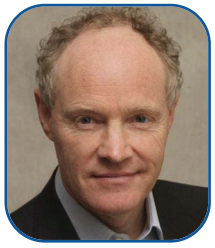
Keeping it Simple: A PCRS consensus on the treatment of COPD in the UK



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In this article the authors review current evidence and guidance for the treatment of Chronic obstructive pulmonary disease (COPD) to bring up to date the Primary Care Respiratory Society (PCRS) consensus approach and algorithm first published in 2017 and then again in 2023 known as 'Keeping it Simple'.

Background

COPD is the second most common lung disease in the United Kingdom.[1] An estimated 2.2% of the adult population are living with a diagnosis of COPD in 2022, equating to more than 1.2 million people.[1] While the prevalence of COPD in the UK is comparable to that of other European countries, we have the 3rd highest mortality rate from the disease.[2] These figures are a stark reminder that we still have some way to go to improve the lives and outcomes of people diagnosed with COPD in the UK.

Over the past decade, the UK has been playing catch up in terms of clinical guidelines for the diagnosis and management of COPD. In an attempt to address this, from a primary care perspective, in 2017 PCRS published a treatment algorithm for COPD in the UK focusing on pharmacotherapy.

'Keeping it Simple' was originally developed as a response to requests from local medicines optimisation teams and prescribers in primary care who wanted more clarity about the most appropriate pharmacotherapy for COPD. The National Institute for Health and Care Excellence (NICE) guideline in use at that time had been published in 2010 using at the latest, 2009 evidence and classifying treatment options based on airflow limitation cut-offs. Whereas, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) had been updating its approach every 18-24 months and at the time was sharing a new approach of differentiating treatment based broadly on whether people with COPD experienced predominantly exacerbations or breathlessness.

The 'Keeping it Simple' approach that was developed, like GOLD, recognised that the evidence supported predominant breathlessness or exacerbations treatment pathways, but PCRS in addition added a third pathway for people with both asthma and COPD.

NICE published a new COPD guide in 2018 with an update in July 2019.[3] This update attended to two significant omissions in the 2018 refresh with regard to the role of triple inhaled therapies and the duration of oral corticosteroid (OCS) treatment. This guideline notably now aligned with the PCRS 'Keeping it Simple' third treatment pathway for people with 'COPD with asthma', with its focus on the presence of asthmatic features as a main 'treatable trait'.

GOLD published for 2023[4] a new pharmacological approach and taxonomy that represented such a material change that it has now prompted PCRS to review 'Keeping it Simple' to ensure that it reflects the current evidence and the practicalities of prescribing within a UK health economy. The GOLD report incorporates the results of recent longitudinal studies and Phase 3 drug trials. These studies are changing how

we view COPD at the most fundamental level and consequently how we approach the treatment of patients. GOLD has a 2025 update which maintains the same key messages as the 2023 guideline, with a few important additions.[5]

