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PrescQIPP Community Interest Company

Pharmacological management of chronic obstructive pulmonary disease (COPD)

This bulletin discusses the pharmacological management of chronic obstructive pulmonary disease (COPD), with a focus on inhaled therapies and supporting the implementation of National Institute for Heath and Care Excellence (NICE) guidance. It considers the evidence and rationale for the NICE recommendations and summarises a number of prescribing considerations that affect choice of treatment. Other key issues in COPD management, such as exacerbations, self-management and safety are also considered.

Recommendations

- Local commissioning bodies should ensure that up-to-date local guidance is in place for the management of COPD. The guidance should be produced collaboratively with local experts after a consideration of recommendations from NICE (last updated 2019), Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidance on COPD management and the Primary Care Respiratory Society (PCRS).[1-3]
- Local guidance should direct prescribers to cost-effective products on the local formulary that will be suitable for most people. It should include a range of inhaler device options, so that the choice can be tailored to the individual's preference, ability to use the inhaler device and environmental considerations. A pathway document (based on NICE guidance) that can be adapted for local use is available.
- Ensure that people with COPD (and their family members or carers, where appropriate) receive education about their condition at diagnosis and at each review appointment.[1]
- The fundamentals of COPD care should be revisited at every review:
  - Offer treatment and support to stop smoking
  - Offer once-only pneumococcal vaccine and annual influenza vaccine
  - Offer pulmonary rehabilitation if indicated
  - Co-develop a personalised self-management plan
  - Optimise treatment for co-morbidities.[4]
- Where inhaled therapy for COPD is needed for breathlessness and exercise limitation, offer a short-acting beta$_2$ agonist (SABA) or short-acting muscarinic antagonist (SAMA) as needed.[1]
- For people with spirometrically confirmed COPD who are limited by symptoms or have exacerbations despite using a short-acting bronchodilator, offer either:
  - Long-acting muscarinic antagonist (LAMA) + long-acting beta$_2$ agonist (LABA) inhaler, if they do not have asthmatic features or features suggesting steroid responsiveness, or
  - LABA + inhaled corticosteroid (ICS) inhaler, if they do have asthmatic features or features suggesting steroid responsiveness.[1]
- If escalating treatment to LAMA + LABA + ICS (triple therapy) inhaler, undertake a clinical review to ensure that:
  - the person's non-pharmacological COPD management is optimised and they have used or been offered treatment for tobacco dependence if they smoke

Recommendations

  - acute episodes of worsening symptoms or the person's day-to-day symptoms that are adversely impacting their quality of life are caused by COPD and not by another physical or mental health condition.
- Triple therapy with LAMA + LABA + ICS inhaler should be:
  - offered to people on LABA + ICS that continue to have, either symptoms that adversely impact quality of life or one severe or two moderate exacerbations within a year
  - considered for people on LAMA + LABA inhaler who have one severe or two moderate exacerbations within a year
  - considered for a three month trial for people on LAMA + LABA inhaler who do not fit the exacerbation criteria, but continue to have day to day symptoms that adversely impact on quality of life. Revert to LAMA + LABA inhaler if there is no improvement.[1]
- Clinicians should minimise the number of inhalers and the number of different types of inhaler used by each person as far as possible.[1]
- Long-acting drugs should be prescribed by brand and device to ensure that people receive inhalers they have been trained to use.[1]
- Do not routinely prescribe mucolytics to prevent exacerbations in people with stable COPD.[1]
- Consider mucolytics for people with a chronic cough productive of sputum. Commence treatment as a trial, with an acute prescription issue and planned review. Continue treatment only if there is symptomatic improvement.[1] Prescribers should select the lowest cost preparation that is suitable for the individual.
- Prophylaxis with azithromycin (unlicensed indication) may be considered in certain people with COPD. However, respiratory specialist input is likely to be necessary before commencing treatment due to the large number of factors that must be addressed first.[1]
- Oral corticosteroids should be considered for exacerbations that cause a significant increase in breathlessness that interferes with daily activities. NICE recommend 30mg of oral prednisolone daily for five days.[1]
- An antibiotic should be considered when features of the exacerbation include sputum colour changes and increases in volume or thickness beyond the person's normal day-to-day variation.[5]
- People that are at risk of an exacerbation should have an individualised exacerbation action plan, which may include keeping a short course of oral corticosteroids and a short course of oral antibiotics at home under specified circumstances.[1]
- Ensure that patients know to contact a healthcare professional if they start their self-management oral corticosteroids and/or antibiotics.[6]
- Monitor the use of oral corticosteroids/oral antibiotics to ensure that they are being used appropriately and that exacerbations are recorded in the person's clinical record. If people use three or more courses of oral corticosteroids/oral antibiotics in a year, the reasons for this should be investigated.[1]
- Practices should have robust systems in place to ensure that people with COPD are reviewed appropriately. This includes:
  - a minimum of annual review for people with mild, moderate or severe COPD
  - a minimum of review twice a year for people with very severe COPD.[1]
- Consideration of adherence and a review of inhaler technique should be part of medication reviews for people with COPD.[4] Importantly, these factors should be considered before concluding that current therapy is insufficient.

Recommendations

- For anybody whose COPD treatment includes ICS, the reason for continuing ICS use should be documented in clinical records and reviewed at least annually.[1] Practices that use a standard template for COPD reviews should ensure that this is part of the template.
- Delay any planned withdrawal of ICS during the COVID-19 pandemic and review this when updated NICE guidance is available. If the person experiences side-effects that make the balance of benefit e.g. vs. risk unfavourable for ICS then an individual assessment of ICS discontinuation can be made, in line with NICE guidance.[7] See below for information about management of COPD during the COVID-19 pandemic.
- There is a greater risk of pneumonia in people treated with LABA + ICS or LAMA + LABA + ICS inhalers, compared with other treatments.[7] Be aware of, and be prepared to discuss with the person, the risk of side effects, including pneumonia, in people who take ICS inhalers for COPD.[1]
- Long-term use of oral corticosteroid therapy in COPD is not normally recommended. Some people with advanced COPD may need long-term oral corticosteroids when these cannot be withdrawn following an exacerbation. In such cases, referral to a specialist is indicated and the dose should be kept as low as possible.[1]
- 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.[8]
  - » Monitor people who are having long-term oral corticosteroid therapy for osteoporosis (see PrescQIPP 231 Bisphosphonate treatment for osteoporosis) and give them appropriate prophylaxis. Start prophylaxis without monitoring for people over 65.
  - » Think about osteoporosis prophylaxis for people who need frequent courses of oral corticosteroids.[1]
- Ensure that steroid cards and steroid emergency cards are issued to appropriate people.[9] PrescQIPP resource: Implementing the NHS Steroid Emergency Card National Patient Safety Alert (NatPSA)
- For ICS, the London Respiratory Network have developed a high dose ICS safety card for adults, along with guidance on when they should be issued.[10]
  https://www.respiratoryfutures.org.uk/media/1704/sfd10680-nhs-high-dose-ics-safety-card-guidance-notes-1.pdf
  https://www.networks.nhs.uk/nhs-networks/london-lungs/documents/high-dose-inhaled-corticosteroid-alert-card-order-form
- Make use of community pharmacy services that can support people in getting the most from their COPD medication. Services include:
  - » the New Medicines Service (NMS) in England,
  - » the NHS Medicines: Care and Review service in Scotland, and
  - » Discharge Medication Reviews (DMRs) in Wales
- Be aware of environmental issues relating to inhaler devices and be able to discuss them as part of shared decision-making.
  - » Information on the inhaler carbon footprint is available in the PrescQIPP resource 'Inhaler carbon footprint' https://www.prescqipp.info/our-resources/bulletins/bulletin-295-inhaler-carbon-footprint/

Recommendations

» A NICE patient decision aid to support people with asthma in choosing their inhaler device is available.[11] This could also be useful to explain about inhaler carbon footprint to people with other respiratory conditions. Soft mist inhalers (SMIs) such as the Respimat® device, which are relevant in COPD were not included in the patient decision aid because there was only one medicine available for asthma in this device. NICE do state in the patient decision aid that SMIs do not contain a propellant, so they have a lower carbon footprint than pMDIs.

