, and
- the person has had ≥2 exacerbations in the previous 12 months despite triple inhaled therapy

Ongoing GP prescribing and care of patients on roflumilast should only be considered if patient is stable and free from adverse reactions, **after a minimum of 3 months roflumilast treatment under the Respiratory Specialist**.

Clinic letter from specialist should highlight:

- Assessment of any potential adverse effects including weight loss and psychiatric symptoms
- Response to treatment & reason for continuation of treatment

On-going management by GPs

Body weight	Stop treatment and refer to specialist if unexplained and clinically concerning weight loss occurs
Psychiatric symptoms	Stop if new or worsening symptoms are experienced and refer to specialist
On-going benefits	Monitor exacerbations/clinical well-being/persistent intolerance
Inform specialist if patient: • Develops any adverse effects related to treatment • Is not responding to treatment • Declines further treatment or discontinues treatment for other reasons.	

Managing exacerbations

An exacerbation is a sustained worsening of the patient's symptoms from their usual stable state, which is beyond normal day-to-day variations, and is acute in onset. Commonly reported symptoms are worsening breathlessness, cough, increased sputum production and change in sputum colour. Change in these symptoms often necessitates a change in medication.

Medication requirements for an exacerbation -

- increase bronchodilator therapy to control symptoms
- short course of oral ***prednisolone 30mg daily 5 days***, if significant increase in breathlessness which interferes with daily activities
- short course of **oral antibiotics**. See NICE NG114 on antimicrobial prescribing for acute exacerbations of COPD

NICE recommends patients who have had an exacerbation of COPD are provided with individualised exacerbation action plan, for early recognition of future exacerbations, management strategies (including appropriate provision of antibiotics and corticosteroids for self-treatment at home) and a named contact.

Offer patients a short course of oral corticosteroids and a short course of oral antibiotics to **keep at home** to respond to an exacerbation if:

1. they have had an exacerbation within the last year, and remain at risk of exacerbations
2. they understand and are confident about when and how to take these medicines, and the associated benefits and harm.
3. **Their use can be monitored and supported and there is a mechanism within primary care to identify those using 3 or more rescue packs per year. These patients should be reviewed.**

People receiving long-term oral corticosteroids and those needing frequent courses (three or four per year) are at risk of systemic adverse effects. These include osteoporosis, new-onset or worsening of diabetes mellitus, weight gain, adrenal insufficiency, gastrointestinal ulceration, hypertension, ocular effects and psychiatric effects. Ensure that steroid cards and steroid emergency cards are issued to appropriate people.

Anxiety and depression

NICE recommends that healthcare professionals should be alert to the presence of anxiety and depression in people with COPD, and that if present, these should be managed appropriately. Anxiety and depression should be considered if patients:

- have severe breathlessness
- are hypoxic
- have been seen at or admitted to a hospital with an exacerbation of COPD.

Appendix 1: Inhaled corticosteroids

Local side effects

Local side effects of inhaled corticosteroids
Oral candidiasis
Cough at time of inhalation
Hoarse voice
Dysphonia (disorder of the voice)

Cough is a local irritant effect and can usually be overcome by a change in the delivery device. For instance, when using metered dose inhaler (MDI), the addition of a large volume spacer will reduce the cough.

Oral candidiasis is dose-related and can be prevented by gargling, washing and spitting out after using the inhaler.

Hoarse voice and dysphonia are caused by the inhaled steroid being deposited on the vocal chords. These effects tend to be worse with dry powder inhaler than MDIs, where the effect can be decreased by using a large volume spacer. Hoarse voice and dysphonia are dose-related and are not usually a problem at low doses (except in those who use their voice professionally such as actors or singers).

Systemic side effects

Potential systemic side effects of inhaled corticosteroids
Adrenocortical suppression
Increased osteoporosis and bone fractures
Skin thinning and purpura
Weight gain
Cataracts
Glaucoma
Diabetes mellitus
Increased pulmonary infections (pneumonia)
Growth retardation in children

Be aware of the potential risk of developing side-effects (including non-fatal pneumonia) in people with COPD treated with high of inhaled corticosteroid dose (particularly with 2000mcg beclometasone or equivalent dose) and discuss these with the patient.