2025 GOLD guidelines

Assessment and classification of COPD

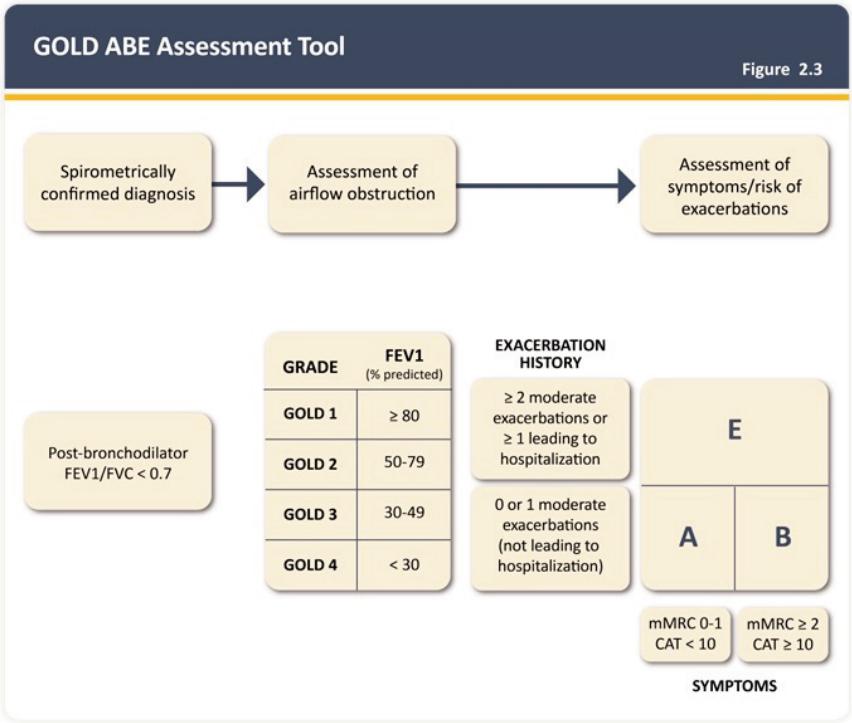
The 2023 GOLD guideline included a major change in the way COPD is assessed and classified. The GOLD Refined Assessment Tool, first introduced in 2017, included spirometric assessment of airflow obstruction and grouping of patients based on symptoms (primarily breathlessness) and recent history of ex- acerbations (as an indicator of future exacerbation risk). The orig- inal model stratified patients into four groups (A, B, C and D) based on high or low exacerbation risk and high or low symptoms. Initial pharmacological treatment was determined on the basis of these groupings. The recommendation for patients with a low exacerbation risk was a bronchodilator for those with a low symptom burden (Group A) and a long-acting bronchodilator (LABA or long-acting muscarinic agent [LAMA]) for those with a high symptom burden (Group B). For patients with a high exacerbation risk, a LAMA was recommended for those with a low symptom burden (Group C) with combination therapy (LAMA + LABA or LABA + inhaled corticosteroid [ICS]) for those with a high symptom burden (Group D).

While the assessment of severity based on spirometric evaluation remained in the 2023 report, the grouping of patients by symptom burden and future exacerbation risk changed (Figure 1) along with the recommended initial pharmacotherapy for each group (Figure 2).

Management of patients with a low risk of future exacerbations. While treatment for patients with a low exacerbation risk and low symptom burden (Group A) remains the same, a monotherapy approach has been abandoned for patients with a low exacerbation risk and high symptom burden (Group B). For these patients, the initial treatment should be LABA + LAMA combination therapy, preferably in a single inhaler. These recommendations are based on the results of Phase 3 clinical trials of several LABA/LAMA combinations which consistently demonstrated improved lung function and health-related quality of life compared with either agent alone and also when compared with a LABA + ICS regimen.[6] Indeed, the 2023 report was very clear that there is no longer a role for the LABA + ICS combination for the initial treatment of patients with COPD at low risk for exacerbations. The recommendation is maintained in the 2025 guidance.

