

Chronic Obstructive Pulmonary Disease (COPD) Monitoring Program

Clinical Protocol



Patients who are ineligible for the COPD Monitoring Program:

- Patients who are planning a pregnancy or pregnant
- Patients aged < 35 years
- Patients with no persistent COPD symptoms or risk factors (without a previous diagnosis)
- Patients receiving specialist treatment for COPD or another respiratory condition (e.g., by a specialist respiratory physician currently, or within the previous 12 months) without a written referral from the treating specialist(s) for the COPD Monitoring Program
- Patients with moderate or severe COPD or who have had ≥ 2 moderate COPD exacerbations (that required systemic corticosteroids and/or antibiotics to treat) in the previous 12 months, or who have ever been hospitalised for a COPD exacerbation
- Patients with any of the following conditions:
 - Asthma
 - Complex, established cardiovascular disease, including pulmonary hypertension and Cor pulmonale
 - Diabetes
 - Psychiatric comorbidities e.g., depression, anxiety disorder/panic attacks.



Warning signs at patient presentation that necessitate urgent referral to emergency medical care or a medical practitioner:

- Patients in respiratory distress (e.g., unable to complete a whole sentence in one breath)
- Patients with chest tightness or discomfort during/after exercise, without other symptoms of asthma.

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How to use this document

This clinical protocol details how patients in the COPD Monitoring Program should be managed, including referral to other health services and medical practitioners, pharmacological interventions, and protocol-based/structured prescribing of specific medicines for the management of COPD.

The following pages provide detailed information that corresponds to the numbered phases in the COPD Monitoring Program overview algorithm (refer to Figure 1).

When applying the information contained within this clinical protocol, pharmacists are advised to exercise professional discretion and judgement. The clinical protocol does not override the responsibility of the pharmacist to make decisions appropriate to the circumstances of the individual, in consultation with the patient and/or their carer.

Key points

- The purpose of the COPD Monitoring Program (the Program) is to provide an accessible, community-based health care service to identify and improve outcomes for patient with COPD.
- Chronic obstructive pulmonary disease (COPD) is a progressive respiratory disease characterised by persistent airflow limitation and respiratory symptoms due to small airway abnormalities and/or alveolar destruction (emphysema) ⁽¹⁻⁵⁾.
- COPD is caused by an abnormal inflammatory response in the lungs to noxious particles or gases, generally resulting from tobacco smoke (either directly or passively) or other environmental exposures to air pollution or other occupational dust ⁽²⁻⁶⁾.
- COPD is preventable and treatable, but not fully reversible. Management is stepwise and aims to:
 - relieve symptoms
 - prevent and treat exacerbations
 - improve of exercise tolerance
 - improve of health-related quality of life
 - delay/slow the progression of the disease ^(2, 3, 5).
- Patients with COPD may also experience exacerbations/flare ups (acute worsening of symptoms that extends beyond expected day-to-day symptom variation) that increase in frequency as the disease progresses and require additional therapy ^(4, 7). Exacerbations may be:
 - mild (treated with short acting bronchodilators and usually self-managed)
 - moderate (requiring systemic corticosteroid treatment and/or antibiotic therapy)
 - severe (requiring hospitalisation) ⁽⁴⁾.



Refer when

During the Program, patients must be referred to a medical practitioner for ongoing management if:

- They have or develop any alarm signs and symptoms including haemoptysis, unexplained weight loss, recurrent pneumonia and oedema
- They develop any symptoms or features that suggest the COPD has progressed to moderate or severe COPD
- They have symptoms and features that favour both asthma and COPD or suggestive of another respiratory condition other than asthma or COPD that is not suitable for management under the program
- They are diagnosed with, or develop signs or symptoms of a serious comorbidity or pathology
- They have a suspected bacterial infection that requires antibiotic therapy.
 - They may continue to be managed in the program following concurrent referral to a medical practitioner for antibiotic therapy
- Their symptoms do not improve after 1 month or worsen following commencement of step 3 long-acting bronchodilator dual therapy (LAMA + LABA)
- They have spirometry results that do not demonstrate persistent airflow limitation, or results that are unexpected/difficult to interpret.

Overview of the COPD Monitoring Program

There are two entry points for patients who are appropriate for enrolment in the Program:

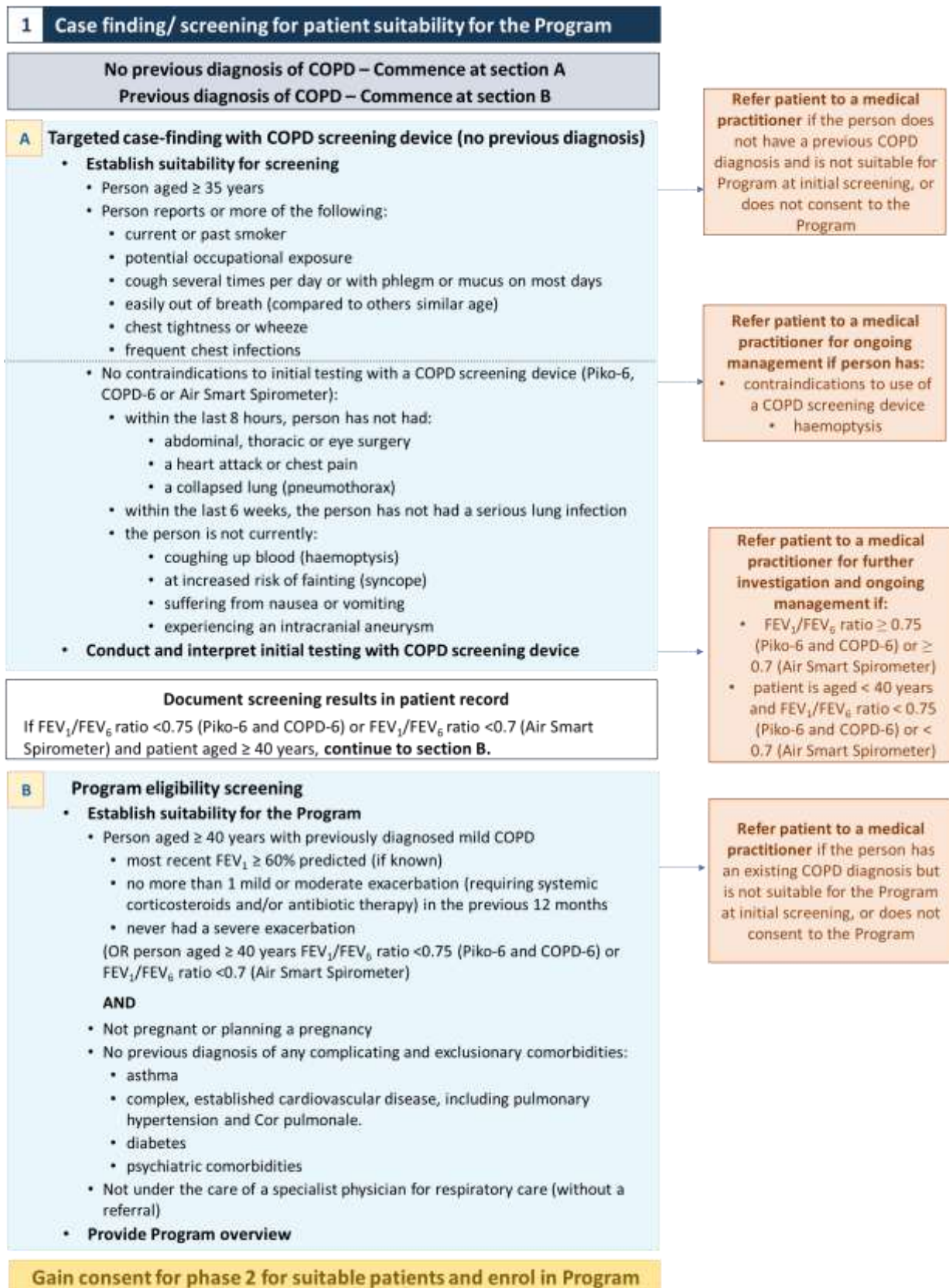
- Patients **without a previous diagnosis** of COPD may be enrolled in the program and commence management concurrent to referral to a medical practitioner for further review and collaborative care.
- Patients **with an existing diagnosis** of COPD may be enrolled in the Program and commence management provided the patient's usual medical practitioner is notified and updates are provided following each occasion of care.

