

Single-Inhaler Triple Therapy in Primary Care Across Europe: Expert Panel Consensus on the Consequences of Payer-Driven Access Rules and Call to Action

Fabiano Di Marco¹, Orjola Shahaj², Arschang Valipour³, Bertrand Legrand⁴, Claudio Jommi⁵, Claudio Micheletto⁶, Claus Franz Vogelmeier⁷, Daryl Freeman⁸, Janwillem WH Kocks⁹, Luis Alves¹⁰, Myriam Calle Rubio¹¹, Rudi Peché¹², Susanna Palkonen Snr¹³, Tonya Winders¹⁴, Nicolas Roche¹⁵

¹Department of Health Sciences, Università Degli Studi Di Milano, Milan, Italy; ²Aquarius Population Health, London, UK; ³Department of Respiratory and Critical Care Medicine, the Karl-Landsteiner-Institute for Lung Research and Pulmonary Oncology, Vienna, Austria; ⁴Lille University Hospital Centre, Lille University, Lille, France; ⁵Department of Pharmaceutical Sciences, Università degli Studi Del Piemonte Orientale, Novara, Italy; ⁶Respiratory Division, Università Di Verona, Verona, Italy; ⁷Department of Pulmonology, University Hospital Marburg, Marburg, Germany; ⁸Norfolk Community Health and Care, Norwich, UK; ⁹Department of Pulmonology, University of Groningen, Groningen, the Netherlands; ¹⁰EPIUnit Instituto de Saúde Pública, Universidade Do Porto, Porto, Portugal; ¹¹Pulmonology Department, Instituto de Investigación Sanitaria Del Hospital Clínico San Carlos (Idissc), Madrid, Spain; ¹²Pulmonology Department, Charleroi, Belgium; ¹³European Federation of Allergy and Airways Diseases Patients Associations (EFA), Brussels, Belgium; ¹⁴Global Allergy & Airways Patient Platform, Vienna, Austria; ¹⁵Respiratory Medicine, Paris Cité University, Paris, France

Correspondence: Orjola Shahaj, Aquarius Population Health, Unit 16 Tileyard Studios, London, N7 9AH, UK, Tel +44 207 993 2930, Email orjola.shahaj@aquariusph.com

Background: Chronic obstructive pulmonary disease (COPD) is a prevalent condition characterized by persistent airflow obstruction and respiratory symptoms. Single-Inhaler Triple Therapy (SITT) has been shown to improve patient adherence, reduce exacerbations, and lower healthcare resource utilization in patients who are not controlled despite being on dual therapy or Multiple-Inhaler Triple Therapy (MITT). Despite evidence supporting SITT, payer-driven access rules across Europe sometimes limit its use in primary care, creating barriers to optimal COPD management.

Purpose: Through expert consensus, the study seeks to generate a shared understanding of the unintended consequences of payer-driven access criteria for SITT in managing moderate-to-severe COPD in primary care.

Methods: A targeted literature review (TLR) was conducted to assess SITT initiation in primary care across Europe and examine the impact of access criteria. Semi-structured interviews were held with 14 experts from nine European countries, including clinicians, health economists, and patient advocacy representatives. A consensus generation workshop was conducted, where experts evaluated the findings and developed position statements to highlight the challenges posed by payer-driven access criteria.

Results: The TLR identified variability in access to SITT in Europe, with several countries restricting its initiation to specialists, thus limiting primary care physicians' (PCPs) ability to prescribe SITT. The expert panel generated seven consensus points stating that enabling PCPs to step up or switch eligible patients to SITT has the potential to support care continuity, enhance clinical autonomy for PCPs, reduce reliance on potentially less effective treatment options, improve patient and healthcare system outcomes, avoid unnecessary referrals to specialists, enable prompt initiation of guideline-directed medical therapy for COPD in primary care and reduce access inequalities.

Conclusion: Restrictions for SITT initiation in primary care may need to be revisited to mitigate their unintended health and cost consequences and improve equitable access to treatment. This should take into consideration each country's unique healthcare system.

Keywords: COPD, single-inhaler triple therapy, payer, access, reimbursement, primary care, expert consensus

Introduction

Chronic obstructive pulmonary disease (COPD), characterized by permanent airflow obstruction and respiratory symptoms, represents a widespread condition; recent estimates suggest that the global prevalence could be as high as 392 million people^{1,2} while many cases remain undiagnosed. A review of community-based studies concludes that between 50%-70% of COPD worldwide may be undiagnosed.³ In 2021, COPD caused 45.2 deaths per million population worldwide, making it the third leading cause of mortality (excluding COVID-19).⁴ COPD patients typically suffer from reduced quality of life and increased susceptibility to comorbidities, especially cardiovascular disease.⁵ The disease course for moderate-to-severe COPD is often marked by acute respiratory events (exacerbations) and hospitalizations.⁶