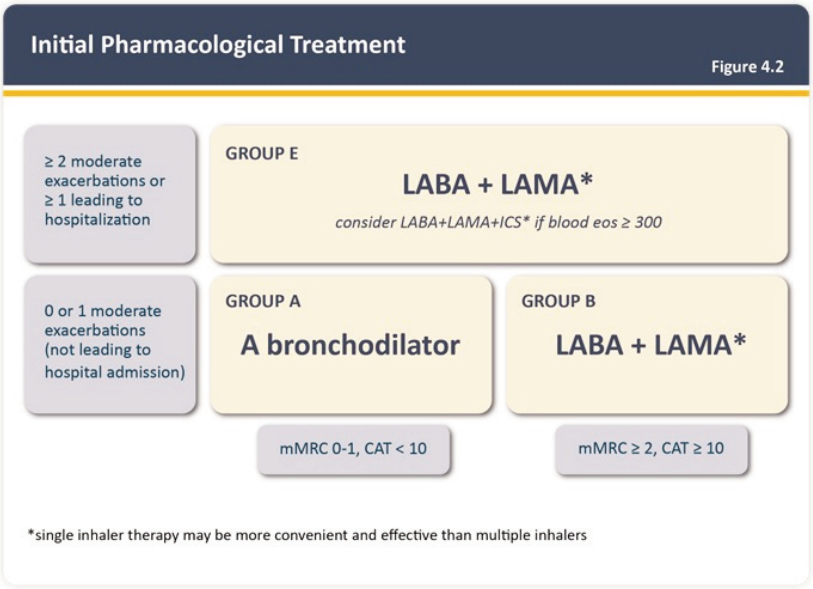
Management of patients with a high risk of future exacerbations. Perhaps the most significant change is that patients at high risk for exacerbations are no longer stratified by symptom burden. Instead, these patients are grouped together as Group E, with initial treatment being a LABA + LAMA combination (Figure 2). For these patients, a more rational approach to ICS use is recommended, guided by clinical factors and blood eosinophil levels. Patients that are unlikely to benefit from an ICS are those with a blood eosinophil count <100 cells/µL. ICS therapy can be considered for patients with a blood eosinophil count between 100 and <300 cells/µL who have had one moderate COPD exacerbation in the previous year. Patients most likely to benefit from ICS therapy are those with a blood eosinophil count >300 cells/µL, a history of hospitalisation for COPD exacerbations, ≥2 moderate exacerbations a year or with a history of, or concomitant asthma. When considering starting an

Figure 1. The GOLD ABE Assessment Tool[5]



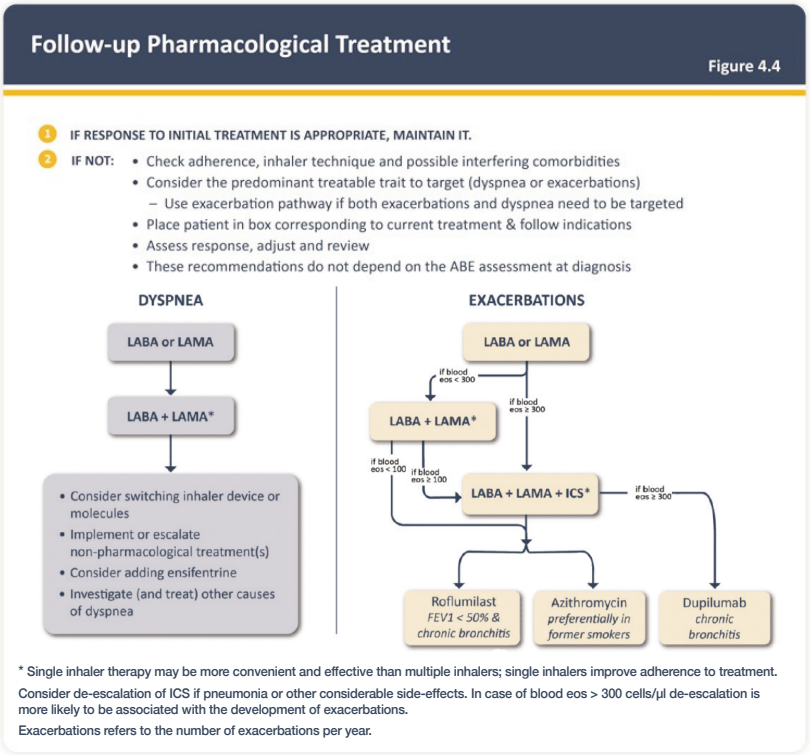
CAT, COPD Assessment Test; MRC, Medical Research Council; FEV1, forced expiratory volume over 1 second; FVC, forced vital capacity.

Figure 2. Initial pharmacological treatment of COPD[5]



CAT, COPD Assessment Test; ICS, inhaled corticosteroid; LABA, long-acting bronchodilator; LAMA, long-acting muscarinic agent; MRC, Medical Research Council.