» Materials to prevent inhaler waste are available as part of PrescQIPP 255: Prevent Medicine Waste Campaigns.

NICE Guideline 168: COVID-19 rapid guideline: community-based care of patients with chronic obstructive pulmonary disease (COPD)[7]

The guideline includes the following advice (see https://www.nice.org.uk/guidance/ng168 for further information and full guidance)

- Explain to patients with COPD, and their families and carers, that they are at increased risk of severe illness from COVID-19.
- Tell all patients to continue taking their regular inhaled and oral medicines in line with their individualised COPD self-management plan to ensure their COPD is as stable as possible. This includes those with COVID-19, or who are suspected of having it. Keep their self-management plan up to date, and remind them that online video resources on correct inhaler technique are available.
- At every interaction, be alert for new or increased issues with mental health and wellbeing, particularly anxiety and depression.
- Tell patients established on ICS to continue to use them, and delay any planned trials of withdrawal of ICS. While there is some evidence that use of ICS in COPD may increase the overall risk of pneumonia (see the 2014 MHRA drug safety update on inhaled corticosteroids: pneumonia), do not use this risk alone as a reason to change treatment in those established on ICS and risk destabilising COPD management.
- Tell patients on long-term oral corticosteroids that they should continue to take them at their prescribed dose, because stopping them can be harmful. Advise patients to carry a Steroid Treatment Card.
- Tell patients that if they think they are having an exacerbation, they should follow their individualised COPD self-management plan and start a course of oral corticosteroids and/or antibiotics if clinically indicated.
- Tell patients not to start a short course of oral corticosteroids and/or antibiotics for symptoms of COVID-19, for example fever, dry cough or myalgia.
- Do not offer patients with COPD a short course of oral corticosteroids and/or antibiotics to keep at home unless clinically indicated, as set out in the NICE guideline on chronic obstructive pulmonary disease in over 16s.
- Strongly encourage patients with COPD who are still smoking to stop, to reduce the risk of poor outcomes from COVID-19 and their risk of acute exacerbations.

Background

COPD is a condition characterised by airflow obstruction.[1] Rather than being a single, homogenous disease, the term COPD encompasses chronic airflow limitation caused by a mixture of small airways disease (e.g. obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary from person to person. Some people may have clinical features of both asthma and COPD. In the past, this may have been described as Asthma-COPD Overlap (ACO). Experts are however moving away from this description, preferring to emphasise that asthma and COPD are different disorders, although they may share some common traits and clinical features (e.g. eosinophilia, some degree of reversibility).[2]

COPD is caused by significant exposure to noxious particles or gases, most commonly from tobacco smoking, although other causes (e.g. occupational) are possible.[6] It is estimated that 1.2 million people in the UK have a diagnosis of COPD, making it the second most common lung disease, after asthma. Around 2% of the whole population (4.5% of all people aged over 40) live with diagnosed COPD, and many people may remain undiagnosed.[12] Most people are not diagnosed until they are in their fifties or older and many more people remain undiagnosed.[1]

Chronic and progressive dyspnoea is the most characteristic symptom of COPD. Cough with sputum production is present in up to 30% of patients. Other problems such as fatigue, weight loss and anorexia are common in people with severe and very severe COPD.[2]

Inhaled COPD therapies are targeted at either improvement in symptoms of breathlessness by bronchodilation, or reduction in exacerbations by reducing airway inflammation. Despite the introduction of many new inhalers for COPD, including various combination products, the number of treatment options by therapeutic class remains relatively small. They consist of:

- SABAs
- SAMAs
- LABAs
- LAMAs and
- ICS.[9,13]

Medicines optimisation in COPD focuses on cost-effective and rational prescribing to maximise benefit and minimise the risk of harm. This encompasses prescribing the most appropriate medication in a suitable device for the individual, and ensuring that the person is properly trained (and able) to use it correctly. Inhaler technique training and reinforcement are essential to ensuring maximal benefit and avoiding inappropriate escalation of treatment. Another key medicines optimisation theme is the avoidance of unjustifiable risk, and potential harm, from the use of inappropriate treatments that expose the person to the risk of clinically important side effects. An important example is the use of high-dose ICS in people for whom the treatment-related risks outweigh the expected benefits.[14]

National guidance

NICE issued new guidance on the diagnosis and management of COPD in 2018, with further updates in July 2019. Previously to this NICE guidance on COPD had not been updated since 2010. During the relatively long period between updates, some clinicians sought more up-to-date guidelines from other sources. This resulted in GOLD guidance (from the Global Initiative for Chronic Obstructive Lung Disease) on COPD diagnosis, management and prevention gaining more prominence in the UK.[15] The most recently published GOLD guideline is the 2022 update.[2]

Since the 2010 published NICE guidance, COPD treatment has changed from being based on severity of FEV1 (forced expiratory volume in one second) impairment to focusing on 'treatable traits' or phenotypes.[3] Current NICE and GOLD guidelines both consider whether people are affected by

exacerbations or are predominantly affected by symptoms without exacerbations. Both guidelines consider if the person has asthmatic features. However the way in which these traits are used to construct the pathways differ. NICE start by categorising people by the presence or absence of asthmatic features or features suggesting steroid responsiveness.[1] The approach used in GOLD is centred on whether the person is predominantly breathless or predominantly exacerbating.[2]

The pharmacological treatment pathway recommended by NICE for stable COPD is discussed below. Some of the differences between the NICE and GOLD guidance are also considered.

Fundamentals of care

The following treatments and plans should be revisited at every review:

- Offer treatment and support to stop smoking
- Offer once only pneumococcal and annual influenza vaccines*
- Offer pulmonary rehabilitation if indicated
- Co-develop a personalised self-management plan
- Optimise treatment for co-morbidities.[4]

*Note that people with COPD are included as a priority group in the initial phase of the COVID-19 vaccination programme.[16]

The evidence base for pulmonary rehabilitation is strong and it is a very cost-effective intervention.[17] Pulmonary rehabilitation should be offered to people who view themselves as functionally disabled by COPD. This is usually considered to be people at Medical Research Council (MRC) grade three and above (see Table 1). Pulmonary rehabilitation is not suitable for people who are unable to walk, who have unstable angina or who have had a recent myocardial infarction.[1]

The British Lung Foundation website signposts online pulmonary rehabilitation resources, which can support people when face-to-face pulmonary rehabilitation sessions are not possible, as is currently the case due to the COVID-19 pandemic.

Table 1. MRC dyspnoea scale[1]

Grade	Degree of breathlessness related to activities
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower than 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 metres or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing
Adapted from Fletcher CM, Elmes PC, Fairbairn MB et al. (1959) The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population. British Medical Journal 2: 257–66.	

Initial inhaled therapies

Inhaled therapies should be started after the above interventions have been offered (if appropriate), where they are needed to relieve breathlessness and exercise limitation. As in their previous guidance, NICE continue to recommend initial inhaled therapy with a SABA or SAMA as needed.[1]

Escalating treatment

Health care professionals should ensure that treatment has been optimised before it is escalated. This includes considering inhaler technique and adherence (see below). It also involves revisiting the

fundamentals of COPD care to ensure that people have been given access to these interventions, where relevant, because they are beneficial for people with COPD. This should not be a barrier to treatment escalation, and it does not imply that pharmacological treatments should be withheld until the fundamentals of care have been undertaken.[18]

Inhaled combination therapy

There is a choice of treatment options for people with spirometrically confirmed COPD who are limited by symptoms or have exacerbations despite using a short-acting bronchodilator. The route taken depends on whether or not the person has asthmatic features or features suggesting steroid responsiveness.