COPD, alongside other respiratory conditions, results in significant healthcare resource utilization (HCRU) and imposes a substantial burden on healthcare systems.⁷⁻¹⁰ In the European Union (EU), respiratory diseases account for about 6% of the yearly healthcare budget, with COPD responsible for 56% of these costs, approximately 38.6 billion euros.¹¹ Exacerbations are frequently reported as the key driver of COPD's economic burden,¹² ranging from 45% to 70% of the total cost of managing the disease.¹³ Moderate-to-severe COPD patients experience increased likelihood and severity of exacerbations,¹⁴ contributing substantially to the disease burden and HCRU.¹⁵

COPD's optimal management aims to reduce symptoms and improve quality of life while preventing exacerbations, disease progression and mortality. It requires a multifaceted approach, including pharmacological and non-pharmacological interventions tailored to patients' needs^{16,17} and collaborative efforts between primary and secondary care providers. Pharmacological treatment choices are guided by the patient's symptoms, exacerbation risk, existing comorbidities, treatment response, preference, and ability to use different drug delivery devices.¹⁸ Adherence to guideline-directed medical therapy ensures that treatment plans consider all these elements and lead to better outcomes for patients and healthcare systems.¹⁹

The Global Initiative for Obstructive Lung Disease (GOLD) strategy document recommends the combination of a long-acting muscarinic antagonist (LAMA), long-acting β_2 -agonist (LABA) and an inhaled corticosteroid (ICS), referred to as "triple therapy", in moderate-to-severe COPD patients who are not adequately treated by dual therapy (LAMA/LABA). GOLD now also proposes first-line use of triple therapy in GOLD E patients (at risk of exacerbations) with > 300 blood eosinophils/ μL .¹⁷ Triple therapy can be administered as Multiple Inhaler Triple Therapy (MITT) or Single Inhaler Triple Therapy (SITT). The approved European Medicine Agency (EMA) indication for SITT is for patients who are not adequately controlled by dual therapy.²⁰⁻²²

Large randomized controlled trials (RCTs) comparing SITT to dual therapy (LABA/LAMA or ICS/LABA) demonstrated lower exacerbation rates and potentially decreased mortality for patients receiving SITT.^{23,24} Reductions in COPD-related HCRU and costs have also been found,²⁵⁻²⁸ mainly linked to the enhanced convenience and improved adherence that SITT offers compared to MITT.²⁹⁻³³ Despite this evidence, access to SITT in primary care for moderate-to-severe COPD patients differs widely across Europe,³⁴ influenced, among other factors, by payer-driven access criteria.³⁵

These criteria are typically intended to ensure prescription appropriateness and control costs.³⁵⁻³⁷ On the other hand, they may affect the management of moderate-to-severe COPD patients in some primary care settings³⁵ because they restrict the range of treatment options that primary care providers (PCPs) can prescribe. However, no studies have described or quantified this impact so far.

This expert panel aims to generate a shared understanding of the potential consequences of payer-driven access criteria for SITT in primary care in various EU healthcare systems and assess whether there is a need to revisit these criteria. Through a comprehensive review of the available evidence and expert opinion (the authors), this statement provides key arguments highlighting the importance of ensuring equitable access to SITT for moderate-to-severe COPD patients across primary and secondary care settings.

Materials and Methods

This study used three methods. First, a targeted literature review (TLR) was conducted to summarize the available evidence around SITT (clinical and economic impact compared to MITT and dual therapy) and how access to SITT in primary care varies across Europe. This was followed by in-depth semi-structured interviews to understand the views of various experts on how payer-driven access criteria that prevent PCPs from initiating SITT in eligible patients may affect

clinical practice, patients and healthcare systems. Lastly, a consensus generation workshop was run to develop a series of position statements that deliver evidence- and expert-backed arguments about the impact of payer-driven access criteria in primary care to inform policy recommendations.

Targeted Literature Review (TLR)

Initial scoping searches were used to draft a series of hypotheses (potential arguments) and link them to relevant research questions for the TLR (see [1 Appendix](#)). The research questions were then used to develop a PICO framework (see [2 Appendix](#)) to guide pragmatic PubMed and Google Scholar searches. Manual searches of grey literature were conducted to identify information about payer-driven access criteria (eg, HTA and reimbursement policy documents, etc). Published articles and grey literature items were included based on their relevance to answering the research questions.

A refined structure of the hypotheses outlined in [3 Appendix](#) was discussed with the experts; this was modified if there was insufficient evidence to back the arguments. Further amendments to the arguments were made based on the feedback provided by the experts (see section below on “Consensus generation activities”).

Predetermined data extraction frameworks were used to sort the TLR evidence, and narrative synthesis was used to analyze the findings.

In-Depth Semi-Structured Interviews

The semi-structured interviews were carried out by a team of two researchers (distinct from the expert panel) with a total of 14 experts: 11 clinicians involved in managing COPD (seven pulmonologists and four PCPs), one health economist, and two Patient Advocacy Group (PAG) representatives. The qualitative analysis followed the consolidated criteria for reporting qualitative research (CORE-Q) checklist.³⁸ Anonymized interview data were analyzed using reflexive thematic analysis.