The Program (Figure 1) is based on information provided in the Therapeutic Guidelines and the 2021 COPD-X Plan, and involves:

- **case finding (and referral if indicated)** for patients aged 35 years and older, as per Figure 1
- **standardised and structured assessment** for patients aged 40 years and older, as per Figure 3
- **management of mild COPD** (FEV₁ between 60% and 80%) for adults aged 40 years and older, including patients identified through the Program
- **monitoring** of disease progression and referral for multidisciplinary team care (including to a medical practitioner) when required.

Patients with an existing diagnosis of mild COPD may be referred into the Program for management and monitoring by a medical or other health practitioner. Alternatively, patients may self-refer or request screening for COPD, or the pharmacist may suggest initial screening or enrolment if they believe the patient may be eligible and benefit from the Program.

Figure 1. Overview of the COPD monitoring program



See over page

2 Conduct initial assessment

C Take a detailed patient history:

- Patient characteristics
- Medical history
- Lifestyle/ social history
- Review previous test results (if available)

If the person has no previous diagnosis of COPD – consider contraindications to spirometry

D Assess severity of COPD symptoms (COPD Assessment Test)

E Conduct physical examination

F Conduct (or refer for) spirometry testing (If no previous diagnosis, no recent results (within previous 3 months) and not contraindicated)

G Interpret spirometry

- Persistent airflow limitation ($FEV_1/FVC \leq 0.7$, with an FEV_1 of $< 80\%$ of the predicted value (post-bronchodilator))
 - **Mild COPD:** $FEV_1 = 60$ to 79% of predicted lung function
 - **Moderate COPD:** $FEV_1 = 40$ to 59% of predicted lung function
 - **Severe COPD:** $FEV_1 = < 40$ of predicted lung function

Initiate collaborative care for persons suitable for phase 3

Existing diagnosis of COPD – Notify the person’s medical practitioner

No previous diagnosis of COPD – The person must be concurrently referred their medical practitioner

Refer to a medical practitioner for ongoing management if clinical features or symptoms indicate:

- a respiratory condition other than, or coexisting with COPD
- alarm symptoms or findings
- moderate or severe COPD (and/or CAT score = high/very high impact)

Refer to a medical practitioner for ongoing management if the person has contraindications to spirometry (that will not resolve with time)

Refer to a medical practitioner for ongoing care if spirometry results:

- are inconsistent with COPD (or difficult to interpret)
- indicate a respiratory condition other than, or coexisting with COPD
- alarm symptoms or findings
- show abnormal restrictive or mixed ventilatory patterns.
- indicate moderate-severe COPD

3 Develop and implement management plan

H General measures

- **Manage risk factors**
 - Avoidance of exposure to risk factors
 - Smoking cessation
 - Immunisation
- **Optimising function**
 - Exercise and physical activity
 - Pulmonary rehabilitation
 - Diet and nutrition

I Pharmacotherapy

- **Stepwise pharmacological management of stable COPD**
 - Step 1 – 3 as per Therapeutic Guidelines
- **Managing exacerbations (self-management)**
 - Initial and secondary pharmacotherapy: inhaled bronchodilator and prednis(ol)one as per Therapeutic Guidelines

J Confirm management plan is appropriate

K Communicate agreed management plan

Communicate with person’s usual medical practitioner to enable collaborative care (with person’s consent):

- Provide a copy of the COPD Action Plan and Program Lifestyle Prescription (appendix 1) that includes:
 - current level of symptom control (CAT score)
 - new pharmacotherapy or changes to existing pharmacotherapy for COPD
 - next scheduled review appointment.

See over page

4 Ongoing management and monitoring

L Clinical review

- **3 months** after commencement of Program or after initiation/changes to pharmacotherapy, including step up
- **6 months** for patients with stable pharmacotherapy and COPD (with no increase in symptom frequency, severity or exacerbations)
- **As soon as possible (unscheduled):**
 - if there is any deterioration in condition
 - if adverse effects are experienced
 - after an exacerbation (where pharmacotherapy is used by the patient)

At each review appointment (either scheduled or unscheduled):

- review and update patient history
- assess level of symptom control
- review the patient's suitability to continue participating in the Program
- review and reinforce inhaler technique and adherence to pharmacotherapy
- update the COPD Action Plan and reinforce general measures
- Consider appropriateness of pharmacotherapy
- ensure patient has enough medication until next scheduled review
- provide referrals for multidisciplinary care (if required).

Communicate with person's medical practitioner to enable collaborative care (with person's consent):

- Advise of changes to COPD Action Plan
- Person no longer suitable for Program - Refer for ongoing management

The patient's suitability for the Program may change at any point.

Refer to a medical practitioner for ongoing management if the person:

- develops alarm symptoms or findings
- develops new or worsening clinical features or symptoms, including symptoms not adequately managed with pharmacotherapy at step 3 (indicating progression to moderate-severe COPD)
- has ≥ 2 mild exacerbations within 12 months or a moderate or serious acute exacerbation.

