NICE National Institute for Health and Care Excellence

NICE guidance

myCOPD for managing chronic obstructive pulmonary disease

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB214.

1 Recommendations

1.1 More research is recommended on myCOPD for managing chronic obstructive pulmonary disease (COPD) in adults. Using it for self-managing COPD and remote pulmonary rehabilitation could provide significant patient and healthcare system benefits if uncertainties in the evidence are addressed.

1.2 Research should compare myCOPD with standard care for:

- people who use it to self-manage COPD
- people who are referred for pulmonary rehabilitation.

Find out more in the further research section of this guidance.

Why the committee made these recommendations

Standard care for COPD includes a range of interventions such as self-management, pulmonary rehabilitation (a face-to-face programme of exercise and education) and inhalers. myCOPD is an app that helps people with COPD understand their condition and manage symptoms. It also has a pulmonary rehabilitation programme, so people can do this remotely.

Clinical trial evidence is uncertain because the trials were short and included few people. But it suggests that using myCOPD for self-management improved COPD symptoms, walking distance and inhaler technique compared with standard care. The evidence also suggests that pulmonary rehabilitation using myCOPD works as well as face-to-face sessions.

The cost savings are uncertain because of limitations in the clinical evidence. There is also a lack of information about how much myCOPD affects healthcare resource use, such as unscheduled hospital appointments. More evidence is needed to resolve these uncertainties, so further research is recommended.

2 The technology

Technology and intended use

2.1 myCOPD is a digital tool for people with chronic obstructive pulmonary disease (COPD) and healthcare professionals. It is intended to support people to manage COPD. It can be used by people with any stage of COPD. Functions within the myCOPD app include:

- education on how to use inhalers correctly
- a self-management plan to help people understand what medicine to take and when
- a prescription assessment function to cross-check prescribed medicine, and identify any conflicts
- a COPD assessment for people to track their symptoms and learn how to control them
- access to an online 6-week pulmonary rehabilitation course including an incremental exercise programme and education sessions to help promote self-management.

2.2 People can use myCOPD with any digital device that connects to the internet, such as smartphones, tablets, televisions and computers. Users' data will be shared with clinical teams if people accept the terms and conditions when registering with myCOPD. Clinicians can review the person's data to remotely monitor their symptoms and if appropriate suggest a change to their medicines. These suggestions are automatically shared with the person through the app.

2.3 The technology was supported by NHS England's innovation and technology tariff in 2017. The company states that the technology is compliant with the NHS Digital Technology Assessment Criteria (DTAC).

Care pathway

2.4 The NICE guideline on chronic obstructive pulmonary disease in over 16s: diagnosis and management provides recommendations on managing stable COPD, covering smoking cessation, inhaled therapy, oral therapy, oxygen therapy, pulmonary rehabilitation and managing pulmonary hypertension. A recent update of the guideline focuses on monitoring, education and self-management. The guideline notes that most people with COPD can develop adequate inhaler technique if they have training. The guideline also recommends making pulmonary rehabilitation available to all people with COPD if appropriate, including people who have had a recent hospitalisation for an acute exacerbation. Pulmonary rehabilitation programmes should include multicomponent, multidisciplinary interventions tailored to the individual's needs. The rehabilitation process should incorporate a programme of physical training, disease education, and nutritional, psychological and behavioural interventions.

2.5 NICE's COVID-19 rapid guideline on community-based care of patients with COPD recognises the need to reduce face-to-face contact and recommends people use online pulmonary rehabilitation resources.

Innovative aspects

2.6 In the UK, face-to-face appointments are a standard approach when reviewing or monitoring COPD. myCOPD allows health service providers to offer a combination of remote care and face-to-face support. Using myCOPD could potentially minimise health service contacts and help with delivering care remotely.