Participant Selection

A total of 15 potential participants (internationally recognized external experts whose clinical and research work includes COPD and inhaled therapy) were approached through an email invitation, and 14 agreed to participate in the study. The participants that were approached met one of the following criteria: 1) PCPs or respiratory specialists involved in the management of moderate-to-severe COPD patients working in any of the following countries at the time of the study: Austria, Belgium, England, France, Germany, Italy, Netherlands, Portugal or Spain; or 2) COPD PAG representatives with a global or European remit; or 3) health economist or policy expert with a deep understanding of payer rules for the pharmacological management of COPD in primary and secondary care.

Purposive sampling was used to identify experts from various European countries to provide a balanced comparison across healthcare systems that apply different rules to accessing SITT in primary and secondary care.

Data Collection

Interviews took place between December 2023 and January 2024 online via Microsoft Teams®. All participants were provided with documentation outlining the nature and purpose of the study and how the data would be used, stored, and shared (the use of recordings and any future uses of the data). Participants provided informed written consent to participate, including consent to quote their words to substantiate the findings. All communications with the experts who participated in the study were managed online, including initial contact, scheduling, and conducting the interviews via emails and virtual meetings.

An example of an interview discussion guide is provided in [4 Appendix](#). Two interviewers were present in each call: a lead and a notetaker. Transcripts were not returned to participants for correction, but a summary of key findings was shared with all participants, and they were requested to corroborate the interpretation of interview data. All participants consented to receive follow-up emails with clarifying questions regarding the interview content.

Data Analysis

A mix of deductive and inductive approaches was used. A predetermined coding framework derived from [1 Appendix](#) guided the line-by-line coding in NVivo® to ensure that the interview data were organized in a similar structure as the TLR hypothesis. New codes were added to the framework wherever necessary (inductive component).

Consensus Generation Activities

Following the individual interview process, the experts were invited to participate in a consensus-generation workshop that shaped agreement on the consensus arguments.

The experts received a pre-read prior to the workshop, which included the results of the TLR, themes from in-depth interviews, and an initial draft of the consensus arguments for validation (3 Appendix). Given the different nature of challenges in each country, the experts ranked the arguments and statements based on their applicability and relevance to each expert’s country (5 Appendix).

A consensus generation workshop was then launched as a videoconference, with a moderator (distinct from the expert panel members) leading all the sessions. The experts were organized into four panels based on the status of payer-driven access criteria in their countries: a) PCPs face restrictions to prescribe SITT, b) no restrictions, c) restrictions lifted recently and d) experience from PAGs. Each expert was actively involved by asking questions about the impact of the payer-access criteria, focusing on identifying the key components of the “call to action” and optimal solutions.

The consensus arguments and their corresponding rankings of relevance were shared and discussed in the workshop. Group agreement was reached on (1) streamlining the arguments by removing those that did not apply to all countries and (2) refining the language for the arguments.

Finally, a written document including unanimously endorsed position statements and a summary of the evidence from the TLR and qualitative research were shared offline with the experts for their final approval, alongside a live version to provide comments. Similar to the workshop, an independent moderator (not part of the expert panel) facilitated the resolution of contradicting views through mutual agreement between the experts to reach full alignment.

Ethics

No personal or patient-specific information was collected during the interviews and workshop discussions. Participants were asked questions regarding the healthcare services for COPD in their country. Therefore, the project was deemed a service evaluation, and no ethics approval or review was necessary. Any data collected before, during and after the interview was handled following the European Union’s General Data Protection Regulation (GDPR) legislation.

Results

Targeted Literature Review

Only one published article described how access to triple therapy (focusing specifically on SITT) varies across Europe,³⁴ most of the evidence on the status of payer-driven access rules for SITT was informed by grey literature. Table 1 describes some of the payer-driven access criteria that affect the pharmacological management of COPD in primary care. In most European countries, these restrictions are not in place or have been lifted recently (France and Spain). However, in several others (eg, Austria, Bulgaria, Czech Republic, Greece, Hungary, Italy, Lithuania, and Romania), PCPs cannot initiate SITT because its initial prescription is limited to a respiratory specialist (or in some cases to other specialists such as internists).

Table 1 Description of Some Payer-Driven Access Rules for Triple Therapy in Primary Care Across European Countries

Country ^a	Access Rules for Triple Therapy (Including MITT and SITT) ^b in Primary Care	Other Access Rules Around the Pharmacological Management of COPD in Primary Care	Reference
Austria	Initiation limited to pulmonologists; PCPs can repeat	The initiation of dual therapy (ICS/LABA or LAMA/LABA) is also limited to specialist initiation	Osterreichische Sozialversicherung ³⁹
Bulgaria	Initiation limited to pulmonologists; PCPs can repeat	The initiation of all pharmacological treatment for COPD is limited to specialists; PCPs can repeat	National Health Insurance Fund ⁴⁰

(Continued)

Table 1 (Continued).