5 Completion of the Program

Patients who leave the Program for any reason

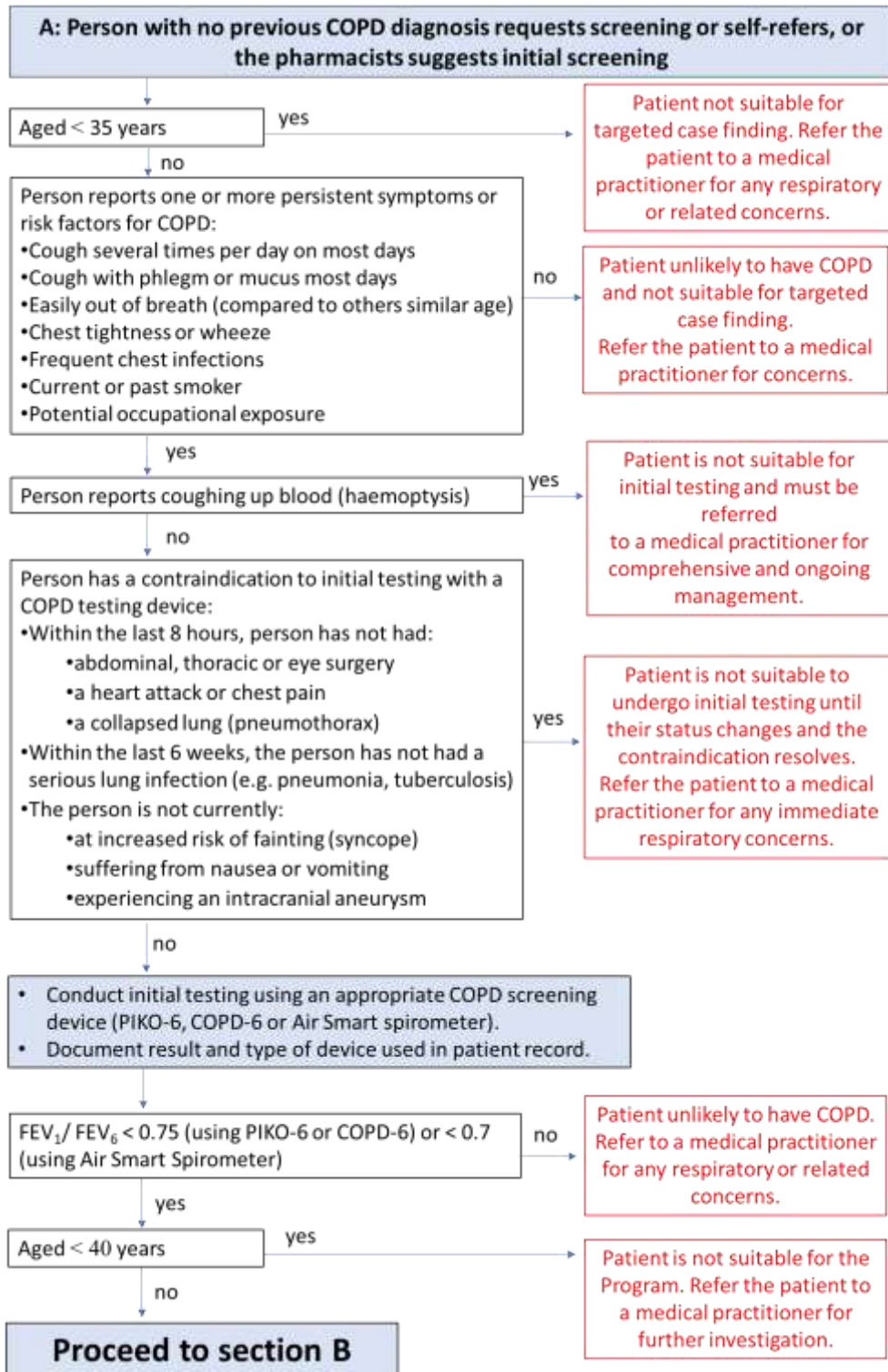
Refer the patient back to their medical practitioner with a comprehensive clinical handover at Program completion.

Phase 1: Screen for patient suitability

A. Targeted case-finding

Conduct targeted case-finding for patients **without** an existing diagnosis of COPD (refer to Figure 2).

Figure 2. Targeted case finding



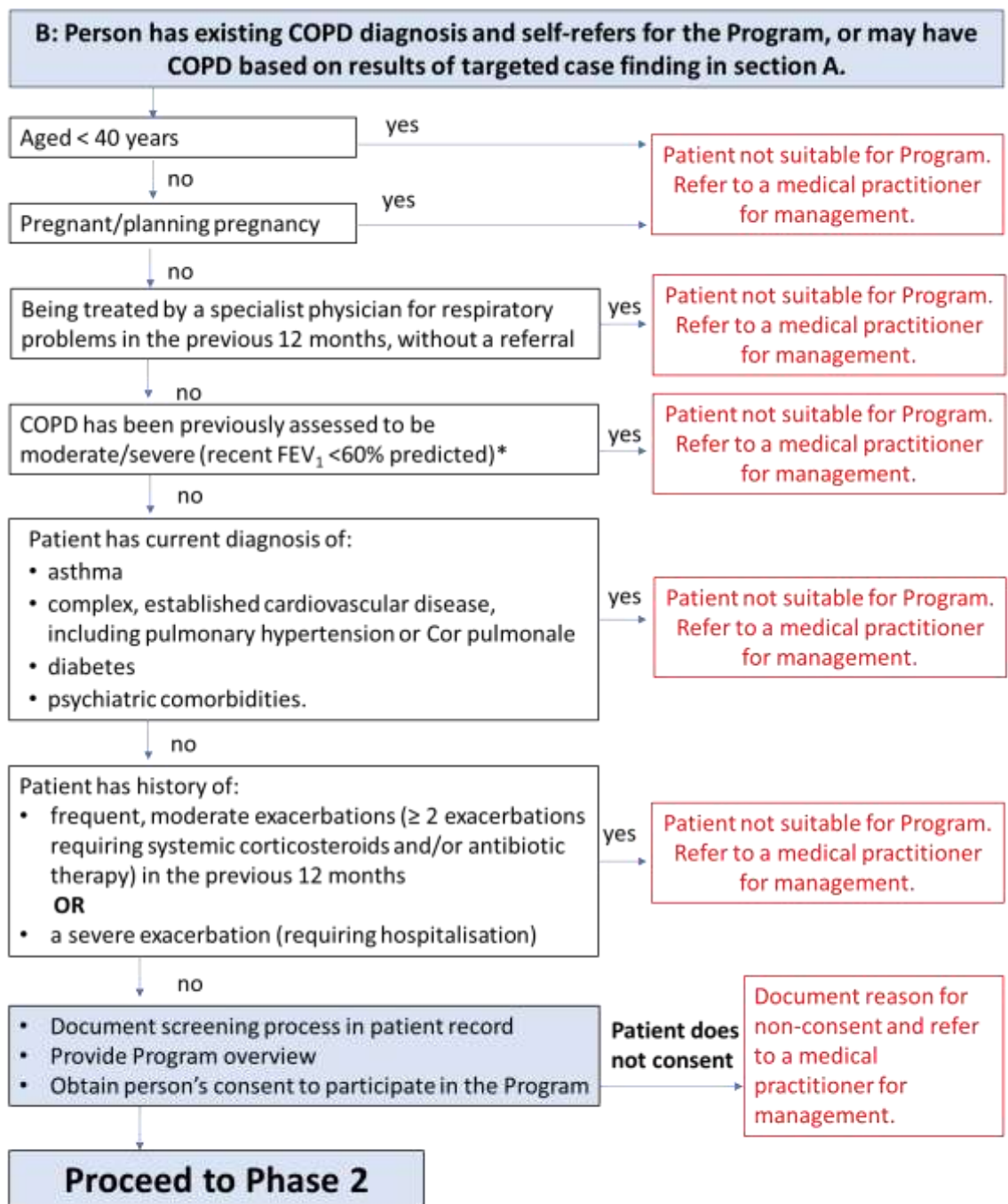
COPD screening using COPD screening devices in the Program should be guided by the Lung Foundation Australia [Position Paper: COPD case finding in community settings](#) ⁽⁸⁾.

The [Community Pharmacy COPD case finding results form](#) can be used to record the results of COPD targeted case finding ⁽⁹⁾.

B. Brief screening

Screen patients with a previous COPD diagnosis and those who have been identified through targeted case finding in section A. Refer to Figure 3.