No asthmatic features or features suggesting steroid responsiveness	Asthmatic features or features suggesting steroid responsiveness
Offer LAMA + LABA	**Consider LABA + ICS**

In this context, asthmatic features or features suggesting steroid responsiveness include:

- any previous secure diagnosis of asthma or atopy
- a higher blood eosinophil count (see 'Eosinophil levels' below)
- substantial variation in FEV1 over time (at least 400ml) or substantial diurnal variation in peak expiratory flow (at least 20%).[1]

In contrast with their previous COPD guidance and with GOLD guidance, NICE do not recommend LABA or LAMA monotherapy as treatment options. NICE base this on the results of a network meta-analysis (carried out by the Cochrane Airways Group) and economic modelling. The clinical and cost-effectiveness of LAMA + LABA was compared with:

- LAMA monotherapy,
- LABA monotherapy, and
- LABA + ICS.[18]

Evidence was stratified by risk of exacerbation based on the previous exacerbation history of the study participants. For people at high-risk of exacerbations, LAMA + LABA had the highest probability of being ranked best for outcomes where there were meaningful differences between treatment alternatives. This included increased FEV1 and reductions in moderate to severe and severe exacerbation rates. LAMA + LABA was the most cost-effective choice for the majority of scenarios.[18]

In the low-risk of exacerbations group the outcomes followed a similar pattern to the high-risk group, however many did not reach the minimally important difference between treatment alternatives. The exception to this was moderate to severe exacerbations, where LAMA + LABA was meaningfully better than LABA at reducing exacerbations.[18]

NICE considered the potential resource impact, as dual therapy with LAMA + LABA is typically more expensive than monotherapy. They were confident in the recommendation, noting the robust economic and clinical evidence supporting it. Furthermore, many of the modelled scenarios showed a downstream reduction in costs due to prevented exacerbations, which may (partially or totally) mitigate the total resource impact.[18]

NICE recognise that some people will already be managing their COPD with long-acting bronchodilator monotherapy. They state that, if the person's symptoms are under control, they can continue with their current treatment until both they and their healthcare professional agree it is appropriate to change.[1]

The exclusion criteria for COPD clinical trials often incorporate co-morbidities such as asthma. As a result, the NICE clinical guidelines committee had to rely on their clinical expertise to make a recommendation for people with asthmatic features or features suggesting steroid responsiveness. They

reasoned that it would be clinically inappropriate for people with these features not to be on ICS, as they are likely to benefit from the use of ICS in a similar manner to people with asthma. They therefore felt that LABA + ICS was likely to be a better initial treatment combination than LAMA + LABA for this group. Weaker wording ('consider') was used for this recommendation, to reflect the lack of direct evidence in this group.[18]

The risk of pneumonia was increased in people taking LABA + ICS compared to other treatments (see 'Safety' section below).[1]

Triple therapy

A review of triple therapy with LAMA + LABA + ICS was not within the original scope of the NICE update. New clinical evidence was highlighted during consultation on the draft guideline, which resulted in NICE commissioning an update.[19] This was subsequently published in July 2019.[20]

NICE specify that a clinical review should be undertaken before starting LAMA + LABA + ICS. This is to ensure that:

- the person's non-pharmacological COPD management is optimised and they have used or been offered treatment for tobacco dependence if they smoke
- acute episodes of worsening symptoms are caused by COPD exacerbations and not by another physical or mental health condition
- the person's day-to-day symptoms that are adversely impacting their quality of life are caused by COPD and not by another physical or mental health condition.[1]

The review should take the form of a conversation with the person with COPD. Tools such as the MRC dyspnoea scale or COPD Assessment Test (CAT) score could be used as part of the assessment if time permits, but not at the expense of a conversation with the person. Any moderate exacerbations that have occurred should be explored to ensure that they have been correctly identified, rather than relying on rescue medication use alone to capture this.[20]

NICE base their recommendations on triple therapy on their own meta-analysis and economic modelling, comparing the clinical and cost-effectiveness of triple therapy with LABA + ICS and with LAMA + LABA. There were some difficulties in interpreting the data as few studies examined the effects of triple therapy for people who were previously taking LABA + ICS or LAMA + LABA. The majority of studies included people with COPD who were taking any combination of mono, dual or triple therapy. The NICE committee therefore had to use the evidence to infer which treatment options might be best.[20]

For those on LABA + ICS, NICE recommend the following:[1]

If the person has:

- day-to-day symptoms that adversely impact quality of life, or
- one severe exacerbation within a year, or
- has two moderate exacerbations within a year

Offer LAMA + LABA + ICS

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

Data from twelve studies were included in the meta-analysis on triple therapy versus LABA + ICS. NICE found clear benefits for the use of triple therapy over LABA + ICS, in particular for a reduction in the rate of severe exacerbations and improvements in FEV1. There was no detectable difference in the number of people experiencing pneumonia between the two groups, which is expected since all treatment strategies included ICS. Despite triple therapy being the more expensive option, the economic model found that triple therapy is likely to be cost effective compared to LABA + ICS in

people who continue to exacerbate or remain breathless on dual therapy if quality-adjusted life years (QALYs) are valued at £20,000. It was noted that the increased cost is at least partially offset by savings from prevented exacerbations.[20]

The studies that NICE based their recommendation on excluded people with a current diagnosis of asthma and provided limited information on other asthmatic features (e.g. eosinophil count). NICE did not therefore make a specific recommendation for people with asthmatic features, although they note that this group is likely to be covered already by the pathway route to treatment with LABA + ICS.[1]

For those taking LAMA + LABA the recommendation differs according to whether the person is exacerbating or has symptoms affecting their quality of life:

Person has one severe or two moderate exacerbations within a year **Consider** **LAMA + LABA + ICS** Document the reason for continuing ICS use in clinical records and review at least annually.	Person has day to day symptoms that adversely impact on quality of life **Consider 3-month trial of** **LAMA + LABA + ICS** **After 3 months:** **If no improvement – revert to LAMA + LABA.** Document the reason for continuing ICS use in clinical records and review at least annually.

This means that NICE recommend a trial of ICS (within triple therapy) in some people with COPD that have already been categorised within the pathway (at the preceding step) as not having features suggesting steroid responsiveness. This may reflect the fact that the definition NICE use for asthmatic features/features suggesting steroid responsiveness does not consider exacerbations.[1] However there is consensus that ICS have a role in the reduction of exacerbations in COPD.[3] So considering adding ICS to LAMA + LABA treatment where exacerbations continue to be problematic is not contentious. This is in contrast with their addition to treatment based on continuing symptoms without exacerbations, which some experts question (see below).[3,21]

NICE considered data comparing triple therapy to LAMA + LABA from four studies in their meta-analysis, the largest of which was the IMPACT study.[20,22] Triple therapy resulted in a reduction in the rate of severe exacerbations and provided some quality of life benefits. However the differences were smaller than the ones for people who were taking LABA + ICS before they started triple therapy.[20]

The methodology of the included studies was a key discussion point for the guideline committee. Some study participants who were previously taking LABA + ICS were randomised to LAMA + LABA, and some who were taking triple therapy were randomised to dual therapy. This could lead to the studies detecting withdrawal effects from a person's step-down in medication rather than the effectiveness of treatment.[20] The IMPACT study was noted in particular.[22] This large study had a high weighting in many of the outcomes for the meta-analysis. A high proportion (69%) of people who were randomised to the LAMA + LABA arm of the trial were previously on medication that included an ICS component.[20]

After consideration, the NICE guideline committee decided to include the IMPACT study in their analysis, as other outcome data suggested there may be long-term benefits of triple therapy besides the effect on exacerbations. They were also reassured by low heterogeneity in the results for the majority of outcomes.[20]

People who switched from LAMA + LABA to triple therapy were more likely to get pneumonia (see 'Safety' section below).[1] This should be discussed with people before changing therapy.