Costs

2.7 The company provides an unlimited licence plan to healthcare organisations such as clinical commissioning groups or integrated care systems who want to make the technology available across their regions. Based on a 3-year contract, this unlimited licence plan has an annual cost of £0.25 per person registered with a GP in the region. Alternatively,

pulmonary rehabilitation service providers who do not have regional access to the technology can obtain an unlimited licence plan at a cost of £10,000 per year.

For more details, see the website for myCOPD.

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

The clinical evidence comprises 4 UK comparative studies

3.1 There were 4 peer-reviewed studies on myCOPD, including 3 randomised controlled trials (RCTs) and 1 observational study. All trials were done in the NHS with 6 weeks or 3 months of follow up. The sample sizes ranged from 41 to 90 people with mild, moderate or severe chronic obstructive pulmonary disease (COPD). Of the 3 RCTs, TROOPER used a non-inferiority design comparing myCOPD with a face-to-face pulmonary rehabilitation programme in people who were referred for rehabilitation (Bourne et al. 2017). The other 2 trials examined the use of myCOPD as a self-management tool: RESCUE, a feasibility trial, compared myCOPD with usual care including a written self-management plan in people who were discharged from hospital after an acute exacerbation (North et al. 2020). EARLY was a superiority RCT that compared myCOPD with standard care in people with mild to moderate COPD or recently diagnosed COPD (Crooks et al. 2020).

Real-world evidence from 10 local evaluations is generalisable to the NHS

3.2 There was also real-world evidence on clinical benefits, health service use, patient experience and usage of the myCOPD app from 10 local evaluations. A service evaluation from Southend University Hospital explored using myCOPD to support a home-based pulmonary rehabilitation programme. Other local evaluations assessed the effect of myCOPD on self-managing COPD. Most evidence was from interim evaluations designed to inform commissioning decisions or service

developments. The methodology, patient numbers or characteristics, clinical outcomes and follow-up periods were not fully reported in these evaluations. However, the EAC concluded that the real-world evidence reflected the use of myCOPD in clinical practice and the findings of these evaluations would be generalisable to local health services.

Evidence on using myCOPD for self-managing COPD shows improvements in clinical outcomes

3.3 Evidence on using myCOPD for self-managing COPD showed improvements in clinical outcomes. There was evidence from trials and real-world evidence evaluating myCOPD for self-managing COPD in people with different COPD severity and exacerbation history. Results suggested improvements in clinical outcomes such as the COPD assessment test (CAT) score, 6-minute walking test (6MWT) distances and inhaler techniques after using myCOPD. Of those who were admitted to hospital because of an acute exacerbation, RESCUE showed a significant CAT score mean difference of -4.49 (95% confidence interval [CI] -8.41 to -0.58, n=41) in all people in the study regardless of whether they completed the study. RESCUE also showed a non-significant CAT score mean difference of -2.94 (95% CI -6.92 to 1.05, n=35) with myCOPD in people who completed the study at 3-month follow up (North et al. 2020). RESCUE showed a significant reduction in inhaler errors in people using myCOPD compared with people having standard care (relative risk, 0.38; 95% CI 0.18 to 0.80). Compared with people having standard care, people using myCOPD were less likely to have exacerbations (relative risk, 0.58; 95% CI 0.32 to 1.04).

Pulmonary rehabilitation with myCOPD is comparable to face-to-face rehabilitation

3.4 TROOPER reported no statistically significant difference in CAT score and 6MWT between the intervention groups, indicating myCOPD was not inferior to face-to-face care for pulmonary rehabilitation (Bourne et al. 2017). Health-related quality of life was not worse in people using myCOPD for pulmonary rehabilitation compared with those having face-to-face rehabilitation. The EAC considered that the TROOPER trial was well designed, but the sample size was small. The company provided

further information on the sample size calculation to show non-inferiority at consultation. The additional information did not address the EAC's methodological concerns, such as the choice of the non-inferiority limit, and the EAC considered a larger trial would probably be needed to confirm the results. Real-world evidence also reported improvements in CAT scores and 6-minute walk test with myCOPD to support home-based pulmonary rehabilitation (NHS Southend clinical commissioning group [CCG] evaluations).