Figure 3. GOLD follow-up pharmacological treatment[5]



CAT, COPD Assessment Test; eos, eosinophils; FEV_1, forced expiratory volume over 1 second; ICS, inhaled corticosteroid; LABA, long-acting bronchodilator; LAMA, long-acting muscarinic agent; MRC, Medical Research Council.

ICS, blood eosinophils are not the only useful factor. There are known harms of ICS use, including an increased risk of pneumonia and of mycobacterial infection. Patients with a history of recurrent pneumonia and those with a previous mycobacterial infection should not routinely be started on ICS as the harms may well outweigh the benefits. These fundamental changes to the classification and initial treatment of patients with a high risk of future exacerbations reflect the findings of the ECLIPSE study. This study showed that eosinophil count, an indicator of underlying inflammation, was a better predictor of response to ICS therapy than was a high symptom burden.[7]

Management of patients with ongoing symptoms or exacerbations. The rational approach to the use of ICS therapy based on evidence of an underlying inflammatory process, greatly simplifies both the approach to initial treatment and the follow-up treatment decisions (Figure 3). The first step for any patients with ongoing symptoms or repeated exacerbations is to review and optimise their current treatment regimen – check inhaler technique, consider whether any comorbid conditions are present or require review. Next steps depend on whether the patients have ongoing breathlessness or repeated exacerbations, regardless of their initial grouping.

Patients with ongoing breathlessness who were receiving bronchodilator monotherapy can be escalated to combination LABA + LAMA therapy. For those already on combination therapy, switching to an alternative device or molecule can be considered alongside a focus on treatment optimisation, non-pharmacological management, and investigation of alternative causes of breathlessness.

Patients with ongoing exacerbations can be escalated to triple therapy including an ICS if elevated eosinophils to >300 cells/µL, or to roflumilast (for those

with an FEV_1 <50% and chronic bronchitis) or azithromycin (preferentially in former smokers). The 2025 report has added dupilumab for consideration in patients on triple therapy, with an eosinophil count above 0.3 and chronic bronchitis. This is based on the results from 2 phase III trials (BOREAS and NOTUS).[8,9] Dupliumab is currently under review by NICE. However, the reliance on elevated blood eosinophils as the single biomarker for ICS initiation in exacerbating patients has its critics, not least because the question remains as to when to assess for eosinophils as a patient with a recent exacerbation who has received oral steroids (prescribed or via their emergency pack) may not meet the 300 cells/µL cut-off.

2019 NICE guidelines

So where are we with NICE guidance? Initial therapy for all patients with COPD remains single bronchodilator therapy with a short-acting bronchodilator (SABA) or short-acting muscarinic antagonist (SAMA) (Figure 4). Patients limited by symptoms or exacerbations can then be treated more aggressively if asthmatic features are present.

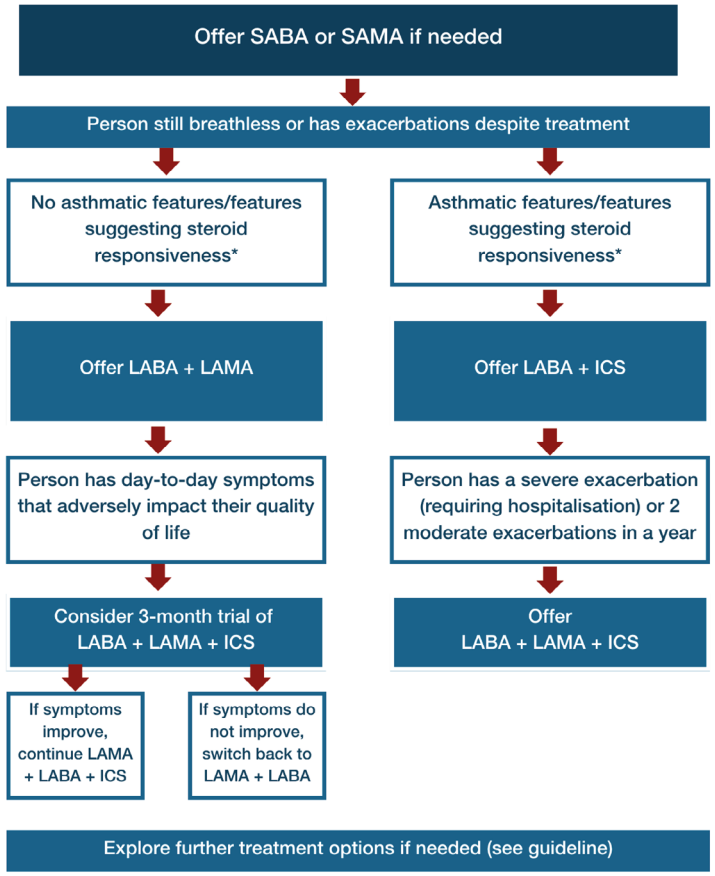
This is the first and major difference from the 2025 GOLD guidelines. Whereas GOLD focuses on symptoms and future exacerbation risk as the 'treatable traits' guiding pharmacotherapeutic decision making, NICE has continued to focus on the presence of asthmatic features as the main 'treatable trait'.