The guideline committee noted that the study by Ferguson et al (KRONOS, 2018) did not report recent exacerbations as part of the inclusion criteria and did not detect an effect on the rate of moderate to severe exacerbations, but did report improvements in quality of life at six months. This suggests that there may still be some benefits in the use of triple therapy for people with less severe COPD

symptoms, although NICE acknowledge that the balance of risk versus benefit is less clear in this group. They therefore recommend a three month trial of triple therapy in people prescribed LAMA + LABA that do not meet the exacerbation criteria, but continue to have day to day symptoms that impact their quality of life.[20] Implementing this requires clinicians to step down treatment in people commenced on triple therapy who don't improve, but who are still experiencing chronic breathlessness that impacts on their day to day quality of life. This may be challenging in practice, and clinicians should consider how to communicate this effectively on initiation of triple therapy in this group. A patient information leaflet for people using ICS as part of their COPD treatment is available to support these discussions.

Some experts have expressed reservations about allowing progression to triple therapy for people that continue to be breathless without exacerbations.[3,21] The GOLD guideline considers the use of ICS to treat symptoms without a history of exacerbations inappropriate. It suggests considering treatment de-escalation for people prescribed ICS in such circumstances.[2] The PCRS have commented that the consensus view on the role of ICS in COPD is in the reduction of exacerbations and not in the treatment of breathlessness.[3]

The PCRS have proposed an alternative 'Keeping it Simple' COPD treatment algorithm (See PCRS Update, Spring 2019), which encompasses the treatable traits used in the NICE and the GOLD guidelines (predominant breathlessness, exacerbations +/- breathlessness, COPD with asthma). It includes the option of LABA or LAMA monotherapy in those with COPD without asthma, and triple therapy is not included as an option for those without exacerbations or asthma.[3]

Agree locally the COPD treatment pathway taking recommendations made by NICE, GOLD and PCRS into account.

Eosinophil levels

Eosinophilic inflammation appears to be important in some people with COPD. Post-hoc analysis of several trials has suggested that blood eosinophil levels may be helpful in identifying those more likely to respond to ICS.[23] Definitive randomised controlled trial (RCT) evidence to guide practice in this matter is not currently available, making this an area of debate in COPD management.

Based on the randomised controlled trial (RCT) evidence reviewed for dual and triple therapy, NICE were unable define a specific blood eosinophil threshold or to decide whether single or repeated measurements should be carried out.[18,20] They noted that the normal levels of eosinophils vary within the population and that different thresholds are used by different centres.[19] NICE therefore refer to 'a higher blood eosinophil count' as a sign that the person has asthmatic features/features suggesting steroid responsiveness.[1]

In contrast with NICE, GOLD guidance does propose threshold eosinophil levels for identifying those with the greatest likelihood of benefitting from ICS. They are clear that the thresholds given should be regarded as estimates, rather than precise cut-off values, and that blood eosinophil counts can be used as a biomarker in conjunction with clinical assessment when making decisions regarding ICS use.[2]

GOLD guidance recommends considering LABA + ICS in those with:

- Blood eosinophil counts of ≥300 cells per microlitre (0.3 x 10^9/L), or
- Blood eosinophil counts of ≥100 cells per microlitre (0.1 x 10^9/L) if the person has had at least two moderate exacerbations, or one exacerbation requiring hospitalisation in the previous year.

Furthermore, they suggest adding ICS to LAMA + LABA in people with blood eosinophil counts of ≥100 cells per microliter (0.1 x 10^9/L), if they continue to exacerbate on the dual treatment regimen.[2]

Locally agree what eosinophil count range will be considered 'higher' in the context of COPD management.

Oral treatments

NICE recommend some oral treatments for COPD in certain circumstances. These include:

Oral corticosteroids

Long-term use of oral corticosteroid therapy in COPD is not normally recommended. Some people with advanced COPD may need long-term oral corticosteroids when these cannot be withdrawn following an exacerbation. In such cases, referral to a specialist is indicated and the dose should be kept as low as possible.[1]

Theophylline (slow-release)

Theophylline should only be offered only after a trial of short-acting bronchodilators and long-acting bronchodilators, or for people who are unable to use inhaled therapy, as plasma levels and interactions need to be monitored. Particular caution is needed in older people, because of differences in pharmacokinetics, the increased likelihood of comorbidities and the use of other medications.[1]

Mucolytics

NICE recommend considering mucolytics for people with a chronic cough productive of sputum. Treatment should be commenced as a trial and should only be continued if there is symptomatic improvement (for example, reduction in frequency of cough and sputum production). Mucolytics should **not** be used routinely to prevent exacerbations in people with stable COPD.[1] Suitable licensed products are available for carbocisteine and acetylcysteine.[9] Erdosteine is only licensed for short term use for a maximum of ten days in acute exacerbations of chronic bronchitis in adults,[24] which is not in line with the NICE recommendations. There is a wide variation in the costs of products (see 'Costs' section). Prescribers should select the lowest cost preparation that is suitable for the individual.

A pragmatic approach to ensuring appropriate review is to issue the first carbocisteine or acetylcysteine prescription as an acute issue for a 28 day supply, with a review planned after a month to consider if continued treatment is warranted. Ensure that this is communicated to people at the outset of treatment so that they understand the purpose of both the treatment and the review. For example, the prescriber could explain:

'Carbocisteine / acetylcysteine belongs to a group of medicines called mucolytics. Some people with COPD have problems with an ongoing productive cough - a cough with lots of mucus / phlegm. This group of people might find a mucolytic medicine helpful. They work by making the mucus in your lungs less thick and sticky, which should make it easier to cough up. Not everyone finds them helpful though, so it is important that we check back in one month to see how you are getting on. If there is no improvement in your symptoms, or if you no longer have a problem with mucus, we will stop the carbocisteine / acetylcysteine.'

People that have already been on a mucolytic for COPD for more than 28 days without evaluation of benefit should be identified and reviewed appropriately. Development of local recommendations on mucolytic prescribing can support these reviews, e.g. Leicestershire Medicines Strategy Group

Points to consider:

- For carbocisteine, a higher dose is used initially which should be reduced to a maintenance dose if a satisfactory response is obtained, or stopped if not (see table 3). This is the point at which carbocisteine should be added to the person's repeat medication list i.e. at a maintenance dose.
- Acetylcysteine has a simpler dosing regimen, with most formulations requiring once daily dosing (see table 3).[25] Even though the acetylcysteine dose does not need to be adjusted after an initial period, a review should still be undertaken to establish benefit.
- Some acetylcysteine formulations are high in sodium and require caution in people on a sodium-restricted diet (check individual product details).

- Side-effects of carbocisteine and acetylcysteine include gastrointestinal disorders and both should be used with caution in people with a history of gastroduodenal ulcers.[26,27] Carbocisteine is contraindicated in active peptic ulceration.[26]

Azithromycin

NICE found evidence that prophylactic antibiotics reduce the risk of people having an exacerbation, and that they reduce the number of exacerbations per year in people with COPD and sputum production. Azithromycin had the most evidence of effectiveness out of the antibiotics included in the evidence review.[1] NICE therefore recommend considering azithromycin (usually 250mg three times a week – unlicensed indication) for people with COPD if they:

- Do not smoke i.e. if they are ex-smokers or non-smokers (based on evidence of a lack of effect of prophylactic antibiotics in smokers) **and**
- Have optimised non-pharmacological management and inhaled therapies (consider inhaler technique as well as drug choice), relevant vaccinations and (if appropriate) have been referred for pulmonary rehabilitation **and**
- Continue to have one or more of the following, particularly if they have significant daily sputum production:
  - frequent (typically four or more per year) exacerbations with sputum production
  - prolonged exacerbations with sputum production
  - exacerbations resulting in hospitalisation.[1]

Before prophylactic azithromycin is offered, the person should have had:

- Sputum culture and sensitivity (including tuberculosis culture), to identify other possible causes of persistent or recurrent infection that may need specific treatment (for example, antibiotic-resistant organisms, atypical mycobacteria or Pseudomonas aeruginosa)
- Training in airway clearance techniques to optimise sputum clearance
- A CT scan of the thorax to rule out bronchiectasis and other lung pathologies
- An electrocardiogram (ECG) to rule out prolonged QT interval and
- Baseline liver function tests.[1]