Country ^a	Access Rules for Triple Therapy (Including MITT and SITT) ^b in Primary Care	Other Access Rules Around the Pharmacological Management of COPD in Primary Care	Reference
Czech Republic	Initiation and repeat prescriptions are limited to pulmonologists; PCPs cannot initiate or repeat prescriptions	The initiation of ICS/LABA (fixed-dose), LAMA/LABA (fixed-dose) and LAMA are limited to pulmonologist only; PCPs cannot initiate or repeat prescriptions; ICS and LABA separately are not limited to specialists	Database of registered and reimbursed products ⁴¹
Estonia	Initiation limited to pulmonologists; PCPs can repeat	All treatment options for COPD need to be initiated by a specialist	Estonian Health Insurance Fund ⁴²
Greece	Pulmonologist initiation required for SITT, PCPs can repeat it	PCPs can initiate MITT; LAMA/LABA requires specialist initiation	Greece Ministry of Health ⁴³
Hungary	Initiation limited to pulmonologist initiation, PCPs can repeat		Healthcare Professional Guideline On the diagnosis, treatment, and management of chronic obstructive pulmonary disease (COPD) - State Secretariat for Health ⁴⁴
Italy	Specialist initiation required for SITT, PCPs can repeat if a specialist-approved treatment plan is available	PCPs can initiate MITT	Agenzia Italiana del Farmaco; Nota 99 ⁴⁵
Lithuania	Pulmonologist initiation for severe COPD	PCPs can initiate triple therapy for moderate COPD	Expert opinion
Romania	Pulmonologist initiation, PCPs can repeat		Expert opinion

Notes: ^aThis list is informed by the desk research for this expert panel consensus, and it may not represent an exhaustive list of all countries that apply payer-driven access criteria in the EU; ^bOnly rules that touch upon the initiation of MITT and SITT in primary care were scrutinized- other payer-driven access criteria affecting triple therapy (and the wider pharmacological management of COPD) are in place in these countries.

Abbreviations: MITT, multiple-inhaler triple therapy; SITT, single-inhaler triple therapy; PCP, primary care provider; COPD, Chronic Obstructive Pulmonary Disease; LAMA, long-acting muscarinic antagonist; LABA, long-acting beta agonist; ICS, inhaled corticosteroid.

No published evidence was identified to describe the impact of payer-driven access criteria for SITT in primary care. There was good availability of evidence on the impact of using triple therapy (both SITT and MITT) on patients and healthcare systems. [Appendix 6](#) provides details from 46 articles that compared SITT with dual therapies, six articles that compared prompt initiation of triple therapy (both SITT and MITT) after a COPD exacerbation to delayed treatment initiation, and 23 articles comparing SITT to MITT.

Themes From Qualitative Analysis of Interview Data with the Experts

Following the in-depth interviews with 14 experts, we identified five themes: *1-Variations between countries; 2-Unintended consequences; 3-Specialist access; 4-Remaining challenges; and 5-Access inequalities for patients*. The detailed themes and subthemes are presented in [Table 2](#).

The experts confirmed the TLR findings that while triple therapy is authorized in the EU as maintenance treatment for moderate-to-severe COPD patients who remain uncontrolled despite being on dual therapy, in some countries, it is subject to payer-driven access criteria that prevent its initiation in primary care. In these cases, either specialist initiation or approval of the therapeutic plan by a specialist is required. These restrictions may apply to MITT and SITT, but SITT seems disproportionately affected (in some countries, dual therapy initiation is also limited to specialist initiation only; see [Table 1](#)). The experts referred to cases where restrictions apply only to SITT while PCPs can initiate MITT (eg in Italy and Greece), posing logical inconsistencies and further complicating the treatment landscape.

Table 2 Themes and Subthemes From Analyzing 14 Interview Transcript With Experts Across Nine Countries: Austria, Belgium, England, France, Germany, Italy, Netherlands, Portugal and Spain

Theme	Interpretation	Subthemes
I. Variations between countries	Variations in access criteria about TT that affect the clinical management of moderate-severe COPD patients in primary care	1.1 The initiation of TT in primary care is to some extent determined by the presence or lack of payer-driven access rules 1.2 There is variation in how limiting or strict these criteria are, but they usually limit PCPs ability to initiate treatment with TT 1.3 In some settings, PCPs can prescribe MITT but not SITT, posing logical inconsistencies in access-rules 1.4 Payer-driven access criteria about TT may be linked to other requirements that aim to improve the clinical management of COPD patients, such as spirometry results 1.5 The criteria are often in place to ensure the appropriateness of prescriptions or contain costs
I. Unintended consequences	Payer-driven access criteria around the pharmacological management of COPD may have unintended consequences	2.1 Reduced autonomy of primary care physicians when they cannot prescribe the full range of available treatment options for their COPD patients 2.2 Payer-driven access criteria perpetuate a lack of awareness among PCPs about the availability of better treatment options (ie, SITT versus MITT) 2.3 Access criteria contribute to interrupted care journey for COPD patients who struggle with access to specialists 2.4 Increased barriers to timely access to guideline-directed medical therapy may lead to suboptimal outcomes, resulting in higher costs in the long-term 2.5 Some payers have changed some access criteria when sufficient evidence of the unintended consequences is provided (France, Spain)