Trial evidence shows adherence to myCOPD declines over time

3.5 For self-managing COPD, usage data of myCOPD reported in the RESCUE and EARLY trials showed its use declined over time. TROOPER used myCOPD for pulmonary rehabilitation. It showed that although adherence declined over time it was comparable in both groups (Bourne et al. 2017). After 6 weeks, 66% of people using myCOPD had completed 2 or more sessions compared with 69% of people in the comparator group who attended 2 or more face-to-face sessions. Real-world evidence showed varying use of the app. There is no direct evidence on the relationship between adherence and clinical outcomes using myCOPD.

myCOPD is easy to use and improves confidence in managing COPD

3.6 NICE's public involvement programme did a survey of people using myCOPD. In this, people reported that myCOPD was easy to use (n=297/359, 82.7%) and helped improve their understanding of the condition and manage symptoms. Three-quarters of people who responded (n=267/358, 74.6%) felt confident in managing COPD symptoms after using the app. Of those who used the app to control COPD symptoms, 66.1% (n=220/333) felt there had been a reduction in the number of exacerbations experienced after using the app. People thought that myCOPD was a helpful tool and provided useful information that improved their confidence in managing COPD.

Cost evidence

The company's cost models are in 2 populations

3.7 The company submitted cost models in 2 different populations:

- people discharged from hospital after an acute exacerbation of COPD who used myCOPD for self-managing their condition (the AECOPD model)
- people eligible for pulmonary rehabilitation who used myCOPD for pulmonary rehabilitation (the PR model).

The company also presented results for 2 different pricing scenarios. For healthcare providers who purchased a population-based unlimited myCOPD licence package, the company's AECOPD model showed that myCOPD was cost saving by £204,641 per CCG over 1 year compared with standard care (not accounting for savings from pulmonary rehabilitation). The estimated savings in the PR model within the population licence package was £20,269 per CCG per year. Also, if the myCOPD licence package is purchased solely for pulmonary rehabilitation services, the estimated saving is £8,707 per pulmonary rehabilitation service per year.

The EAC's changes to the cost models more accurately reflect the uptake rate of myCOPD for self-management and pulmonary rehabilitation

3.8 The EAC considered the company's 2 model structures to be appropriate. But it did not agree with the 100% uptake rate in the company's models. For the AECOPD model, the EAC used an uptake rate of 46% based on data from the RESCUE study (North et al. 2020). This rate is the proportion of people who chose to use myCOPD in the RESCUE trial.

3.9 For the PR model, the EAC changed the decision point from when people were referred to a pulmonary rehabilitation service to the point at which people have opted in or shown they would be willing to use myCOPD.

myCOPD is cost saving in both cost models

3.10 In the AECOPD model, the EAC base-case results showed that myCOPD saved £86,297 per CCG per year. The saving was influenced by the myCOPD uptake rate and the 90-day readmission rate. The EAC's threshold analysis suggested that using myCOPD becomes cost incurring if the uptake rate is below 26% or the 90-day readmission rate is higher than 0.30 admissions per person. It judged that both these values were plausible. At consultation, the company noted that the national activation rate was 48%. The EAC did an additional analysis of the AECOPD model using this activation rate for the uptake, which resulted in a small increase in the cost savings.

3.11 For the PR model, the EAC's base case showed cost savings of £22,779 per CCG per year or £11,093 per pulmonary rehabilitation service per year depending on the licence package purchased. These savings were influenced by the number of people being referred and the uptake rate of pulmonary rehabilitation programmes. The EAC's threshold analysis suggested that using myCOPD becomes cost incurring if:

- the referrals to the pulmonary rehabilitation service are below 249 people per year or
- the uptake rate is below 9.8% for myCOPD alone or
- the uptake rate for myCOPD alone is below 1.9% and the uptake rate for a hybrid option is below 12.2%.