These strict conditions were recommended in order to ensure that prophylactic antibiotics were restricted to individuals where they were safe and likely to be effective, and to avoid the risk of widespread overuse that could raise antimicrobial stewardship concerns.[28] It is also important that an accurate assessment of baseline exacerbation rate is recorded before starting long-term macrolides.[29]

NICE recommend thinking about whether **respiratory specialist input** is needed before starting prophylactic antibiotic therapy in a person with COPD.[1] This is due to the large number of factors that need to be considered and addressed before commencing treatment.[28] The British Thoracic Society (BTS) stipulate that long-term macrolides should only be started following discussion and shared decision-making between the patient and a respiratory specialist.[29]

People should be advised of the small risk of hearing loss and tinnitus with azithromycin. They should contact a healthcare professional if this occurs.[1] A process for reviewing azithromycin should be in place, including monitoring requirements and who is responsible for undertaking it. NICE recommend a review after the first three months, and then at least every six months. Treatment should be continued only where the benefits outweigh the risks. NICE highlight the lack of long-term studies on the use of prophylactic antibiotics in people with COPD.[1]

Good practice points recommended by the BTS include:

- Liver function tests one month after starting treatment and then every six months.
- An ECG one month after starting treatment to check for new QTc prolongation. If present, treatment should be stopped.
- Subsequent follow-up at six and 12 months should determine whether benefit is being derived from therapy by using objective measures such as the exacerbation rate, CAT score or quality of life as measured by a validated assessment tool such as St George's Respiratory Questionnaire. If there is no benefit, treatment should be stopped.
- Repeat microbiological assessment of sputum is recommended with clinical decline or during exacerbations to monitor resistance patterns.[29]

The full guideline from the BTS on the use of long-term macrolides in adults with respiratory disease can be found at https://www.brit-thoracic.org.uk/quality-improvement/guidelines/long-term-macrolide-use/. Further resources from the BTS include a template patient information leaflet (PIL) which can be customised for local use. It should be noted that prophylaxis of exacerbations in COPD is currently an unlicensed indication for azithromycin,[9] and this information should be incorporated into any local patient information leaflet (PIL). Sign-posting to the manufacturer's PIL should also be considered as much of the information will be relevant (e.g. precautions, side-effects). It is essential to present this alongside a clear explanation of the unlicensed nature of long-term use, and to clarify that the manufacturer's PIL discusses licensed indications only.

Roflumilast

Roflumilast is a long-acting phosphodiesterase-4 (PDE4) inhibitor.[30] PDE4 is an enzyme found in structural and inflammatory cells, including those with a role in the pathogenesis of COPD.[31] A NICE technology appraisal of roflumilast considered pooled data from two studies in people with severe COPD, chronic bronchitis and two or more exacerbations in the previous year. In the subgroup of patients with severe COPD having exacerbations despite triple inhaled therapy, the NICE committee found sufficient evidence of the clinical efficacy of roflumilast compared with placebo (in terms of a reduction in the rate of moderate or severe exacerbations).[30]

As an add-on to bronchodilator therapy, NICE recommend roflumilast as an option for treating severe COPD in adults with chronic bronchitis, only if:

- The disease is severe, defined as FEV1 after a bronchodilator of less than 50% of predicted normal, and
- The person has had two or more exacerbations in the previous 12 months despite triple inhaled therapy with LAMA + LABA + ICS.[30]

Roflumilast should be started by a **specialist in respiratory medicine**.[30] Patients should be informed about the potential adverse effects of roflumilast, which include weight loss and psychiatric disorders.[32] Roflumilast is not recommended for people with a history of depression associated with suicidal ideation or behaviour. It should be discontinued if new or worsening psychiatric symptoms or suicidal behaviour are identified.[33]

Management of exacerbations

An exacerbation is a sustained worsening of the person's symptoms from their usual stable state which is beyond normal day-to-day variations, and is acute in onset. Symptoms include worsening breathlessness, cough, increased sputum production and change in sputum colour.[1]

Exacerbations can be classified as:

- Mild - the person has an increased need for medication, which they can manage in their own normal environment
- Moderate - the person has a sustained worsening of respiratory status that requires treatment with systemic corticosteroids and/or antibiotics
- Severe - the person experiences a rapid deterioration in respiratory status that requires hospitalisation.[1]

Increased breathlessness is usually managed by taking increased doses of short-acting bronchodilators.[1]

Oral corticosteroids should be considered for exacerbations that cause **a significant increase in breathlessness that interferes with daily activities**. NICE recommend 30mg of oral prednisolone daily for five days. The evidence NICE reviewed showed no benefit from taking corticosteroids for more than seven days, so a five day course was recommended on the basis that this was already routine clinical practice.[1]

An antibiotic should be considered when features of the exacerbation include **sputum colour changes and increases in volume or thickness** beyond the person's normal day-to-day variation. When an oral antibiotic is indicated, first choice empirical options are amoxicillin, doxycycline or clarithromycin.[5] A non-macrolide should be selected for people taking prophylactic azithromycin. The azithromycin does not need to be stopped during the exacerbation[1] unless another antibiotic with potential to affect the QT interval has also been prescribed.[29]

People that are at risk of an exacerbation should have an individualised exacerbation action plan. Offer a short course of oral corticosteroids and a short course of oral antibiotics to keep at home as part of their exacerbation action plan if:

- They have had an exacerbation within the last year and remain at risk of an exacerbation
- They understand and are confident about when and how to take these medicines, and the associated benefits and harms
- They know to tell their healthcare professional when they have used the medicines, and to ask for replacements.[1]

Tell patients not to start a short course of oral corticosteroids and/or antibiotics for symptoms of COVID-19, for example fever, dry cough or myalgia.[7] If a person with COPD is feeling unwell and is unsure if it's a flare-up, symptoms of COVID-19 or something else, they should call NHS 111 or get in touch with their health care professional.[34]

The Asthma + Lung UK (www.blf.org.uk) produce a number of resources for people with COPD, including patient information and a range of self-management tools. Much of the information can be accessed freely online, and some of it is available for purchase. Free resources include a flare-up action plan and information on the website about managing flare-ups, which can help people to understand what action to take when their symptoms worsen.

Ensure that patients know to contact a healthcare professional if they start their self-management oral corticosteroids and/or antibiotics.[6] An appropriate contact telephone number can be included in their exacerbation action plan to facilitate this. Monitor the use of oral corticosteroids/oral antibiotics to ensure that they are being used appropriately and that exacerbations are recorded in the person's clinical record. If people use three or more courses of oral corticosteroids/oral antibiotics in a year,

the reasons for this should be investigated.[1] Clinical system searches for people with COPD that have had three or more courses of oral corticosteroids or oral antibiotics in the last year are available to help identify people for review (refer to the PrescQIPP support resources available at the end of this bulletin).

Before issuing prednisolone and oral antibiotic rescue packs prescribers should ensure that the person has been appropriately educated about their use and assess whether the patient is willing and able to take the medication as prescribed.[35] An example of a patient information leaflet on, COPD Prednisolone and antibiotic rescue packs advice for patients, has been produced by the Leicestershire Medicines Strategy Group. The information should also be fully covered in a patient held resource, such as their individualised COPD self-management plan.

Self-management is not always appropriate. Advise people to seek urgent medical advice if they experience a rapid or severe deterioration in symptoms at any time, even if they have already started oral corticosteroids/oral antibiotics.[1,5,35]

The Clinical Knowledge Summary for COPD recommends that follow-up for a person that has had a COPD exacerbation should include an assessment at a later date when they are clinically stable (e.g. six weeks after onset of the exacerbation):

- Assess any residual or changed symptoms.
- Optimise COPD management to reduce the risk of further exacerbations.
- Ensure the person knows how to use prescribed medications appropriately and assess for adverse effects.
- Consider the need for referral (to a specialist and/or pulmonary rehabilitation).
- Offer a short course of oral corticosteroids and a short course of oral antibiotics to keep at home as part of the person's exacerbation action plan if appropriate (see above).
- Review the number of courses of oral corticosteroids and/or oral antibiotics in the last year (see above)
- Review the person's self-management plan.[6]

Involving a specialist

Indications for referral to a specialist include:

- Diagnostic uncertainty
- Suspected severe COPD
- Assessment for oral corticosteroid therapy
- The person with COPD requests a second opinion
- Onset of cor pulmonale
- Assessment for oxygen therapy
- Assessment for long-term nebuliser therapy
- Assessment for roflumilast.