Appendix 2: Spirometry

Spirometry is essential for making a correct diagnosis and determining the severity of COPD in conjunction with a detailed history and examination and should never be used solely in determining diagnosis. Spirometry is a reliable and effective tool if used correctly. The spirometer should be accurate, reliable and produce a copy of the graph with a volume/time plot. It should also include the following readings: Slow vital capacity (VC), Forced vital capacity (FVC), Forced expiratory capacity in one second (FEV1) and FEV1/FVC ratio (i.e., <0.7). This is mandatory to meet specifications within the COPD guidelines for the management of the disease.

Other aspects which need to be taken into consideration are user friendliness and portability. You may also wish to consider a memory facility to store traces. Many electronic spirometers also display a flow volume curve. You do not need this information to calculate FEV1 and FVC values. However, as you become more experienced you may want to have this facility.

Training

Training is important for health professionals responsible for performing spirometry. At least one member of staff from each practice should attend an accredited course which includes professional tuition on the practical application of spirometry and the correct interpretation of the results.

Health care professionals who perform spirometry should have completed an approved competency based training course in spirometry and will be expected to keep their skills up to date.

See ARTP page for further information on training
https://www.artp.org.uk/Training

Appendix 3: Oxygen therapy

Oxygen therapy should only be given to patients who have proven hypoxaemia (SaO_2 <92%, PaO_2 <7.3 kPa).

Record oxygen saturation on all patients with moderate to severe COPD.

Long Term Oxygen Therapy (LTOT)
If oxygen saturation ≤ 92% on 2 occasions (2-3 weeks apart), refer to oxygen assessment service for LTOT assessment. Further information on LTOT can be found in local **Oxygen guidance.**

Appendix 4: Nebuliser for COPD patients

- All routine requests for a nebuliser should be sent to the relevant community respiratory team
- Patients purchasing their own nebulisers are responsible for provision of disposables required for that device and arranging the servicing as per manufacturers guidance.
- All palliative care requests for nebulisers to treat patients without COPD/Asthma should be dealt with by the community clinician involved in their end of life care (i.e. District nurse, Macmillan nurse)
- Existing COPD patients using nebulisers that have never undergone a formal assessment can be referred into respiratory services if there is doubt about clinical appropriateness.
- COPD patients not benefiting from nebuliser treatment over the long term can be re-referred into the respiratory service for assessment
- Patients should be identified from the following indications **BEFORE** being referred for an assessment:
    - Experiencing persistent symptoms despite optimised bronchodilator therapy
    - Frequent exacerbations
    - Inability to use inhalers
- Carry out the following assessment **BEFORE** referring patients for a nebuliser assessment:
    - Confirm COPD diagnosis
    - Carry out COPD treatment review as per guideline
    - Confirm patient has optimal therapy with hand-held inhalers and check they are used correctly with good technique
    - Confirm that the patient, or carer, has a good level of understanding and dexterity required to take part in a nebuliser trial

Community Specialist Respiratory Teams
North Derbyshire (Derbyshire Community Health Services)
Email referral to DCHST.Respiratory@nhs.net
Tel 01246 253067 Welbeck Suite, Walton Hospital, Chesterfield, S40 3HW

Southern Derbyshire and Erewash (The ImpACT+ team)
Email referral to dhft.ImpACT-plus@nhs.net
Tel 01332 788225 London Road Community Hospital, London Road, Derby, DE1 2QY

The community team will arrange to see the patient within 4 weeks following referral for nebuliser assessment

Appendix 5: Cost comparison (*Doses given do not imply therapeutic equivalence)*

For information on inhaler carbon footprint please see JAPC Greener inhaler guideline