Figure 3. Screening for eligibility



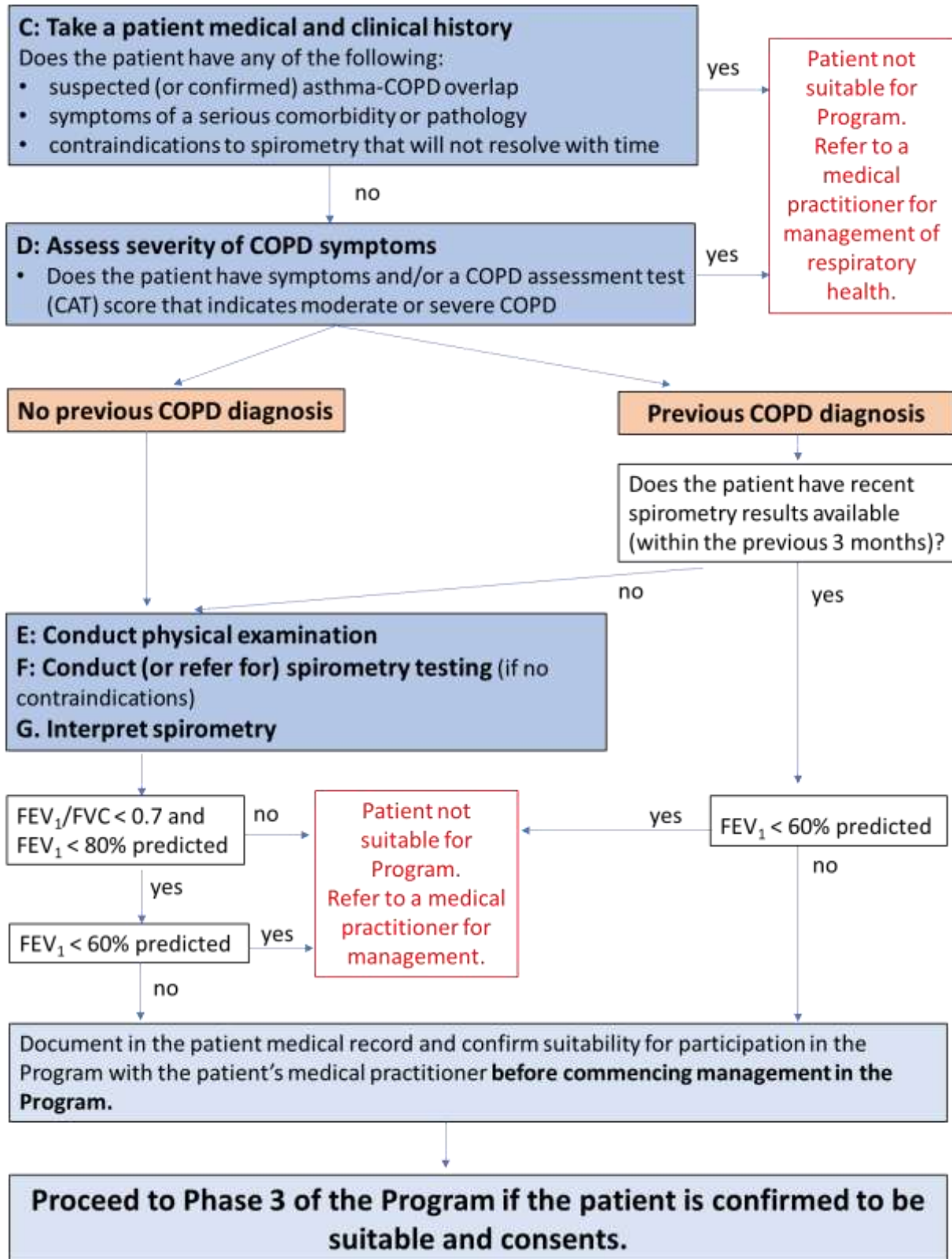
* Ask the patient to provide a copy of their most recent COPD Action Plan (if they have one) to assist with screening and initial assessment if they are eligible for the Program.

- 1. Ask the initial screening questions to assess the patient's eligibility and suitability for the Program.**
- 2. Provide an overview of the Program, including:**
 - possible timeframes for involvement including the number of appointments and testing required, including the costs of appointments and testing
 - how the patient's medicines may be managed and how medicine costs may differ when prescribed by a pharmacist or medical practitioner
 - other interventions that may be recommended as part of the Program e.g., smoking cessation and weight management, and the likely costs
 - that the patient may leave the Program, including by opting-out or becoming ineligible at any time and be referred to a medical practitioner.
- 3. Gain informed consent from the patient for participation, as per the Pilot Handbook.**
- 4. Document all findings in patient record and refer as required.**

Phase 2: Initial assessment

Take a detailed patient medical and clinical history, assess the severity of symptoms, and conduct (or refer for) spirometry testing (if indicated). Refer to Figure 4.

Figure 4. Conducting an initial assessment



C. Patient history

Sufficient information should be obtained from the patient to assess the patient's condition, suitability for participation in the program, and the safety and appropriateness of any recommendations and medicines.

Responses to the previous screening questions in phase 1 should inform the patient history:

- age
- pregnancy and lactation status (if applicable)
- if previous diagnosis of COPD - history of COPD exacerbations in the previous 12 months
- underlying or associated conditions and comorbidities that require referral to a medical practitioner for comprehensive and ongoing management:
 - asthma
 - complex, established cardiovascular disease, e.g.:
 - pulmonary hypertension, Cor pulmonale, congenital heart disease, rheumatic heart disease, heart failure, arrhythmias, atrial fibrillation, peripheral arterial disease, heart block, pericarditis, valvular disease, angina, cardiomyopathy and cardiomegaly, aortic aneurysm, ischaemic heart disease
 - history of acute coronary syndrome, stroke or other cerebrovascular disease, deep vein thrombosis, pulmonary embolism, cardiothoracic surgery
 - diabetes
 - psychiatric co-morbidities.
- history of respiratory tract infections in the previous 12 months
- presence of COPD risk factors (refer Appendix 1), smoking history and current status, and family history of COPD.

Additional information required:

- Aboriginal and/or Torres Strait Islander status
- if previous diagnosis of COPD:
 - date of diagnosis, last medical review for COPD, most recent spirometry testing
 - current/most recent COPD Action Plan (if available) and prescribed treatment
 - current or previous pulmonary rehabilitation
- relieving factors e.g., short acting beta agonist (SABA) inhaler use
- presence, pattern and severity of all respiratory symptoms (refer to Table 1):
 - frequency and time of day
 - impact on daily activities
 - triggers and precipitating factors

- other relevant medical conditions, including systemic and/or chronic conditions and those that may be contraindications to spirometry (refer to [Conduct \(or refer for\) spirometry testing](#))
- alarm signs and symptoms that require further investigation e.g., unexplained weight loss, recurrent pneumonia, haemoptysis, oedema
- all current and recently commenced medication (including prescribed medicines, vitamins, herbs, other supplements and over-the-counter medicines)
- drug allergies/adverse drug events
- smoking status and history, consider tobacco, cannabis, vaping, passive smoking
- diet/nutrition status
- levels of physical activity
- recreational drug and alcohol use
- vaccination status, specifically pneumococcal and influenza.

Table 1. Symptoms of stable COPD (2,4,5,10)

Table 1. Symptoms of stable COPD (2, 4, 5, 10)
<ul style="list-style-type: none"> • Breathlessness that is unexplained or inappropriate for level of exertion, as per the Modified Medical Research Council Dyspnoea Scale • chronic cough (several times most days for two months), intermittent, or unusual • frequent or unusual sputum production (cough up phlegm or mucus most days) • wheeze or chest tightness • frequent/relapsing acute chest infections e.g., acute infective bronchitis.