Referral should also be considered before starting oral antibiotic prophylaxis and in people with rapidly progressing COPD. The need for other referrals, such as for dietetic advice, stop smoking support, pulmonary rehabilitation or to other therapy services should be considered regularly.[1]

Review

People with mild, moderate or severe COPD should have a review at least annually. Those with very severe COPD should be reviewed at least twice a year. Table 2 summarises the follow-up of people with COPD in primary care, according to NICE guidance.[1]

Table 2. Summary of follow-up of people with COPD in primary care[1]

	Mild/moderate/severe (stages 1 to 3)	Very severe (stage 4)
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 • Person with COPD's 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 • Oxygen saturation of arterial blood (SaO2)

*** For anybody whose COPD treatment include ICS, document the reason for continuing ICS use in clinical records and review at least annually.**

Before the COVID-19 pandemic, discussions about COPD treatment would generally have taken place face-to-face. However, the new risks associated with this mean that other consultation methods (such as by telephone, video or email) should be considered and used where appropriate to minimise face-to-face contact during the pandemic. NICE have issued rapid COVID-19 guidance on the community-based care of patients with COPD.[7] The guideline focuses on what healthcare practitioners need to stop or start doing during the pandemic, and is available at https://www.nice.org.uk/guidance/ng168.

Changes to COPD QOF indicators

The 2020 update to the GP contract includes the following changes to COPD Quality and Outcomes Framework (QOF):

- Entry to the COPD register will be determined by the presence of a clinical diagnosis plus a record of post bronchodilator spirometry FEV1/FVC ratio below 0.7 recorded between three months before or six months after diagnosis in diagnoses made on or after 1 April 2020.

- The annual review will include a requirement to record the number of exacerbations in order to help guide future management and potentially avoidable emergency admissions.[36]

Withdrawing inhaled corticosteroids

The NICE COVID-19 rapid guideline on the community-based care of patients with COPD advises healthcare professionals to tell patients established on ICS to continue to use them, and delay any planned trials of withdrawal of ICS. They state that while there is some evidence that use of ICS in COPD may increase the overall risk of pneumonia (see the 2014 MHRA drug safety update on inhaled corticosteroids: pneumonia), do not use this risk alone as a reason to change treatment in those established on ICS and risk destabilising COPD management.[7]

Adherence

Consideration of adherence and a review of inhaler technique should be part of medication reviews for people with COPD.[4] Importantly, these factors should be considered before concluding that current therapy is insufficient. Both NICE and GOLD guidelines emphasise the importance of education and training in inhaler device technique.[1,2] A compatible spacer should be supplied (with training) where appropriate. NHS branded inhaler and spacer technique videos and leaflets that can be embedded on local websites are available to PrescQIPP subscribers as a support resource at https://www.prescqipp.info/our-resources/webkits/respiratory-care/

A relationship between inhaler mishandling and reduced clinical control in people with COPD or asthma has been demonstrated. An observational study collected 2288 records for 1633 patients of inhaler technique. Inhaler misuse was found to be common and was associated with increased risk of hospitalisation, emergency room visits, courses of oral steroids and courses of antimicrobials.[37] Poor inhaler technique may be more likely in older age, in people who use multiple devices, and where there has been a lack of previous education on this matter.[2]

Local COPD guidelines should include a range of inhaler device options, so that the choice can be tailored to the individual's preference and ability. Clinicians should minimise the number of inhalers and the number of different types of inhaler used by each person as far as possible. Long-acting drugs should be prescribed by brand and device to ensure that people receive inhalers they have been trained to use.[1]

A central concept in supporting good adherence is involving people in decisions about their medicines. There is evidence that people make decisions about medicines based on their understanding of their condition and the possible treatments, their view of their own need for the medicine and their concerns about the medicine.[38] NICE COPD guidance emphasises the need for people (and their family members or carers, where appropriate) to receive education about their condition at diagnosis and at each review appointment. Disease education also forms part of pulmonary rehabilitation programmes, as well as physical training, and nutritional, psychological and behavioural intervention. Furthermore, education is a key part of self-management plans. NICE recommend that education on COPD should cover the following (as a minimum):

- An explanation of COPD and its symptoms
- Advice on quitting smoking (if relevant) and how this will help with the person's COPD
- Advice on avoiding passive smoke exposure
- Managing breathlessness
- Physical activity and pulmonary rehabilitation
- Medicines, including inhaler technique and the importance of adherence

- Vaccinations
- Identifying and managing exacerbations
- Details of local and national organisations and online resources that can provide more information and support
- How COPD will affect other long-term conditions that are common in people with COPD (for example hypertension, heart disease, anxiety, depression and musculoskeletal problems).[1]

Safety

Inhaled corticosteroids

Local adverse effects with ICS such as oral candidiasis and hoarseness are well known. Systemic adverse effects are generally less common, but can occur, particularly where high doses are prescribed for prolonged periods. They include reduced bone mineral density which can increase the risk of fractures, adrenal suppression and psychological and behavioural changes.[39] The use of other corticosteroid therapy (including topical) or concurrent use of drugs which inhibit corticosteroid metabolism should be taken into account when assessing systemic risk.[9]

For several years there has been growing concern regarding an increase in the risk of pneumonia in people with COPD treated with ICS. In 2016, the European Medicines Agency Pharmacovigilance Risk Assessment Committee published a review confirming an increased risk of pneumonia with the use of ICS-containing treatments in people with COPD.

- Pneumonia was found to be a common side effect (i.e. affecting between 1 in 100 and 10 in 100 people with COPD using these medicines) of all of the ICS reviewed.
- No convincing evidence of a difference in risk between products was identified.
  - » However no clinical trials directly examined the risk of pneumonia with ICS head to head, so only indirect comparisons were possible. Variability in the clinical data and uncertainties with study methodologies mean that the review does not provide conclusive evidence for intra-class differences in the magnitude of risk.
- Some evidence of an increased risk of pneumonia with increasing steroid dose was apparent, but it was not demonstrated conclusively across all studies.[40]

The Committee's view was that the benefits of ICS continue to outweigh their risks. People with COPD and health care professionals caring for them should however be alert for signs and symptoms of pneumonia, bearing in mind that the clinical features of pneumonia overlap with those of a worsening (exacerbation) of the underlying disease.[40] It should be noted that the higher strength of Relvar Ellipta (fluticasone furoate 184 micrograms / vilanterol 22 micrograms) is not licensed for treating COPD. Clinical studies found no additional benefit of the 184/22 micrograms dose compared to the 92/22 micrograms dose coupled with an increased risk of pneumonia and systemic corticosteroid-related adverse reactions.[41]

NICE state that health care professionals should be aware of, and be prepared to discuss with the person, the risk of side effects (including pneumonia) in people who take ICS for COPD.[1]

For LABA + ICS, the benefits are considered to outweigh the harms in those with asthmatic features or features suggesting steroid responsiveness.[18]

For LAMA + LABA + ICS (triple therapy)

- For people taking LAMA + LABA who continue to have severe or frequent exacerbations, the potential harm of pneumonia is outweighed by the potential benefits.
- For those prescribed LAMA + LABA that do not meet the exacerbation criteria, but continue to have day to day symptoms that impact their quality of life, NICE acknowledge that the balance of risk versus benefit is less clear.[20] The guideline therefore recommends considering triple therapy as

a three month trial in this group. The intention is to identify those that benefit whilst avoiding the situation where people continue on triple therapy, with the accompanying risks, without seeing any benefit.[1]

Ensure steroid cards are issued to appropriate people. The London Respiratory Network have developed a high dose ICS safety card for adults, along with guidance on when they should be issued.[10]

https://www.respiratoryfutures.org.uk/media/1704/sfd10680-nhs-high-dose-ics-safety-card-guidance-notes-1.pdf

https://www.networks.nhs.uk/nhs-networks/london-lungs/documents/high-dose-inhaled-corticosteroid-alert-card-order-form

A National Patient Safety Alert has been issued by NHS England and NHS Improvement's national patient safety team in relation to a new Steroid Emergency Card. An NHS Steroid Emergency Card should be issued to all patients with adrenal insufficiency or steroid dependence as they are at risk of an adrenal crisis during intercurrent illnesses or an invasive procedure/surgery if not managed appropriately. This is relevant to people receiving COPD steroid treatments at certain doses and prescribers should ensure they are familiar with the directive.[42,43] Further information is available in a PrescQIPP Hot Topic Document – Implementing the NHS Steroid Emergency Card National Patient Safety Alert (NatPSA).