LABA/LAMA combination inhaler (choice should be driven by patient choice and device acceptability)							
Drug	**Brand name**	**Device**	**Traffic light classification**	**Daily dose range**	**30 day cost**	**Annual cost**	
Indacaterol 85mcg /Glycopyrronium 43mcg	Ultibro Breezhaler and caps	DPI Breath actuated	**GREEN**	1 inhalation od	£32.50 (30 dose)	£390	
/Formoterol 12mcg /aclidinium 340mcg	Duaklir Genuair	DPI Breath actuated	**GREEN**	1 inhalation bd	£32.50 (60 dose)	£390	
Vilanterol 22mcg /umeclidinium 55mcg	Anoro Ellipta	DPI Breath actuated	**GREEN**	1 inhalation od	£32.50 (30 dose)	£390	
Olodaterol 2.5mcg /tiotropium 2.5 mcg	Spiolto Respimat	Multi-dose solution for inhalation. Preferred choice for patients who cannot use a DPI	**GREEN**	2 inhalations od	£32.50 (60 dose)	£390	
Formoterol 5mcg /glycopyrronium 7.2mcg	Bevespi Aerosphere	MDI	**GREEN**	2 inhalations bd	£32.50 (120 dose)	£390	

LABA/ICS Combination inhalers (ICS should only be used for patients with asthmatic features or features suggesting steroid responsiveness)							
Drug	**Brand name**	**Device**	**Traffic light classification**	**Daily dose range**	**30 day cost**	**Annual cost**	
Budesonide 200mcg /formoterol 6mcg Budesonide 400mcg /formoterol 12 mcg	**Fobumix 160/4.5** **Fobumix 320/9**	DPI Breath actuated	**GREEN** **1st line LABA/ICS (DPI)**	2 puffs bd 1 puff bd	£21.50 (120 dose) £21.50 (60 dose)	£258	
Budesonide/formoterol 160/4.5 Budesonide/formoterol 320/9	WockAIR 160/4.5 WockAIR 320/9	DPI Breath actuated	**GREEN**	2 puffs bd 1 puff bd	£19.00 (120 dose) £19.00 (60 dose)	£228	
Beclomethasone 100mcg /formoterol 6mcg	**Luforbec 100/6**	MDI	**GREEN** **1st line for patients requiring MDI**	2 puffs bd	£13.98 (120 dose)	£168	
	Bibecfo 100/6			2 puffs bd	£13.98 (120 dose)	£168	
Beclomethasone 100mcg /formoterol 6mcg	Fostair NEXThaler100 /6 (DPI)	DPI Breath actuated	**GREEN**	2 puffs bd	£29.32 (120 dose)	£352	
Budesonide 200mcg /formoterol 6mcg	DuoResp spiromax 160/4.5	DPI Breath actuated	**GREEN**	2 puff bd	£27.97 (120 dose)	£336	

Budesonide 400mcg /formoterol 12mcg	DuoResp spiromax 320/9	DPI Breath actuated	**GREEN**	1 puff bd	£27.97 (60 dose)	£336	
Budesonide 200mcg /formoterol 6 mcg	Symbicort 200/6	DPI Breath actuated	**GREEN**	2 puffs bd	£28.00 (120 dose)	£336	
Budesonide 400mcg /formoterol 12 mcg	Symbicort 400/12	DPI Breath actuated	**GREEN**	1 puffs bd	£28.00 (60 dose)	£336	
Budesonide 200mcg /formoterol 6mcg	Symbicort 200/6 MDI	MDI	**GREEN**	2 puffs bd	£28.00 (120 dose)	£336	
Fluticasone 500mcg / salmeterol 50mcg	Fixkoh Airmaster 50/500	DPI Breath actuated	**GREY** Cost effective alternative to Seretide Accuhaler	1 puff bd	£16.12 (60 dose)	£193	
Fluticasone 500mcg /salmeterol 50mcg	Fusacomb easyhaler 50/500mcg	DPI Breath actuated	**GREY** cost effective alternative to seretide accuhaler	1 puff bd	£26.99 (60 dose)	£324	