NB: Symptoms may be subtle and not noticeable to the patient until the disease has significantly progressed and lung damage has occurred.

Asthma-COPD overlap

COPD and asthma may coexist:

- patients with a history of asthma are at increased risk of developing COPD
- patients with COPD often report a history of asthma ⁽²⁾.

Clinical features that can aid in differentiation between asthma and COPD are shown in Appendix 2.

Check referral points

D. Assess COPD severity

Appendix 2 details the classification of stable COPD severity as per the [Therapeutic Guidelines: Stable COPD](#) ⁽²⁾ and the [COPD-X Plan: Assessing the severity of COPD](#) ⁽⁵⁾.

The COPD Assessment Test (CAT)

The self-administered online [COPD Assessment Test \(CAT\)](#) should be used (in combination with patient reported symptoms and recent spirometry results) to assess disease severity and monitor disease progression.

The total CAT score provides both clinicians and patients with a broad clinical picture of the impacts of COPD on the individual's life:

- very high impact = score of 31-40
- high impact = 21-30
- moderate impact = 10-20
- low impact = <10 ⁽⁵⁾.

The minimal clinically important difference (MCID) is a score of 2 ⁽⁵⁾.

If the patient reports symptoms consistent with moderate or severe COPD (refer to Appendix 2), or the symptoms are having a high or very high impact on the individual's life (determined through the CAT score), they should be referred to a medical practitioner for management. **Do not proceed to spirometry testing.**

Check referral points

E. Physical examination

The pharmacist should perform a physical examination including chest auscultation. However, physical examination is not considered sensitive enough to detect/confirm mild COPD; chest auscultation may be normal; wheeze is not an indicator of severity ⁽⁵⁾.

F. Conduct (or refer for) spirometry testing

Clinical signs alone are insufficient to confirm the presence, severity and reversibility of airflow limitation for mild COPD; recent spirometry results including acute bronchodilator reversibility test results (within the previous 3 months) are required for all patients to:

- measure base-line lung function
- confirm COPD for patients without a previous diagnosis.

If spirometry testing has been conducted within the previous 3 months, the pharmacist should obtain the results through the patient (if possible) to avoid duplication.

Pharmacists may conduct the spirometry in the community pharmacy setting in accordance with National Asthma Council Australia [Spirometry Handbook for Primary Care](#) (the Spirometry Handbook), if they have been appropriately trained and have the appropriate equipment detailed in the Spirometry Handbook, or they may refer to another local practitioner or service that performs lung function testing.

All spirometry in this Program should be conducted in accordance with the Spirometry Handbook, including:

- pre-appointment and pre-test preparation of the patient
- performance and completion of the tests
- identifying abnormal ventilatory patterns
- clinical interpretation of spirometry ⁽¹¹⁾.

Spirometry is generally safe; however, because it involves maximal effort, patients may experience transient breathlessness, cough, syncope, chest pain, oxygen desaturation and/or incontinence ⁽¹¹⁾.

In some cases, spirometry is contraindicated or not recommended at a specific point in time due to risks to the patient or increased likelihood of inaccurate and unrepeatable results, as detailed in the Spirometry Handbook.

- If the contraindication to spirometry is not likely to resolve with time, the patient must be referred to a medical practitioner for management.
- If the contraindication is temporary/transitory in nature, the patient may undertake spirometry when it is safe to do so.

Resources for conducting spirometry

- National Asthma Council Australia 2022 [Spirometry Handbook for Primary Care](#) ⁽¹¹⁾
- [Therapeutic Guidelines: Spirometry](#) ⁽¹²⁾
- American Thoracic Society and European Respiratory Society Technical Statement: [Standardization of Spirometry 2019 Update](#) ⁽¹³⁾.

G. Interpreting spirometry

Interpret spirometry testing in accordance with the [Therapeutic Guidelines: Spirometry](#) ⁽¹²⁾, and the [COPD-X Plan: Spirometry](#) ⁽⁵⁾ and Appendix 4.

Check referral points

Collaborative care

Patients **without** a previous diagnosis of COPD who have symptoms and spirometry results that confirm mild COPD may be enrolled in the Program and management may commence concurrent to referral to a medical practitioner for further review and collaborative care.

Patients **with** an existing diagnosis of COPD who are suitable to participate in the Program may be enrolled in the Program and commence management provided the patient's usual medical practitioner is notified and updates are provided following each occasion of care.

If the patient was referred into the Program by a medical practitioner, they may proceed directly to phase 3 if they are eligible.

Relevant diagnostic information should be shared with the patient's medical practitioner, with the patient's consent, to avoid duplication.

Phase 3: Develop and implement a management plan

Optimal management of COPD involves a multidisciplinary and collaborative team-based approach which includes:

- general measures including avoidance of triggers and minimisation of risk factors
- education and counselling to enable self-management
- pharmacotherapy for stable COPD management and exacerbations based on disease severity
- regular symptom monitoring and review ⁽²⁾.

Each patient within the Program should have the following developed, consistent with the Therapeutic Guidelines, Australian Medicines Handbook and the COPD-X Plan:

- an individualised COPD Action Plan (or existing plan updated), using a validated template, such as the [Lung Foundation Australia - COPD Action Plan](#)
- an accompanying individualised lifestyle prescription detailing non-pharmacological management/general measures (see template for guidance in Appendix 5). Appendix 5 - Program Lifestyle prescription to accompany COPD Action Plan

H. General measures

All Program participants should be counselled and provided with information regarding general measures, regardless of whether pharmacotherapy is also prescribed.

General measures alone may be sufficient for initial management of patients with stable COPD and minimal symptoms (e.g., a CAT score < 10) ⁽²⁾.

Reducing risk factors

Avoidance of exposure to risk factors

Patients should be counselled on the importance of avoiding risk factors, the most critical of which is smoking (including passive smoking) ^(2,5). Avoidance of other environmental risk factors is also recommended, including occupational dust, fumes and gases, indoor and outdoor air pollutants ⁽⁵⁾.

Smoking cessation (if applicable)

Smoking cessation is the most important and beneficial measure to prevent and/or limit lung damage and reduce mortality for patients with COPD ^(2,5).

Detailed guidance for pharmacist supporting smoking cessation is contained in the Smoking Cessation Clinical Practice Guideline.

Immunisation

Patients with COPD should be immunised for pneumococcal disease and annually for influenza ^(2,5). Refer to the Australian Immunisation Handbook for recommendations for vaccination against [pneumococcal](#) and [influenza](#) ⁽¹⁴⁾.

Other recommended vaccines may include those required for a declared public health emergency, e.g., COVID-19. Refer to the [Australian Government Department of Health and Aged Care](#) webpage for up to date clinical guidance for the COVID-19 vaccine.

All vaccinations should be administered in accordance with the Australian Immunisation Handbook, individual vaccine information provided by the TGA and current Australian Technical Advisory Group on Immunisation (ATAGI) advice and the current version of the *Extended Practice Authority – Pharmacists under the Medicines and Poisons (Medicines) Regulation 2021*, available on the [Queensland Health website](#).

Optimising function

Exercise and physical activity

Many patients with COPD have a sedentary lifestyle and find physical activity difficult due to exertional dyspnoea and fatigue; however, there is good evidence that physical activity can reduce the risk of hospitalisations and improve quality of life ⁽⁵⁾.

Patients with COPD should be encouraged to undertake physical activity in line with their age group in the [Physical activity and exercise guidelines for all Australians](#) ⁽¹⁵⁾.