NICE do not make recommendations relating to the dose of ICS in fixed-dose combinations for COPD, as this was outside the scope of the guideline updates.[19,21] When considering inhaled triple therapy, the guideline committee did note that different triple therapy inhalers use different doses of ICS and that some of the doses that will be prescribed to people may be higher than those used in some of the studies or involve more potent formulations of ICS, potentially further increasing the risk of pneumonia. They agreed that it was important that clinicians were aware of the differences in ICS dose between inhalers and triple therapy formulations because they would ideally prescribe the lowest dose of ICS that adequately controls a person's symptoms. They recognised that in practice the prescriber was constrained by the doses available in specific inhalers and that inhaled therapy choice is also informed by patient choice and appropriateness of device.[20]

A spreadsheet of inhalers licensed for COPD is available as a support resource to this bulletin. The spreadsheet can be filtered and sorted according to various product features including the potency of ICS contained in the usual dose for COPD (where applicable).

Oral corticosteroids

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, adrenal insufficiency, gastrointestinal ulceration, hypertension, ocular effects and psychiatric effects.[8] Steroid cards should be issued where appropriate.[9]

NICE advise the following regarding osteoporosis prophylaxis in people with COPD:

- Monitor people who are having long-term oral corticosteroid therapy for osteoporosis, and give them appropriate prophylaxis. Start prophylaxis without monitoring for people over 65.
- Think about osteoporosis prophylaxis for people who need frequent courses of oral corticosteroids.[1]

Long acting muscarinic antagonists

The anticholinergic action of LAMAs necessitates caution in people with certain cardiovascular disorders. In accordance with advice from the Medicines and Healthcare products Regulatory Agency (MHRA), caution is needed with tiotropium in people with arrhythmias (unstable, life-threatening or requiring intervention in the previous 12 months), heart failure (hospitalisation for moderate to severe heart failure in the previous 12 months) and myocardial infarction in the previous six months. People in these groups were excluded from studies.[44] Similar warnings apply to other LAMAs used in COPD, although the specific cautions differ between products.[9]

Caution is also needed when antimuscarinics are used in men with prostatic hyperplasia and bladder-outflow obstruction, due to the risk of worsened urinary retention.[6] Some LAMAs should be used with caution or avoided in the presence of renal impairment, depending on the severity.[9] Renal clearance plays a lesser role in the elimination of both aclidinium (Eklira®) and umeclidium (Incruse®), neither of which require special precautions in the presence of renal impairment.[45,46]

Risk of airway obstruction

The MHRA have warned about the risk of accidentally inhaling loose objects from pressurised metered dose inhalers. People should be told to remove the mouthpiece cover fully, shake the inhaler to remove loose objects that may not be visible, and check the inside and outside of the mouthpiece are clear before inhaling a dose. After use, the cover should be replaced immediately.[47]

The MHRA have also issued a warning in relation to Braltus® (tiotropium) and the risk of inhalation of the capsule if it is placed in the mouthpiece of the Zonda® inhaler. People using this product must be trained to use it appropriately, including how to place the Braltus® capsule in the correct chamber of the Zonda® inhaler. People should also check that the mouthpiece is clear before inhaling.[48]

Community pharmacy services

Community pharmacy services can support people in getting the most from their inhaled medication.

- The New Medicines Service (NMS) is a free to use NHS service provided by community pharmacists for people living in England. The service is only available for people prescribed new medicines for certain conditions, which include COPD. It aims to help patients get the most out of their medicines when they are first prescribed. Patients can get further information about the scheme at on the NHS website at https://www.nhs.uk/nhs-services/prescriptions-and-pharmacies/pharmacies/new-medicine-service-nms/
- People registered with a GP in Scotland can access the NHS Medicines: Care and Review service via their community pharmacy. This service includes a review of medications and care planning. Further information is available at https://www.gov.scot/publications/nhs-medicines-care-review-service-local-pharmacy/
- In Wales, Discharge Medication Reviews (DMRs) can be provided as an advanced service by community pharmacists. Information is available at http://www.cpwales.org.uk/Services-and-commissioning/Advanced-Services.aspx

Environmental considerations

The NHS Long Term Plan outlines environmental commitments in line with national carbon and air pollution reduction targets.[49] It has been estimated that propellants in pMDIs are responsible for around 3.5% of all NHS emissions,[11] and the NHS plans to reduce this with a shift to lower carbon inhalers.[49] The PrescQIPP resource, Inhaler carbon footprint, provides information on lowering the inhaler carbon footprint and is available at https://www.prescqipp.info/our-resources/bulletins/bulletin-295-inhaler-carbon-footprint/

NICE have produced a patient decision aid to support people with asthma in choosing their inhaler device.[11] Currently, there is no similar resource for COPD or other respiratory conditions. Soft mist inhalers (SMIs) such as the Respimat® device, which are relevant in COPD were not included in the patient decision aid because there was only one medicine available for asthma in this device. The patient decision aid states that 'SMIs do not contain a propellant, so they have a lower carbon footprint than pMDIs'.[11]

It is important to recognise that medicines optimisation measures that promote effective management and discourage waste are also key components of environmentally (as well as clinically) responsible medicines usage.

Materials to prevent inhaler waste are available as part of PrescQIPP 255: Prevent Medicine Waste Campaigns.

Costs

A spreadsheet of inhalers licensed for COPD, which includes the cost per device and per day, is available as a support resource to this bulletin. The spreadsheet can be filtered and sorted according to product features including therapeutic class, type of device and potency of ICS (where applicable). It can be used to support the formulary decision making process when comparing the cost of treatments.

Primary care prices for mucolytics (Table 3) and azithromycin (Table 4) are outlined below.

Table 3. Mucolytic prices comparisons

Product	Dosage	Cost of 28 days treatment[50,51]
Carbocisteine 375mg	2 capsules three times a day (initial dose)	£5.08
Carbocisteine 375mg	1 capsule four times a day (maintenance dose)	£3.38
Carbocisteine 750mg	1 capsule three times a day (initial dose)	£26.57
Carbocisteine 750mg	1 capsule twice a day (maintenance dose)	£17.71
Carbocisteine sugar-free oral solution 750mg/10ml	1 sachet three times a day (initial dose)	£21.56
Carbocisteine sugar-free oral solution 750mg/10ml	1 sachet twice a day (maintenance dose)	£14.37
Carbocisteine sugar-free oral solution 750mg/5ml	5ml three times a day (initial dose)	£39.86
Carbocisteine sugar-free oral solution 750mg/5ml	5ml twice a day (maintenance dose)	£26.57
Carbocisteine oral solution 250mg/5ml	15ml three times a day (initial dose)	£22.22
Carbocisteine oral solution 250mg/5ml	15ml twice a day (maintenance dose)	£14.81
Carbocisteine sugar-free oral solution 250mg/5ml	15ml three times a day (initial dose)	£35.24
Carbocisteine sugar-free oral solution 250mg/5ml	10ml three times a day (maintenance dose)	£23.49
Acetylcysteine 600 mg sugar-free effervescent tablets	1 tablet daily	£5.13
Nacsys (Acetylcysteine) 600mg effervescent tablets	1 tablet daily	£5.13
Acetylcysteine 600mg capsules	1 capsule daily	£57.14
Acetylcysteine 200mg sachets (sugar-free powder for oral solution)	1 sachet three times a day	£315.00
Erdosteine 300mg capsule*	1 cap twice daily for max 10 days	£5.00 (for a 10 day course)