  The EAC considered that there was uncertainty around the values used to inform the clinical inputs in the model. (For further details about the threshold analysis, see the EAC assessment report in the supporting documentation for this guidance.)

4 Committee discussion

Clinical-effectiveness overview

myCOPD shows promise for self-managing COPD but the clinical benefit is uncertain because of limitations in the evidence

4.1 The committee noted that evidence from 2 randomised controlled trials (the RESCUE and EARLY trials) and real-world evaluations showed that myCOPD had clinical benefits for self-managing chronic obstructive pulmonary disease (COPD). Populations included in the studies were heterogeneous in terms of the severity of COPD. The committee accepted that the evidence suggests clinical benefits showing improved inhaler technique, COPD assessment test (CAT) score and 6-minute walk test. RESCUE showed encouraging results, but it was designed as a feasibility study. Evidence on the effect of using myCOPD for self-managing COPD on health service use was limited. RESCUE showed that there were fewer hospital readmissions for acute exacerbations of COPD in people using myCOPD compared with people having standard care. The difference was not statistically significant. The external assessment centre (EAC) explained that the small study sample size had limited power to show an effect on clinical outcomes. The committee agreed that more evidence is needed to clearly show the clinical and healthcare system benefits of myCOPD for self-managing COPD (see the section on further research).

Evidence suggests that myCOPD is not worse than face-to-face pulmonary rehabilitation, but the clinical trial assessing this was small

4.2 The evidence presented on using myCOPD for pulmonary rehabilitation included 1 non-inferiority trial (TROOPER) and real-world evidence. In the trial, all clinical outcomes using myCOPD were not worse than conventional face-to-face pulmonary rehabilitation. The committee

accepted that the trial was well designed but noted methodological concerns from the EAC about the power calculations, such as the selection of the non-inferiority limit (for further details, see the EAC assessment report addendum). It also considered that the trial was limited by being a single-site study. The TROOPER study authors acknowledged the small sample size and suggested that a larger randomised controlled trial would be needed to change clinical practice. The committee concluded that a larger randomised controlled trial was needed to be confident in the findings of the TROOPER study.

Other patient benefits or issues

Usability and patient experience are important considerations

4.3 A commissioning expert from NHS Dorset clinical commissioning group (CCG) explained that the evaluation of digital health technologies is complex. They noted that considerations should not only focus on the clinical benefits of the technology, but also the patient experience, the usability of the technology and the role of the health service team. A survey done by NICE's public involvement programme suggested that people found myCOPD easy to use. The committee concluded that the usability and patient experience of the technology for both patients and the healthcare system are important considerations.

NHS considerations overview

Support is needed to help patients to use myCOPD and the health service to implement it

4.4 The company confirmed that myCOPD has been used across health services for self-managing COPD and pulmonary rehabilitation. The clinical experts advised that the health service team, both clinical and non-clinical, plays an important role in keeping people engaged with myCOPD. The commissioning expert stated that their team provided support for people to register and set up the app for self-managing their symptoms. Ongoing support from non-clinical digital support workers is

provided at different time points via text messaging, over the phone or by setting up face-to-face appointments to help maintain patient engagement. Similarly, the clinical expert said that people who used myCOPD for pulmonary rehabilitation in their service had a weekly call from the clinical team during the 6-week pulmonary rehabilitation course to support their progress in the programme. The company also confirmed that digital health advisers have been included as part of a contract to support the implementation of the technology and to ensure that clinical and digital support teams are fully trained.