I. Specialist access	The impact of the access criteria on the utilization of triple therapy depends on the organization of the healthcare systems regarding specialist access	3.1 Areas with reduced access to specialists (eg, rural) may be disproportionately affected by the payer-driven access criteria for TT 3.2 Where no referral to access specialists is required, the impact of the access criteria may be smaller 3.3 The long waiting times to see a specialist in some settings might further worsen the barriers patients face in accessing TT
I. Remaining challenges	The lack of payer-driven access criteria for SITT does not always mean optimal management of COPD patients in primary care	4.1 Insufficient awareness among PCPs about the availability of more cost-effective treatment options (ie, SITT versus MITT) 4.2 The availability and quality of spirometry to diagnose and assess the severity of COPD remain pervasive issues across European countries 4.3 The prescription appropriateness of TT among PCPs can be further improved by education and training
I. Access inequalities for patients	Patients see access criteria for SITT as a driver of inequality, especially when treatment initiation depends heavily on having good access to specialists	5.1 Timely access to effective pharmacological options is more important to patients than which physician provides the treatment 5.2 Treatment optimization at the first point of call following an exacerbation is essential for COPD patients, who are often discharged to see their PCPs

Abbreviations: TT, triple therapy; SITT, Single-inhaler triple therapy; MITT, multiple-inhaler triple therapy; PCPs, primary care providers; COPD, chronic obstructive pulmonary disease.

The experts perceived several potential unintended consequences arising from payer-driven access criteria for SITT in primary care, including reduced PCP autonomy, perpetuation of lack of awareness about SITT, interruption of patient care journeys, and possibly suboptimal outcomes leading to higher long-term costs. The experts explained that the extent of these unintended consequences is influenced by the organization of the healthcare system, particularly regarding specialist access. They suggested that areas with limited specialist access may be disproportionately affected, whereas in healthcare systems where no referral to specialists is required (eg, Austria), some of the unintended consequences may be mitigated by direct access to specialists.

However, even in countries with no payer-driven access criteria for SITT, experts identified ongoing obstacles to optimal COPD management in primary care. These included their perceptions of insufficient PCP awareness about SITT, limited availability of quality spirometry, and the need for improved prescription appropriateness through education.

According to the PAG representatives, patients view payer-driven access criteria as drivers of inequality, especially when treatment initiation depends heavily on specialist access. They reported that patients prioritize timely access to effective treatment options at the first and most convenient point of contact with the healthcare system.

Finally, the experts highlighted the complex interplay between payer-driven access criteria for the pharmacological management of COPD, healthcare system organization, and the need for continuity of care for COPD patients. They suggested the need for potential policy initiatives to reduce avoidable barriers to guideline-directed medical therapy in primary care.

Results From Consensus Generation Activities

After considering the TLR evidence, qualitative evidence from the interviews, and the workshop discussions (see [Appendix 4](#) for the experts' ranking of the initial hypothesis), seven position statements were endorsed by all the 14 experts in the panel ([Figure 1](#)).

Discussion

The findings from the in-depth interviews and the consensus generation activities showed that the views of the experts in this panel were aligned; payer-driven access criteria can have unintended consequences on the clinical practice when managing COPD patients in primary care. The lack of peer-reviewed publications that quantify this impact can be a barrier to providing payers with sufficient evidence for revisiting the criteria. However, the position statements provided by the expert panel could serve as a valid indication that the payer-driven access criteria in primary care represent an avoidable barrier to the continuum of care for COPD patients in countries where they are applicable.

This discussion further elaborates on each statement to showcase the rationale behind each statement and provide further interpretation in light of available evidence on SITT.

The position statements are shaped by the experts' views and their interpretation of the available evidence. The expert's previous experience with inhaled therapy for COPD and, more specifically, with SITT may introduce an unavoidable selection bias that must be considered when interpreting each statement.

Position Statement 1

There is an unmet need for appropriate pharmacological management among COPD patients who remain inadequately treated by dual therapy or MITT in primary care, adding to COPD's clinical and economic burden.

A significant proportion of moderate-to-severe COPD patients in primary care who are eligible for SITT remain inadequately controlled with dual therapy or MITT.^{35,46–55} The persistence of symptoms and exacerbations despite being on treatment highlights potential issues with current COPD management strategies in primary care.⁴⁶ Among other reasons (eg, issues related to medication adherence and the severity of individual cases), inappropriate therapy selection^{53,55,56} and a lack of treatment adjustments⁵⁷ based on patient-specific disease progression are important contributors.

It is worth emphasizing that the nature of the unmet need in primary care may be different for patients on LAMA/LABA dual therapy from those treated with MITT, given that patients on MITT already have an ICS in their regimen and the poor symptom control may be attributable to issues with persistence and adherence⁵⁸ (further explored in Position Statement 2).