*Erdosteine is only licensed for short term use in acute exacerbations of chronic bronchitis in adults, which is not in line with the NICE recommendations.[24]

Table 4. Azithromycin prices in primary care based on usual dose in COPD (unlicensed) of 250mg three times a week

Product	Cost of 12 doses (28 days treatment)[50,51]
Azithromycin tablets 250mg	£3.72
Azithromycin capsules 250mg	£3.54
Zithromax (azithromycin) capsules 250mg	£21.48
Azithromycin 200mg/5ml oral suspension (15ml pack size)	£20.30*
Azithromycin 200mg/5ml oral suspension (22.5ml pack size)	£24.40*

*Azithromycin suspension costs are based on the Zithromax® brand, which has a shelf-life of five days once reconstituted.[52] The larger (30ml) pack size is not listed above as the shelf-life creates unacceptable wastage for this dosing regimen. The shelf-life products from other manufacturers may differ.

Prescribing review and potential savings

The foundation for medicines optimisation work in COPD is up-to-date local guidance. This should incorporate the treatment pathway and should guide prescribers to cost-effective products on the local formulary that will be suitable for the majority of people. Local commissioning bodies should ensure that such guidance is in place to enable primary care prescribers and other members of the healthcare team to initiate new treatment rationally and review existing treatment in line with current best practice. A COPD treatment pathway costing tool is available to enable commissioners to estimate the financial impact of different formulary choices being considered.

Regular COPD review

Undertaking individual review, as outlined in national guidance and in this bulletin, would provide regular opportunities to consider and discuss treatment changes where they are indicated. This should include consideration and discussion of options that would bring the person's treatment in line with up-to-date local guidance. Changes based on cost-effectiveness alone could also be considered, if they are appropriate and acceptable to both the patient and the clinician. Taking this type of integrated approach means that changes to treatment can be considered holistically and discussed with the person. Consideration of adherence and review of inhaler technique are essential aspects of the clinical review process.

Single vs. multiple devices

Single inhalers containing dual or triple therapy is generally more cost-effective than using multiple inhaler devices, and can simplify a person's treatment regimen.[20] Patients who are identified as using combinations of separate LAMA, LABA and ICS inhalers where combination dual or triple therapy inhalers are available should be reviewed. Consider changing treatment to a preferred option from the local formulary, where clinically appropriate. Savings for such changes are difficult to estimate and depend on the doses and types of inhalers that people are using.

Mucolytic review for benefit

Ensure that mucolytic treatment is reviewed for benefit after one month. People that have already been on a mucolytic for COPD for more than 28 days without evaluation of benefit should be identified and reviewed appropriately. For carbocisteine, the dose should be reduced to a maintenance dose once a satisfactory response has been achieved.

A 10% reduction in carbocisteine and acetylcysteine prescribing in primary care would represent an annual saving of £1.6 million across England, Wales and Scotland [NHSBSA (August-October 2021) and Public Health Scotland (July-September 2021)]. **This equates to £2,306 per 100,000 patients.**

Simple savings: mucolytic and azithromycin product selection

Several brands, formulations and strengths of acetylcysteine are available. Prescribing acetylcysteine generically as acetylcysteine 600mg sugar-free effervescent tablets is the least costly option. **If all acetylcysteine prescriptions were written as acetylcysteine 600mg sugar free effervescent tablets, this could produce an annual saving of £559,225 across England, Wales and Scotland** [NHSBSA (August-October 2021) and Public Health Scotland (July-September 2021)]. **This equates to £796 per 100,000 patients.**

Prescribing azithromycin 250mg as generic tablets (rather than capsules or the Zithromax® brand) is the least costly option and could produce an **annual saving of £15,639 across England, Wales and Scotland** [NHSBSA (August-October 2021) and Public Health Scotland (July-September 2021)]. **This equates to £22 per 100,000 patients.**

Liquid preparations of azithromycin and carbocisteine are expensive compared to solid dosage forms. Where they are prescribed regularly (i.e. excluding acute issues of azithromycin liquid) ensure that their use is appropriate. **Switching 50% of prescriptions for azithromycin and carbocisteine suspensions or solutions to capsules or tablets could save £566,650 annually across England, Wales and Scotland** [NHSBSA (August-October 2021) and Public Health Scotland (July-September 2021)]. **This equates to £806 per 100,000 patients.**

Carbocisteine tablets are available in 375mg and 750mg strengths. Prescribing the lower strength tablet is more cost effective as the higher strength tablet is more than 5 times as costly. Switching all carbocisteine 750mg tablets to two 375mg tablets could **save £271,516 annually across England, Wales and Scotland** [NHSBSA (August-October 2021) and Public Health Scotland (July-September 2021)]. **This equates to £386 per 100,000 patients.**

Summary

Treatment for COPD has shifted from being based on severity of FEV1 impairment to focusing on 'treatable traits' or phenotypes.[3] It is now guided by the presence or absence of asthmatic features, troubling breathlessness and exacerbations.[1,2] Inhaled therapies targeting breathlessness or airway inflammation remain key, whilst ensuring that fundamental care (such as smoking cessation, vaccination and pulmonary rehabilitation) is not overlooked.[1] Greater understanding of the role and risks of ICS in COPD management is leading to changes in management strategies, which for some people will mean considering withdrawing ICS treatment. However, at the time of publication, such work may need to be delayed in accordance with NICE advice relating to the COVID-19 pandemic.[7] Other medicines optimisation initiatives, such as ensuring optimal device selection and inhaler technique training are essential to ensuring that people can access the benefit of their medicines and avoid inappropriately escalating their treatment.

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Further resources to support the medicines management of people with COPD

PrescQIPP support resources

Many of the resources listed below have been developed to be used alongside PrescQIPP Bulletin 283 on COPD. Others are related to respiratory prescribing in general. They can be found at https://www.prescqipp.info/our-resources/webkits/respiratory-care/.

- A range of NHS branded inhaler and spacer technique videos and leaflets are also available at https://www.prescqipp.info/our-resources/webkits/respiratory-care/
- Resources on lowering the inhaler carbon footprint https://www.prescqipp.info/our-resources/bulletins/bulletin-295-inhaler-carbon-footprint/
- Prescribing data relating to respiratory prescribing including the respiratory visual snapshot and the COPD bulletin data pack (PrescQIPP log-in required).

Other (third party) organisation resources

Please note that the list of resources developed by third party organisations is not exhaustive. These resources have not been tested or approved by PrescQIPP and PrescQIPP is not responsible for their content.

- Tools developed in partnership between the Midlands Practice Pharmacy Network and Prescribing Decision Support Ltd at Keele University, and sponsored by GlaxoSmithKline:
  - https://asthmacopdtoolkit.org/ Audit and review toolkit incorporating a search report and protocol alerts to identify asthma and COPD patients at risk of unplanned admissions and/or displaying signs of poor disease control.
  - https://www.copd-dst.org/ Decision support tool designed to assist UK healthcare professionals in the diagnosis and management of COPD in people aged 16 and older.
- https://www.accurx.com/ Services include a COPD survey containing standardised COPD assessments, which healthcare professionals can send via SMS.
- GRASP COPD A tool produced by Nottingham University that assists GP practices to interrogate their clinical data, enabling them to improve patient outcomes, reduce costs and avoid inappropriate treatment for patients with COPD.

Additional PrescQIPP resources

	Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-283-copd/
	Implementation tools	
	Data pack	https://data.prescqipp.info/?pdata.u/#/views/B283_COPDupdate/FrontPage?:iid=1

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