Uptake data varies and more should be collected as real-world evidence

4.5 The committee understood that myCOPD uptake data varied widely across services. It acknowledged there are many factors influencing how much it was used, including the COVID-19 pandemic. The commissioning expert said that real-time uptake data was available from Dorset CCG, where uptake for self-management increased from 43% to 65% in 2021. The committee questioned whether the uptake rates observed in Dorset were likely to be realised in other regions. A clinical expert advised that uptake of myCOPD for pulmonary rehabilitation in their service was around 26% in 2018; however, no recent uptake data was available. The committee agreed that understanding the uptake of myCOPD across different regions and settings, for both self-management and pulmonary rehabilitation, is important to ensure its value for money (see sections 3.10 and 3.11). It concluded that this information could easily be collected as real-world evidence.

myCOPD could have an impact on health inequalities

4.6 Clinical experts explained that myCOPD has been implemented as an option alongside existing services in their practice. People have the option to choose whether or not to use it depending on preference. The experts noted that the populations in their regions using myCOPD were mainly older white British people living in areas with different levels of socioeconomic deprivation. The company confirmed that the average age of myCOPD users is 74 years old. The commissioning expert said that the implementation of myCOPD improved patients' access to health

services in areas of deprivation. The committee also discussed the English language skills needed to use myCOPD. The average reading age needed to use myCOPD is between 8 and 12 years. The clinical experts noted that myCOPD may be difficult to use for people who are not able to use a smart device easily, such as those with a visual or cognitive impairment, limited manual dexterity, or with hearing loss. They added that in their experience, some people with COPD would prefer not to use the digital tool, while others found it helpful. The committee concluded that further evidence of myCOPD's use in a wide range of socioeconomic backgrounds, ethnicities and ages is needed to understand its effect on health inequalities.

Cost modelling overview

Uncertainties about the clinical benefits of myCOPD are reflected in the cost modelling

4.7 The committee understood that clinical parameters in the AECOPD model (see section 3.7 for details about the models) for self-management were based on RESCUE, a feasibility trial with fewer than 50 patients. It noted that the key drivers of cost saving in this model were the uptake of myCOPD and hospital readmissions, and both parameters were uncertain (see sections 3.10 and 3.11). The PR model has 3 treatment options, so people were able to choose myCOPD, face-to-face pulmonary rehabilitation or a hybrid format which consisted of face-to-face sessions and myCOPD. Results from TROOPER were used in the PR model. Key drivers for cost savings in this model were the uptake of myCOPD, both alone and in the hybrid format, and the number of people referred for pulmonary rehabilitation. The committee considered that the key uncertainty for the PR model related to the assumption of non-inferiority of pulmonary rehabilitation services delivered by the myCOPD app compared with face-to-face pulmonary rehabilitation (see section 4.2). It also considered that more information is needed on the uptake rate of myCOPD when it is used for pulmonary rehabilitation (see section 4.5).

Further research

Further good quality evidence is needed to address uncertainties about myCOPD's clinical benefits and its effect on healthcare resource use

4.8 myCOPD has potential for clinical benefits, but more evidence is needed to reduce uncertainties. The committee considered that comparative evidence is needed to show the clinical benefits of using myCOPD in 2 populations:

- people using it to self-manage COPD
- people referred to pulmonary rehabilitation.

For self-management, a randomised controlled trial is preferred to show the clinical benefits of myCOPD. This could be powered based on the encouraging results in the RESCUE study. However, a high-quality comparative observational study designed to minimise bias in the results may provide acceptable evidence. Outcomes such as rates of exacerbations, hospital readmissions and unscheduled care appointments should be considered alongside patient-reported outcomes such as health-related quality of life. For pulmonary rehabilitation, further evidence is needed to show the clinical benefits of myCOPD. This could be a randomised controlled trial which is powered based on the encouraging results in the TROOPER study or a well-designed comparative observational study. Key outcomes will be the CAT score and 6-minute walk test, ideally supported by additional longer-term outcomes such as rates of exacerbations and hospital admissions.

4.9 Real-world data could be used to inform the uptake rates in the economic modelling. It should also include qualitative data on patient experience using myCOPD such as patient preferences and adherence.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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