Patients who do not respond to dual therapy often experience a lower quality of life, marked by increased dyspnoea, fatigue, and limited physical activity.^{26,28,46} Frequent exacerbations, which are common in this population, lead to

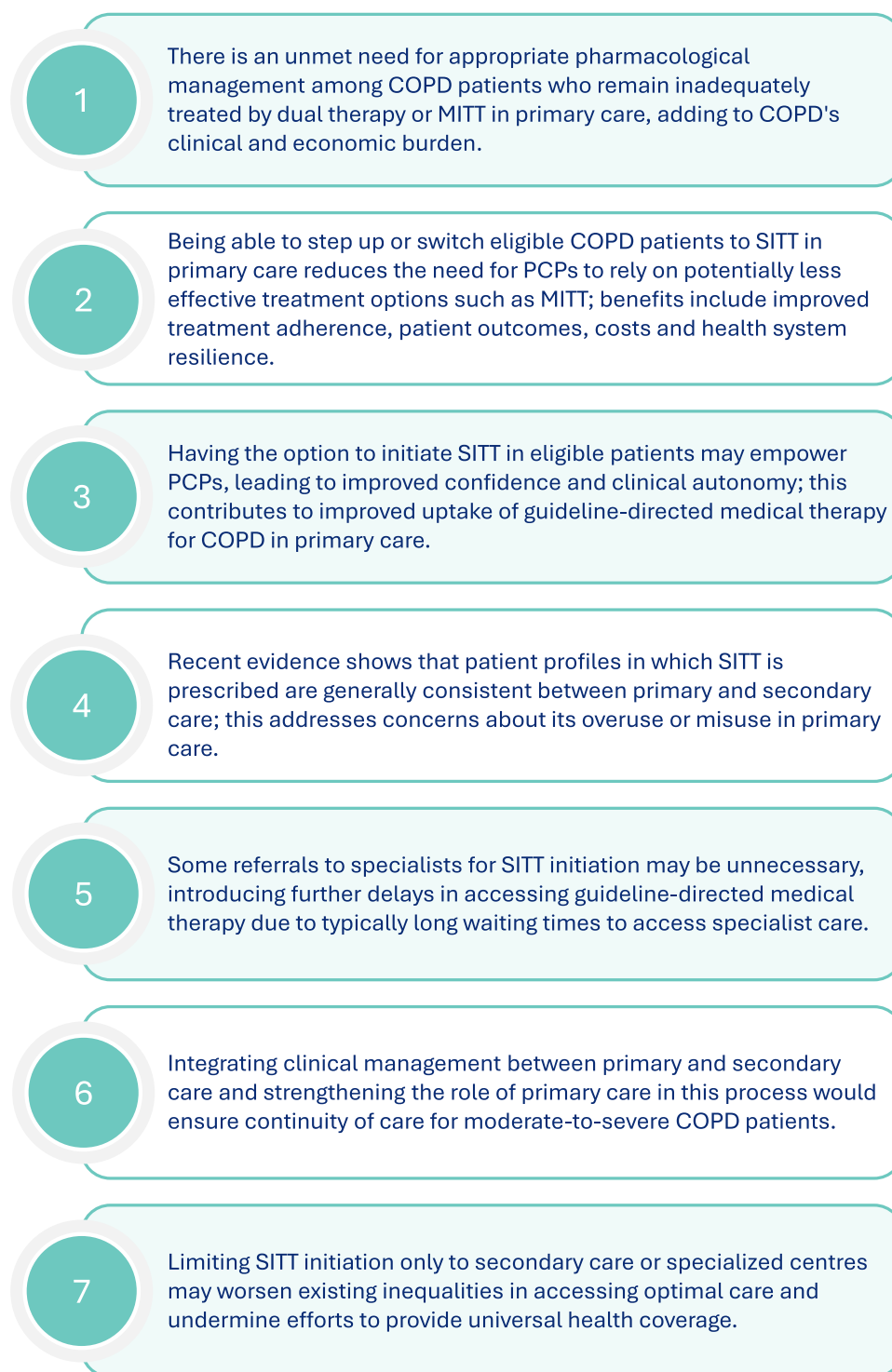


Figure 1 Final position statements (seven) emerging from the expert consensus panel on the need to revisit payer-drive access rules that prevent primary care physicians from prescribing single-inhaler triple therapy to moderate-to-severe COPD patients that meet clinical criteria according to the guidelines.

a further decline in lung function, increased hospital admissions, increased cardiopulmonary risk, and a greater risk of mortality.^{59–62} The physical and psychological distress associated with uncontrolled symptoms significantly impacts patients' overall well-being and ability to perform daily activities.^{46,59}

From an economic perspective, inadequately managed COPD places a burden on healthcare systems; frequent exacerbations, hospitalizations, and cardiovascular events associated with poorly controlled COPD result in high direct medical costs.^{61–64}

Policymakers, payers, and healthcare providers must understand this unmet need and revisit any policies or access rules that further complicate the care pathway to optimized treatment for COPD patients who remain uncontrolled on dual therapy or MITT in primary care.

Position Statement 2

Being able to step up or switch eligible COPD patients to SITT in primary care reduces the need for PCPs to rely on potentially less effective treatment options such as MITT; benefits include improved treatment adherence, patient outcomes, costs and health system resilience.