Fluticasone Furoate 92mcg /Vilanterol 22mcg	Relvar Ellipta	DPI Breath actuated	**GREY** consultant/ specialist recommendation	1 inhalation od	£22.00 (30 dose)	£264	
LABA/LAMA/ICS combination inhaler							
Drug	**Brand name**	**Device**	**Traffic light classification**	**Daily dose range**	**30 day cost**	**Annual cost**	
Beclometasone 88mcg/ Formoterol 5mcg/ glycopyrronium 9 mcg	Trimbow NEXThaler	DPI	**GREY 1st line triple combination**	2 puffs bd	£44.50 (120 dose)	£534	
Fluticasone furoate92 mcg/ Vilanterol 22 mcg/ Umeclidinium 65 mcg	Trelegy Ellipta	DPI Breath actuated	**GREY alternative 1st line triple combination**	1 inhalation od	£44.50 (30 dose)	£534	
Beclometasone 87mcg/ Formoterol 5mcg/ glycopyrronium 9 mcg	Trimbow	MDI (Extra-fine)	**GREY**	2 inhalations bd	£44.50 (120 dose)	£534	
Budesonide 160mcg/ formoterol 5mcg/ glycopyrronium 7.2 mcg	Trixeo aerosphere	MDI	**GREY**	2 inhalations bd	£44.50 (120 dose)	£534	

LAMA inhalers- note single component inhaler no longer recommended first line in COPD

Tiotropium Respimat	Spiriva Respimat 2.5mcg	Multi-dose solution for inhalation	**Grey** 1st line LAMA	5mcg (2 puffs) od	£23.00 (60 dose)	£276	
Tiotropium Tiogiva	Tiogiva 18mcg	DPI Breath actuated	**Grey** alternative 1st line LAMA	10mcg od	£19.99 (30 caps plus device) £19.20 (30 cap refill)	£231	
Glycopyrronium 44mcg	Seebri Breezhaler & caps	DPI Breath actuated	**GREY** 2nd line LAMA	1 inhalation od	£27.50 (30 dose)	£330	
Umeclidinium 55mcg	Incruse Ellipta	DPI Breath actuated	**GREY** 2nd line LAMA	55mcg od	£27.50 (30 dose)	£330	
Aclidinium 322mcg	Eklira Genuair	DPI Breath actuated	**GREY** 3rd line LAMA	1 inhalation bd	£32.50 (60 dose)	£390	

LABA Inhalers- note single component inhaler no longer recommended first line in COPD							
Drug	**Brand name**	**Device**	**Traffic light classification**	**Daily dose range**	**30 day cost**	**Annual cost**	
Formoterol DPI 12mcg	Easyhaler 12mcg	DPI Breath actuated	**GREEN** **1st line LABA**	12mcg bd	£23.75 (120 dose)	£143	

Formoterol MDI 12mcg	Atimos 12mcg	MDI	**GREEN** Alternative 1st line if patient requires MDI	12mcg bd	£30.06 (100 dose)	£216	
Formoterol turbohaler 12mcg	Oxis 12mcg	DPI Breath actuated	**GREEN**	12mcg od - bd	£24.80 (60 dose)	£298	
Salmeterol accuhaler 50mcg	Serevent 50 accuhaler	DPI Breath actuated	**GREEN**	50mcg bd	£35.11 (60 dose)	£421	
Salmeterol MDI 25mcg	Soltel* MDI 25mcg	MDI	**GREEN**	50mcg bd	£19.95 (120 dose)	£239	
Indacaterol 150mcg	Onbrez breezhaler	DPI Breath actuated	**GREY**	150mcg od ↑300mcg od	£32.19 (30 dose) £32.19 (30 dose)	£386 £386	
Olodaterol respimat 2.5mcg	Striverdi respimat	Multi-dose solution for inhalation	**DNP**	5mcg (2 puffs) od	£26.35 (60 dose)	£316	

(All cost obtained from MIMs online October 2022. Prescribe combination inhaler by brand)

***** Soltel CFC-free Inhaler 25 micrograms contains soya lecithin and is contraindicated in patients who have peanut or soya allergies. If the patient has a soya and nut allergy then prescribe salmeterol by brand name – severent.