Management of patients with asthmatic features. For patients with features suggestive of an asthmatic component (secure diagnosis of asthma or atopy, higher blood eosinophil count, substantial variation in FEV_1 over time or substantial diurnal variation in peak expiratory flow), a combination LABA + ICS can be considered. A limitation here is that the cut-off for 'higher eosinophil count' is not specified although it is generally accepted as >300 cells/µL. Triple therapy with the addition of a LAMA can subsequently be offered for patients who experience a severe exacerbation (requiring hospitalisation) or who experience 2 moderate exacerbations within a year.

Management of patients without asthmatic features. Patients without asthmatic features can be offered a LABA + LAMA and, if symptoms continue to impact their quality of life, a 3-month trial of triple therapy with LABA + LAMA + ICS can be considered. This approach differs from the 2023 GOLD report as it still allows for a trial of treatment with ICS even in the absence of a single point of evidence of underlying inflammation – blood eosinophils >300 cells/µL required by GOLD.

Unfortunately, the 2019 update did not address the concern around including an option for a 3-month trial of triple therapy for patients with ongoing breathlessness but no evidence of an increased risk for future exacerbations. As we have seen from the ECLIPSE study,[7] ongoing breathlessness is not a good indicator for response to ICS therapy and it was for this reason that the 2025 GOLD update elected to require elevated eosinophils as a marker of underlying inflammation as a pre-requisite for ICS initiation. Allowing triple therapy as an option for patients with ongoing breathlessness is concerning as it is unlikely to prove benefit in relieving their breathlessness and may cause a delay in seeking alternative causes for their chronic breathlessness. This approach will mean that a proportion of patients will be escalated to triple therapy and receive an ICS from which they will gain no clinical benefit and which may place them at increased risk for

Figure 4. NICE inhaled therapies algorithm[3]



* 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 FEV_1 over time (at least 400ml) or substantial diurnal variation in peak expiratory flow (at least 20%)

pneumonia. While the NICE 2019 update recommends that patients whose symptoms do not improve after a 3-month trial of triple therapy should step down to a dual bronchodilator regimen without an ICS, whether this is feasible and currently part of routine practice is unclear.

Updating the PCRS 'Keeping it Simple' approach

On reviewing the latest approaches from GOLD and NICE and reflecting on the latest evidence at the time of writing, the authors, representing PCRS, have reached a new consensus on the management of patients with COPD in the context of UK primary care and have updated the 'Keeping it Simple' algorithm (Figure 5). Indeed, the recent updates to the GOLD and NICE guidance reflect the approach, laid out by PCRS in the original 2017 document, to initial and follow-up pharmacological management of COPD. PCRS guidance on treatment decision-making considers both the treatable traits described in the 2025 GOLD guidance – breathlessness and exacerbations – as well as the asthmatic component which is a significant feature in the NICE guidance.