- Not all patients will be able to meet the recommendations, however they should be advised that doing any amount of physical activity is better than none and encouraged to gradually build up to the recommendations ⁽¹⁵⁾.
- Patients experiencing difficulty with exercise and physical activity should be encouraged to see a physiotherapist or exercise physiologist.

Referral for pulmonary rehabilitation

Pulmonary rehabilitation improves exercise capacity and quality of life regardless of COPD severity, and can reduce the frequency of hospitalisations for exacerbations ^(2, 7).

Patients with COPD should be encouraged to participate in a pulmonary rehabilitation program when symptomatic and after an exacerbation.

Information about pulmonary rehabilitation programs (and other services including psychosocial support) available throughout Queensland, including how referrals can be made, can be found on the [Lung Foundation Australia - Find a Service](#) website.

Diet and nutrition

Malnutrition, obesity and poor nutritional status, generally resulting from suboptimal eating habits, sedentary lifestyle, smoking and corticosteroid use is common in patients with COPD, and has been shown to contribute to morbidity and mortality ^(2, 5).

Advice should focus on a balanced diet with foods from each of the 5 food groups in appropriate portions to maintain a healthy weight, in accordance with the [Australian Dietary Guidelines](#) ⁽⁵⁾.

Underweight and overweight patients should be encouraged to see a dietitian for tailored nutritional advice.

With the patient's consent, patients requesting assistance with weight management may be:

- concurrently referred to a medical practitioner
- managed by a pharmacist as part of standard pharmacist care
- managed within the Pilot as per the Management of Overweight and Obesity Clinical Practice Guideline.

I. Pharmacotherapy

As COPD progresses, management using general measures alone may become inadequate and pharmacotherapy may be required to relieve symptoms, reduce the frequency of exacerbations and improve overall quality of life ⁽²⁾.

Patients entering the program with an existing drug regimen

When managing patients who enter the Program already on a drug regimen, the pharmacist should ask for the patient's most recent COPD Action Plan (if they have one) and consider whether the current (or most recently prescribed) regimen is:

- concordant with the Therapeutic Guidelines or COPD-X Plan
- appropriate for the patient's symptoms and medical history
- optimised for the patient, including inhaler technique and adherence.

When modifying drug regimens within the Program that have been prescribed by another health practitioner, pharmacists should attempt to make changes in collaboration with the original prescriber or the patient's usual medical practitioner (whichever is most appropriate).

Pharmacists may modify or deprescribe pharmacotherapy, particularly if:

- the patient's response is inadequate (within appropriate clinical timeframes)
- the patient is experiencing intolerable/unmanageable adverse effects
- the medicine is not used for the treatment of another condition, modification/deprescribing is clinically warranted and it is safe to do so.

Stepwise pharmacotherapy for stable COPD

Pharmacotherapy for stable mild COPD within the Program must be in accordance with the [Therapeutic Guidelines: Respiratory – Stepwise management of stable COPD](#) ⁽²⁾, specifically:

- [Step 1: Short-acting bronchodilator therapy](#)
- [Step 2: long-acting bronchodilator monotherapy](#)
- [Step 3: Long-acting bronchodilator dual therapy](#)

Check referral points

Additional considerations

- The entry point to the stepwise pathway should be individualised to the patient's previous medical and medication history. Patients with a new diagnosis of COPD or managing with general measures should generally initiate pharmacotherapy at step 1.
- When commencing any drug therapy, patients should be advised to return if they experience adverse effects, an increase in symptom frequency or type, more severe symptoms or an exacerbation.

- Pharmacists should ensure the patient's prescription(s) (including repeats) generally only allow for a sufficient quantity of medicine to be supplied for the period until the patient's next scheduled review.
- Patients initiated on Step 3 Long-acting bronchodilator dual therapy where the condition has not stabilised or has worsened after 1 month must be referred to a medical practitioner for ongoing management.

Inhaler considerations

- As with asthma, the choice of drug and device should consider patient preference and their ability to use the device correctly, including inspiratory effort, cognition, and dexterity⁽¹⁶⁾.
- Where possible, the number of different devices should be limited to avoid confusion⁽¹⁶⁾.
- Pharmacists should demonstrate the correct use of the patient's prescribed device (which differs between brands) and review inhaler technique at every opportunity.
- Further resources for consumers and health professionals are available in the National Asthma Council of Australia information paper for health professionals – [Inhaler technique for people with asthma or COPD](#)⁽¹⁷⁾.

Management and treatment of COPD exacerbations

All patients should be counselled on how to recognise an exacerbation, including the signs and symptoms that indicate the need for emergency medical care, and treatment to commence at the onset of symptoms. This should also be included in the patient's COPD Action Plan.

Self-management of mild and moderate exacerbations

Self-management of mild and moderate exacerbations, supported by the pharmacist, are as per the [Therapeutic Guidelines: Treatment of a COPD exacerbation](#)⁽⁷⁾.

- A prescription for prednis(ol)one should be provided and dispensed for patients to keep at home in the event of a COPD exacerbation.
- Ipratropium is contraindicated in patients taking a LAMA and has a slower onset of effect than salbutamol.
- Antibiotic therapy is only required when an exacerbation is triggered by a bacterial infection^(7, 18).
 - Signs suggestive of bacterial infection or pneumonia include Increased sputum volume, purulence and change in colour, abnormally rapid breathing while at rest, increased heart rate (over 100 bpm) and rigors⁽¹⁸⁾.
 - Sputum culture is not routinely recommended for COPD exacerbations⁽¹⁸⁾.

All participants should return to the pharmacist for a review of their COPD Action Plan after an exacerbation, even if it was mild and self-managed.



Patients should be advised to seek medical care (including from emergency services if required) if:

- They have chest pain, 'fluttering' in the chest or an abnormally slow or racing heartbeat (arrhythmia) (COPD exacerbations may present similarly to cardiovascular disease)
- They cannot manage or function at home e.g., can't walk between rooms, eat or sleep due to breathlessness
- They cannot tolerate oral prednis(ol)one
- They have drowsiness or confusion that may indicate hypercapnia or risk of hypercapnia
- They notice the onset or worsening of central cyanosis
- Oxygen saturation deteriorates towards 92% spo₂ (if monitors with pulse oximetry) ^(19, 20)
- They have leg swelling (peripheral oedema)
- They notice fluctuating blood pressure
- Bacterial infection or pneumonia is suspected
- Symptoms remain uncontrolled despite treatment with an inhaled bronchodilator and prednis(ol)one.

J. Confirm management plan is appropriate

Pharmacists must consult the Therapeutic Guidelines, Australian Medicines Handbook and other relevant references to confirm the management plan is appropriate, including for:

- contraindications and precautions
- drug interactions
- lactation (patients who are planning a pregnancy or pregnant are not suitable for the Program).

K. Communicate agreed management plan

Comprehensive advice and counselling (including supporting written information when required) as per the Australian Medicines Handbook, Therapeutic Guidelines, COPD-X Plan and other relevant references, should be provided to the patient regarding:

- individual product and medicine use (dosing and inhaler technique)
- how to manage adverse effects
- when to seek further care and/or treatment
- when to return to the pharmacist for clinical review.

It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources provided to patients (and parents/caregivers if applicable), and compliance with all copyright conditions.