In the management of COPD, the availability of SITT can influence the choice of treatment strategies for healthcare providers; when PCPs lack access to initiate SITT, it impacts their prescribing patterns and attitudes towards managing moderate-to-severe COPD patients.^{35,36,65} This limitation often forces PCPs to rely on MITT (in countries where they can initiate it), which involves the use of multiple inhalers.³⁵ This can lead to increased complexity in managing medication regimens for patients and decreased treatment adherence.³⁰ Prescribing MITT instead of SITT can adversely affect patient-reported outcomes; compared to MITT, SITT is preferred by patients and associated with higher quality of life.^{29,66} The impact of prescribing MITT instead of SITT also extends to clinical outcomes. Studies have demonstrated that SITT can lead to better symptom control, reduce the rate of exacerbations, and potentially lower mortality compared to MITT.^{31,32,67,68}

The effectiveness of COPD treatment regimens relies significantly on patient adherence and proper inhaler technique. Current evidence suggests that treatment adherence rates are notably higher with SITT compared to MITT,^{30,32,69,70} supporting a stronger case for the preferential use of SITT in clinical practice for patients who are eligible for triple therapy. This is primarily due to SITT's simplified regimen, which involves only one inhaler instead of the multiple devices required in MITT. This is easier for patients to manage and reduces the likelihood of missing doses, a common issue involving multiple inhalers.⁷¹ Moreover, the potential for inhaler usage errors is markedly reduced with SITT.⁶⁶ The complexity of handling multiple inhalers may lead to incorrect use,^{30,72} which can significantly undermine the effectiveness of the therapy.

Lastly, the economic implications of prescribing SITT versus MITT are significant. SITT is cost-saving compared to MITT due to higher adherence rates, decreased exacerbations, and hospital visits.^{32,33} This reduces direct healthcare costs associated with treating exacerbations and decreases the overall healthcare resource utilization.^{32,73} Patients also benefit from switching to SITT as this reduces out-of-pocket payments due to prescription charges (patients that are prescribed MITT pay more than one prescription charge); in the UK, the prescription charge is £9.99 per medicine⁷⁴).

Enabling step-up or switching to SITT for COPD patients who remain poorly controlled despite receiving dual therapy or MITT can improve prescribing patterns for PCPs, enhance patient-reported and clinical outcomes, and lead to cost savings when managing COPD. Healthcare policies must align to support the use of the most effective and efficient therapies in primary care.

Position Statement 3

Having the option to initiate SITT in eligible patients may empower PCPs, leading to improved confidence and clinical autonomy; this contributes to improved uptake of guideline-directed medical therapy for COPD in primary care.

Primary care settings play a pivotal role in managing COPD,⁷⁵ including regularly reviewing patient conditions, modifying treatment plans, and making necessary specialist referrals.⁷⁶ PCPs' active engagement in these areas is crucial for timely adjustments to treatment as the disease progresses. When PCPs are restricted from initiating treatment options like SITT, their ability to provide optimal care is limited. This impacts PCPs' clinical autonomy, diminishing their ability to make independent, informed decisions regarding the pharmacological management of moderate-to-severe COPD patients. Such constraints can also affect the interest and engagement in managing these patients altogether, leading to therapeutic inertia marked by clinical and economic consequences.^{46,77} Moreover, the restrictions can lead to frustration and dissatisfaction among PCPs, further complicating the management landscape of COPD.

However, all clinicians should recognize the negative consequences of inappropriate prescribing of ICS⁷⁸ and ensure the step-up to SITT is done in line with clinical guidelines and treatment indications. Education of PCPs and improved awareness of guidelines will have an impact on prescribing.

Enabling PCPs to initiate the full range of the necessary treatment options in primary care, alongside improved training and education around SITT, could mitigate some of the therapeutic inertia and the associated burden; a balanced view of benefits and risks is essential to ensure the step-up to SITT leads to improved outcomes.

Position Statement 4

Recent evidence shows that patient profiles in which SITT is prescribed are generally consistent between primary and secondary care; this addresses concerns about its overuse or misuse in primary care.

One of the reasons why payers sometimes impose access rules on SITT is concerns about prescription appropriateness, particularly in primary care settings compared to secondary care.³⁴ These concerns stem from assumptions that PCPs might not have the same specialized expertise as their secondary care counterparts, potentially leading to inappropriate prescribing. However, although relatively limited, the available evidence indicates that the characteristics of the patients for whom SITT is prescribed are the same, irrespective of whether PCPs or specialists in secondary care initiate the treatment.^{70,79–81} This evidence supports the argument for equitable access to SITT across different care settings, ensuring that all patients who meet the clinical criteria can benefit from this treatment option at the earliest point of interacting with the healthcare system without unnecessary restrictions.