In the 2025 update, the three treatment groups remain the same and reflect the different clinical needs and likely underlying pathology associated with these treatable traits. Patients with an asthmatic component will require ICS and this should form a part of their initial treatment regimen.

- Patients with **predominant breathlessness** as their major clinical feature and without asthma will not benefit from ICS therapy and their treatment should focus on bronchodilation; SABA plus LABA or LAMA with progression to LABA + LAMA depending on the impact of their breathlessness on their daily activities. In this update, this pathway does not change.
- Previously, patients who were **predominantly exacerbating** would start on a SABA in addition to a single bronchodilator, either a LAMA or LABA. In this update, PCRS now recommends that the starting point for this group is dual therapy with LAMA+LABA in a single inhaler device in addition to SABA.

ICS (triple therapy) can be used in addition to dual bronchodilation in the predominantly exacerbating group if they continue to experience exacerbations, particularly if these are events that require hospitalisation.

Adding ICS is most likely to give benefit if eosinophils are >300 cells/μL and unlikely to produce benefit if <100 cells/μL. In this update, PCRS now recommends that when deciding to add ICS, attention should be paid to eosinophil levels. The index test should have been taken at a time when the patient is not exposed to oral corticosteroids or unwell with an exacerbation.

A trial of mucolytics can be considered for people with cough productive of sputum but only continued if there is clear symptomatic improvement. Routine use to prevent exacerbations is not recommended. A diagnosis of bronchiectasis should also be considered for people with COPD who have significant mucus production.

- For patients who have **COPD with asthma**, initial therapy in this update has changed to LABA+LAMA+ICS in a single inhaler device with SABA for rescue bronchodilation.

The new position follows the GOLD 2023/2025 approach i.e. when an inhaled corticosteroid (ICS) is indicated, this should be prescribed as a long-acting beta2 agonist (LABA)/long-acting muscarinic antagonist (LAMA)/ICS triple inhaler rather than as part of dual LABA/ICS therapy—this is because LABA/LAMA/ICS triple therapy has demonstrated superior efficacy in reducing exacerbations and lowering mortality compared with dual LABA/ICS therapy.

At each stage, medication optimisation should be undertaken including checking the patient's inhaler technique and their adherence.[10] In the case of any patient with COPD requiring ICS, there should be careful consideration of whether a specialist review is required. People with asthma and COPD who have poor control may benefit from biologic therapies and a referral is required to consider this.