Collaborative care

The pharmacist should provide a copy of the patient's COPD Action Plan to their usual medical practitioner (and any other health professionals involved in the patient's respiratory care). The communication should also include:

- relevant medical history, results of any spirometry testing conducted and level of symptom control (CAT score)
- changes to existing pharmacotherapy prescribed for COPD or new pharmacotherapy (including for exacerbations)
- a summary of advice provided to the patient including recommendations for multidisciplinary care and referrals
- the next scheduled review appointment.

Phase 4: Ongoing management and monitoring

L. Clinical review

All patients should undergo regular clinical review to participate in the Program, as per the Therapeutic Guidelines, outlined below:

- Review patient 3 months after management is first commenced and/or new pharmacotherapy is initiated, including step up of treatment.
- Review patient after 6 months of stable pharmacotherapy (with no increase in symptom frequency or severity, and no exacerbations).
- Review patient as soon as possible:
 - if there are any deterioration in the condition (increased severity and frequency of symptoms)
 - where symptoms have not improved one month after a change to pharmacotherapy
 - if the patient is experiencing adverse effects
 - after any exacerbation.

At each review appointment (scheduled or unscheduled), the pharmacist should:

- Review and update the patient history to reflect changes in the preceding period.
- Review the patient's inhaler technique and adherence to pharmacotherapy.
 - demonstrate appropriate inhaler technique and reinforce the treatment regimen. If a patient is unable to use a device correctly after continued instruction and demonstration, a different device should be tried
 - inspect all equipment to check for breakage or blockage
 - review the benefits and adverse effects of pharmacotherapy.
- Review and update the COPD Action Plan (if required), consider whether the patient's current pharmacotherapy is adequate and reinforce general measures.
- Ensure the patient has enough medicines and prescriptions until their next scheduled review.
- Provide referrals to the patient's multidisciplinary health team (if required).
- Consider the patient's ongoing suitability to be managed in the Program.

Ongoing collaboration during management

The pharmacist should advise the patient's usual medical practitioner when any changes are made to the patient's management plan throughout the Program. Communication should include:

- a copy of the current COPD Action Plan, results of any spirometry testing conducted and lifestyle prescription
- a summary of any advice and counselling provided to the patient including any recommendations for multidisciplinary care and referrals
- the next scheduled review appointment.

Proactive, planned and/or unplanned review may also occur with the patient's usual medical practitioner at any time while the patient is enrolled in the Program.

Patients who are not suitable for further participation in the Program

The pharmacist must refer all patients (with their consent) who are no longer suitable for management within the Program or who do not wish to continue in the Program to a medical practitioner (refer to phase 5).

Phase 5: Completion of the Program

Patients may continue to participate in the Program as long as:

- their condition remains suitable to be managed in the Program
- they wish to remain in the Program and continue to consent
- they attend scheduled reviews.

If a patient leaves the program for any reason, the pharmacist should (with their consent) advise the patient's usual medical practitioner. An update should also be provided to other relevant members of the patient's collaborative care team.

Appendices

Appendix 1 - Known risk factors for COPD

Known risk factors for COPD ^(2, 5)
<ul style="list-style-type: none"> • tobacco or other types of smoking e.g., hookah • exposure to second-hand smoke • prenatal parental smoking • premature birth • childhood respiratory illnesses • asthma • occupation exposure to dust and fumes e.g., agriculture and livestock farming, plastics manufacturing, mining, food and drinks processing • genetic susceptibility • exposure to biomass fuel smoke from cooking or heating (particularly for patients that have come from low- and middle-income countries).

NB: Almost all cases of COPD are the result of an interaction between genetic and environmental factors ⁽⁵⁾.

Appendix 2 - Clinical features to aid with differentiation between COPD and asthma

Clinical features to aid with differentiation between COPD and asthma ⁽²⁾		
	Suggestive of COPD	Suggestive of asthma
Onset	<ul style="list-style-type: none"> • after age 40 	<ul style="list-style-type: none"> • earlier onset, before age of 20
Airflow limitation and symptoms	<ul style="list-style-type: none"> • persistent airflow limitation • symptoms do not respond to usual treatment for asthma e.g., weeks or months of inhaled corticosteroids (ICS) • persistent cough, cough productive of sputum 	<ul style="list-style-type: none"> • day-to-day variability in airflow limitation and symptoms • worse at night or in the early morning • seasonal variability • normal lung function in between • spontaneous improvement in symptoms
Family history	<ul style="list-style-type: none"> • family history of COPD 	<ul style="list-style-type: none"> • family history of asthma or atopy
Other	<ul style="list-style-type: none"> • heavy exposure to tobacco 	

Appendix 3 - Classification of COPD severity

Classification of COPD severity ^(2, 4, 5)	
Severity	Features
Mild	<ul style="list-style-type: none"> • few symptoms with little to no impact/limitations on daily activities • breathless on moderate exertion • cough and sputum production.
Moderate	<ul style="list-style-type: none"> • breathlessness walking on flat ground • recurrent chest infections • increasing limitations on daily activities and quality of life • moderate exacerbations experienced (oral corticosteroids and/or antibiotics required).
Severe	<ul style="list-style-type: none"> • breathlessness on minimal exertion • severe limitations on daily activities and impacts on quality of life • increasingly frequent exacerbations and severe exacerbations (hospitalisation required).

Appendix 4 – Interpretation of spirometry

Interpretation of spirometry ^(5, 11, 12, 21)
<p>The threshold for defining persistent airflow limitation (and when airflow limitation is not fully reversible), is currently accepted to be FEV₁/FVC ≤ 0.7, with an FEV₁ of < 80% of the predicted value (post-bronchodilator)⁽⁵⁾.</p> <ul style="list-style-type: none"> • Spirometry should be repeated if FEV₁/FVC results are around the 0.7 threshold. • If FEV₁ increases >400 mL following bronchodilator, asthma (or asthma/ COPD overlap) should be considered⁽⁵⁾. • Indicative flow-volume loop patterns can be found in the Therapeutic Guidelines: Spirometry⁽¹²⁾, and the COPD-X Plan: Spirometry⁽⁵⁾. <p>NB: The fixed ratio cut-off is arbitrary and may lead to over-diagnosis in older populations, under-diagnosis in younger populations and gender imbalances⁽⁵⁾.</p> <p>Resources for interpreting spirometry</p> <ul style="list-style-type: none"> • Therapeutic Guidelines: Pulmonary function testing⁽¹²⁾ • COPD-X Plan, section C2.3 Spirometry⁽⁵⁾ • European Respiratory Society GLI calculator. • Global Lung Initiative (GLI) 2012 dataset^{1 (21)} <p>NB1: The category GLI-2012 'other/mixed' in the GLI 2012 dataset should be used to analyse the spirometry results for Aboriginal and Torres Strait Islander people^(11, 21).</p>

Appendix 5 - Program Lifestyle prescription to accompany COPD Action Plan

Page 1

Queensland Community Pharmacy Scope of Practice Pilot COPD Monitoring Program Lifestyle Prescription

Plan date:

Patient details

Name:		Date of birth	
Patient support person or carer	Name, relationship and phone number of someone who assists the patient with their home care		

Program pharmacy details

Pharmacist name		Phone number	
Pharmacy name and address		Opening hours	

Next COPD Monitoring Program appointment:	
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Date of enrolment in the COPD Monitoring Program:			
My current FEV₁:	Date:	Date of last vaccinations	(list all applicable)
Current level of symptom control (CAT score):	Date:	Date next vaccinations are due	(list all applicable)