However, even when there are no restrictions in place, there is insufficient awareness among PCPs about the availability of more convenient and effective treatment options such as SITT compared to MITT.⁸² Moreover, the diagnosis and assessment of COPD severity are often hindered by the availability and quality of spirometry,^{36,65,83,84} which can lead to delays in diagnosis or misclassification of disease severity,⁸⁵ affecting the initiation of any COPD treatment, including SITT. Programmes to improve access to and use of spirometry are needed to overcome this challenge. They should be linked to targeted education and training in primary care settings to improve the appropriateness of treatment prescriptions for COPD.⁸⁶

Position Statement 5

Some referrals to specialists for SITT initiation may be unnecessary, introducing further delays in accessing guideline-directed medical therapy due to typically long waiting times to access specialist care.

PCPs are central in COPD management,⁷⁵ including making decisions about when to escalate treatment and refer to a specialist. When PCPs have access to all available treatment options, they are more likely to assume greater responsibilities in managing COPD patients in primary care.^{35,87,88} If they cannot provide the necessary treatment option, they might default to referring patients to specialists. Some of these referrals could be unnecessary or contribute to increased waiting times before COPD care is provided,⁶⁵ leading to inefficiencies in patient pathways.⁸⁹

This is particularly relevant in countries where a PCP referral is requested to see a specialist. The waiting time to see a specialist for COPD varies widely,⁹⁰ and it is determined by various factors, but the experts in this panel reported that it ranges from a few weeks to up to 12 months. The clinical outcomes of delayed access to SITT are significant; prolonged periods without optimal treatment can lead to increased rates of exacerbations,^{91–93} and poor symptom control.⁹⁴ As a correlate, delays in receiving the most effective treatment can lead to increased HCRU, including more frequent hospital admissions, emergency visits, and a general escalation in healthcare costs associated with managing acute exacerbations and complications of inadequately treated moderate-to-severe COPD.^{58,93,95–97}

Streamlining the patient pathway to SITT by removing unnecessary barriers where possible could result in more efficient use of healthcare resources.

Position Statement 6

Integrating clinical management between primary and secondary care and strengthening the role of primary care in this process would improve continuity of care for moderate-to-severe COPD patients.

COPD is a highly prevalent disease,⁹⁸ and integrated clinical management between primary and secondary care is crucial for maintaining continuity of care throughout the healthcare system, particularly for patients with moderate-to-severe COPD.⁹⁹ Strengthening the role of primary care in this integrated model is expected to enhance the patient experience by ensuring that the care journey is responsive to the patient's needs at various stages of their treatment.^{100–102}

Collaboration and integration between primary care and specialists are crucial for limiting therapeutic inertia in COPD, especially in patients with inadequate pharmacological treatment regimens.¹⁰³ Furthermore, such models contribute to better overall health outcomes and have been shown to be cost-effective.^{104–107}

PCPs are well-positioned to manage patients with comorbidities, as they can integrate and coordinate information from different specialities.⁸⁸ This is particularly beneficial in COPD management, where comorbid conditions such as cardiovascular disease, diabetes, and anxiety frequently coexist and can complicate treatment protocols.^{88,108} Primary care physicians' holistic view of their patients' health allows for more comprehensive management for moderate-to-severe COPD patients.¹⁰⁹

Enhancing the role and autonomy of primary care and improving collaboration, communication and integration with secondary care is essential for ensuring continuity of care for moderate-to-severe COPD patients.^{35,110,111}

Position Statement 7

Limiting SITT initiation only to secondary care or specialized centres may worsen existing inequalities in accessing optimal care and undermine efforts to provide universal health coverage.

Access to specialist care for COPD varies between and within countries,^{112,113} often reflecting broader healthcare resource distribution and infrastructure differences.³⁶ In some areas, access to specialists may be limited and requires travel time, which places a burden on patients who need regular and specialized COPD management.^{36,114}

Geographic and socioeconomic factors significantly influence the unequal access to quality care for COPD patients.^{113,115} Those living in remote or economically disadvantaged areas are less likely to have timely access to specialist care, including access to treatment such as SITT.³⁶ This uneven access landscape can lead to disparities in health outcomes.^{116,117}

The timing and appropriateness of pharmacological interventions play a critical role in managing moderate-to-severe COPD,^{91,92} often outweighing the importance of who initiates the treatment (PCP or specialist).^{38,46} For example, treatment optimization at the first point of call following an exacerbation is vital for COPD patients. When access to specialists is limited, PCPs become crucial in ensuring the continuity of care. They carry out critical tasks such as adjusting and optimizing treatment plans based on the current clinical status and recent exacerbations.⁷⁶

Considering all the above, payer-driven access criteria may inadvertently affect the equity and continuity of care for moderate-to-severe COPD patients; health policies must promote equitable access to COPD treatments across all levels of care, ensuring that all patients, regardless of their geographical location or economic status, can receive the best possible care for their condition.

Conclusion

Payers need to consider reassessing the criteria that limit PCPs' ability to initiate SITT in countries where they are still applicable to mitigate the unintended consequences that may affect patient outcomes, healthcare system efficiency, costs and equitable access to care. This reassessment should be done in line with considerations about the unique features of each country's healthcare system and the available evidence that demonstrates the impact.

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