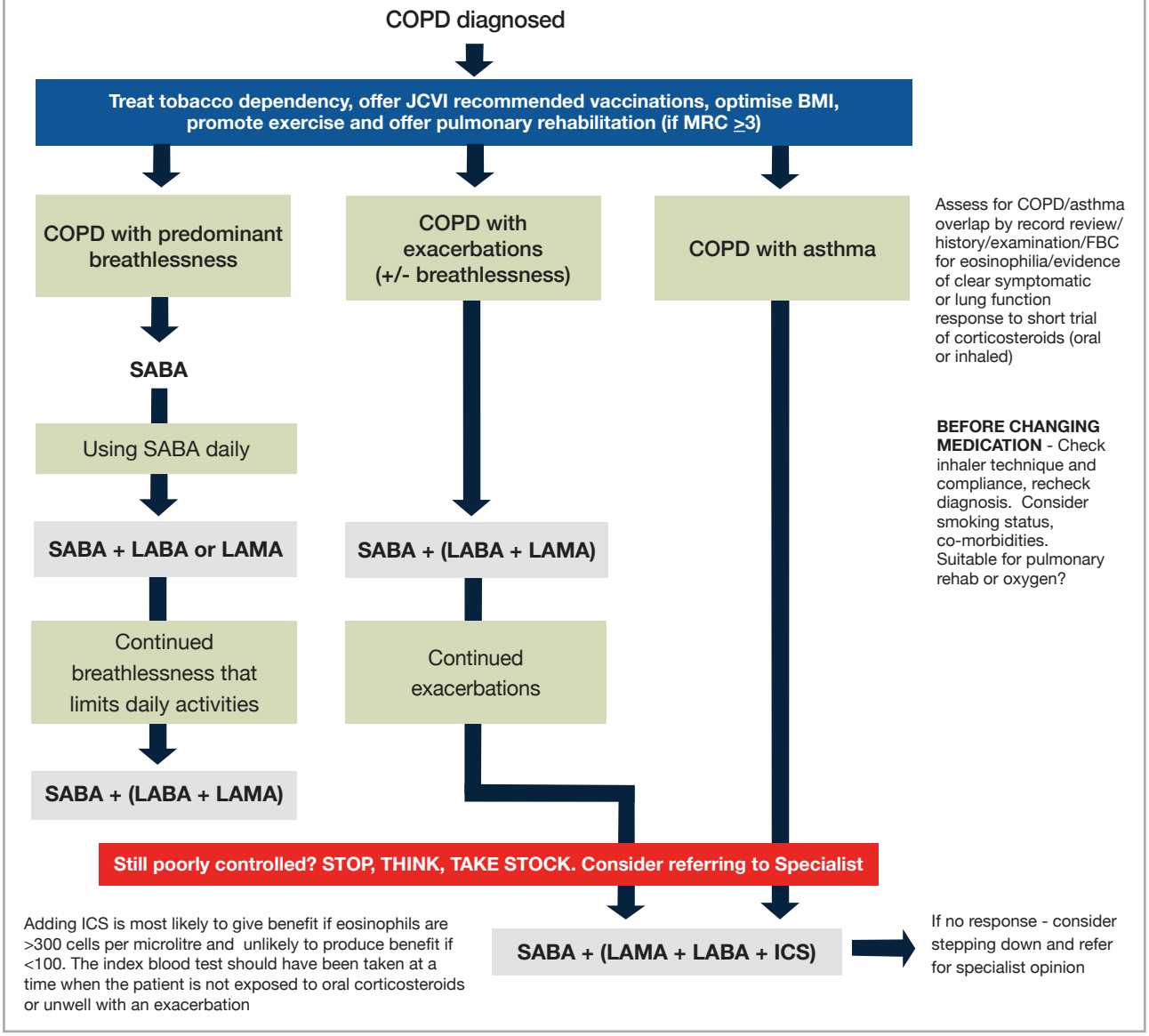
PCRS recommends the use of single inhaler devices where dual or triple therapies are indicated.[11]

In addition, ongoing monitoring of patients should include reviewing for comorbidities (especially alternative causes of breathlessness[12]) and whether pulmonary rehabilitation has been offered and attended as well as treating tobacco dependency.[13] Vaccinations should be offered according to current nationally recommended programmes which would currently include immunisation against influenza annually, SARS-CoV-2 and pneumococcus. The UK Joint Committee on Vaccination and Immunisation (JCVI) has recently approved the Respiratory Syncytial Virus (RSV) vaccination for older adults to reduce the risk of lower respiratory tract infections and exacerbations from patients with COPD.[14]

Conclusion

The 'Keeping it Simple' algorithm seen in Figure 5 describes the 2025 update of the PCRS consensus approach to treating COPD. Overall, both GOLD and NICE appear to be catching up with the pragmatic recommendations PCRS first made in 2017. Steroid stewardship, both oral and inhaled, remains relevant to avoid exposing patients to treatments that will not benefit them and which may in fact place them at risk for side effects. Looking back over the last decade, we have come a long way in our understanding of the heterogeneity of COPD and this has informed how best to manage patients according to the treatable traits that are most significant for them. While a cure for COPD remains elusive and treatment is largely reactive to clinical presentation, there is much we can do to ensure patients receive treatments that relieve their most impactful daily symptoms, optimise their lung function and reduce their risk for life-threatening exacerbations.

Figure 5. PCRS Keeping it Simple approach 2025



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