Health care team

General practitioner and clinic:	Name, address and phone number	Closest 24-hour emergency services:	Name, address and phone number
Pulmonary rehabilitation program	Name, address and phone number	Occupational therapist	Name, address and phone number
Dietitian	Name, address and phone number	Physiotherapist	Name, address and phone number
Speech pathologist	Name, address and phone number	Psychologist/psychiatrist	Name, address and phone number
Other services	Find a Service - Lung Foundation Australia		

Lifestyle prescription

My risk factors and triggers	<ul style="list-style-type: none"> List identified risk factors and triggers and strategies to minimise and avoid exposure
Exercise plan	<ul style="list-style-type: none"> Enter recommendations for physical activity for the patient's age and capability based on the national guidelines: <ul style="list-style-type: none"> Informal exercise e.g. building exercise into everyday activities Formal exercise e.g., walking (moderate intensity) for 30 minutes 5 days of the week strength building 2 days per week individualised guidance for building up to recommendations If required: Referral to a GP, exercise physiologist, physiotherapist or other supports for safe exercise
Diet and nutrition	<ul style="list-style-type: none"> Recommendation for weight loss or gain (if applicable) Summary of nutritional advice for a balanced diet <ul style="list-style-type: none"> more of/ increase... less of/ limit... Referral to Pilot overweight and obesity management program and/or other supports e.g., dietitian
Pulmonary rehabilitation	<ul style="list-style-type: none"> Summary of recommendations Pulmonary rehabilitation program locations
Other management strategies	<ul style="list-style-type: none"> If required: Smoking cessation <ul style="list-style-type: none"> Refer to Pilot smoking cessation program and/or other supports e.g. Quitline or GP If required: Referral to a GP, psychologist or other clinician for mental health support If required: summary of advice regarding alcohol consumption

References

1. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Global Initiative for Chronic Obstructive Lung Disease; 2022 [cited 2022 August 1]. Available from: https://goldcopd.org/wp-content/uploads/2021/12/GOLD-REPORT-2022-v1.1-22Nov2021_WMV.pdf.
2. Therapeutic Guidelines: Respiratory (Stable chronic obstructive pulmonary disease (COPD)) Melbourne: Therapeutic Guidelines Limited; 2021 [cited 2022 September 20]. Available from: <https://tgldcdp.tg.org.au/viewTopic?etgAccess=true&guidelinePage=Respiratory&topicfile=chronic-obstructive-pulmonary-disease>.
3. Australian Medicines Handbook: Drugs for asthma and chronic obstructive pulmonary disease. Adelaide: Australian Medicines Handbook Pty Ltd; 2022 [cited 2022 September 20]. Available from: <https://amhonline.amh.net.au/chapters/respiratory-drugs/drugs-asthma-chronic-obstructive-pulmonary-disease?menu=vertical>.
4. GOLD Science Committee. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Global Initiative for Chronic Obstructive Lung Disease; 2022 [cited 2022 August 1]. Available from: https://goldcopd.org/wp-content/uploads/2021/12/GOLD-REPORT-2022-v1.1-22Nov2021_WMV.pdf.
5. Lung Foundation Australia and Thoracic Society of Australia and New Zealand. The COPD-X Plan: Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease. Milton: Lung Foundation Australia; 2021 [cited 2022 September 20]. Available from: https://copdx.org.au/wp-content/uploads/2022/07/COPDX-V2-65-Q4-2021_FINAL.pdf.
6. Australian Institute of Health and Welfare. Chronic obstructive pulmonary disease (COPD). Canberra: AIHW, Australian Government; 2020.
7. Therapeutic Guidelines: Respiratory (Chronic obstructive pulmonary disease (COPD) exacerbations) Melbourne: Therapeutic Guidelines Limited; 2021 [cited 2022 September 20]. Available from: <https://tgldcdp.tg.org.au/viewTopic?etgAccess=true&guidelinePage=Respiratory&topicfile=chronic-obstructive-pulmonary-disease-exacerbations>.
8. Lung Foundation Australia. Position Paper: COPD case finding in community settings 2019 January 30, 2023 [cited 2023 January 30]. Available from: <https://lungfoundation.com.au/resources/copd-case-finding-position-paper/>.
9. Lung Foundation Australia. Community Pharmacy COPD case finding results form January 30, 2023 [cited 2023 January 30]. Available from: <https://lungfoundation.com.au/resources/copd-case-finding-results-form-community-pharmacy/>.
10. World Health Organisation. Chronic respiratory diseases: WHO; 2020 [cited 2022 September 20]. Available from: https://www.who.int/health-topics/chronic-respiratory-diseases#tab=tab_1.
11. National Asthma Council Australia. The Spirometry Handbook for primary care. Melbourne: National Asthma Council of Australia; 2020 [cited 2022 September 21]. Available from: <https://www.nationalasthma.org.au/living-with-asthma/resources/health-professionals/information-paper/spirometry-handbook>.
12. Therapeutic Guidelines: Respiratory (Pulmonary function testing). Melbourne: Therapeutic Guidelines Limited; 2021 [cited 2022 August 1]. Available from: https://tgldcdp.tg.org.au/viewTopic?etgAccess=true&guidelinePage=Respiratory&topicfile=fitness-for-surgery&guidelinename=Respiratory§ionId=toc_d1e202#toc_d1e155.
13. Graham BL, Steenbruggen I, Miller MR, Barjaktarevic IZ, Cooper BG, Hall GL, et al. Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. American Journal of Respiratory and Critical Care Medicine. 2019;200(8):e70-e88.
14. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook. Canberra: Australian Government Department of Health and Aged Care; 2018

- [cited 2022 September 27]. Available from: <https://immunisationhandbook.health.gov.au/>.
15. Australian Government Department of Health and Aged Care. Physical activity and exercise guidelines for all Australians Canberra: Australian Government Department of Health and Aged Care; 2022 [updated 2021, May 7; cited 2022 September 27]. Available from: https://www.health.gov.au/health-topics/physical-activity-and-exercise/physical-activity-and-exercise-guidelines-for-all-australians?utm_source=health.gov.au&utm_medium=callout-auto-custom&utm_campaign=digital_transformation.
 16. National Asthma Council Australia. Australian Asthma Handbook. Melbourne: National Asthma Council Australia; 2022 [cited 2022 October 4]. Available from: <https://www.astmahandbook.org.au/>.
 17. National Asthma Council Australia. Inhaler Technique for People with Asthma or COPD. National Asthma Council of Australia; 2018.
 18. Therapeutic Guidelines: Antibiotic (Antibiotic management of COPD) Melbourne: Therapeutic Guidelines Limited; 2021 [cited 2022 September 29]. Available from: <https://tgldcdp.tg.org.au/viewTopic?etgAccess=true&guidelinePage=Antibiotic&topicfile=COPD-antibiotic-management>.
 19. Beasley R, Chien J, Douglas J, Eastlake L, Farah C, King G, et al. Thoracic Society of Australia and New Zealand oxygen guidelines for acute oxygen use in adults: 'Swimming between the flags'. *Respirology*. 2015;20:1182-91.
 20. Pilcher J, Beasley R. Acute use of oxygen therapy. *Aust Prescr*. 2015;38(3):98-100.
 21. Quanjer PH, Stanojevic S, Cole TJ, Baur X, Hall GL, Culver BH, et al. Multi-ethnic reference values for spirometry for the 3–95-yr age range: the global lung function 2012 equations. *European Respiratory Journal*. 2012;40(6):1324.