Choose devices the patient can and will use effectively; train the patient to use the device; check the patient's inhaler technique regularly at each visit; try to use same delivery device for each inhaled drug.
### VERSION CONTROL

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Date</th>
<th>Amendments made</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>March 14</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>February 15</td>
<td>Updated to include Spiriva Respimat</td>
</tr>
<tr>
<td>3</td>
<td>March 2015</td>
<td>Link added to MHRA safety update re: tiotropium</td>
</tr>
<tr>
<td>4</td>
<td>December 2015</td>
<td>LABA, LAMA &amp; LABA/LAMA inhalers updated</td>
</tr>
<tr>
<td>5</td>
<td>September 2017</td>
<td>GOLD principles included</td>
</tr>
<tr>
<td>6</td>
<td>October 2017</td>
<td>Trimbow added</td>
</tr>
</tbody>
</table>

Date: October 2017
1. Background Information and the Rationale for Guideline Development.

There have recently been developments in the treatment of COPD with the publication of new national / international guidelines, the licensing of new drugs and devices and requests by clinicians to use new inhalers. As the developments affect the current LMMG COPD guideline, the LMMG requested a review and update of the guideline.

Since the publication of the NICE clinical guideline for COPD (CG 101, June 2010),¹ the Global Initiative for Chronic Obstructive Lung Disease (GOLD)² has published its guideline for the diagnosis, management and prevention of COPD (2017).

GOLD states that pharmacologic therapy for COPD is used to reduce symptoms, reduce the frequency and severity of exacerbations and improve exercise tolerance and health status. GOLD proposes a model for the initiation, and then subsequent escalation and / or de-escalation of pharmacologic management of COPD according to the individualised assessment of symptoms and exacerbation risk.

The proposed LMMG COPD pathway aims to incorporate the GOLD grouping and grading criteria and associated pharmacologic management recommendations. The pathway includes treatment initiation with a long acting bronchodilator (LAMA), step up escalation to a LABA / LAMA combination in patients with moderate, severe and very severe COPD (GOLD groups B, C and D) and a possible further treatment escalation to a LAMA +LABA +ICS combination in patients with moderate to very severe COPD and exacerbations (GOLD groups C and D).

The guideline proposes a choice of three COPD treatment pathways to enable the clinician to ensure that each patient has access to the right drug and device for them. After consultation with various stakeholders it was confirmed that ideally, for both the patient and clinician, there should be continuity of drug / device through the pathway. The treatment pathways will be useful in both primary and secondary care, enabling clinicians make informed choices of the most appropriate device for each patient to ensure full clinical benefit is achieved.

Full medicine reviews have not been carried out for the production of the guideline as one or more national body has performed a full assessment of the evidence, safety and cost effectiveness of the recommended inhalers and these reviews are sufficient for the purposes of the guideline.

2. Review of Existing Guidance & Sources of Information.

The current LMMG guidelines³ for COPD were originally written in 2014 and in the intervening years there have been several new drugs / devices licensed for use in COPD. New national and international guidelines have also been published:

- Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017²
- NICE Chronic obstructive pulmonary disease in over 16s: diagnosis and management.¹ Clinical guideline [CG101] Published date: June 2010 was reviewed in April 2016 and is currently being updated with an expected publication date of November 2018.

A review of the non-pharmacological treatment pathway is also currently being undertaken by a Respiratory Consultant to be used alongside the updated guideline, emphasising the role of pulmonary rehabilitation.
3. Guideline Development

In developing the treatment pathways, account was taken of all the drugs and devices currently licensed for the treatment of COPD and after consultation with various stakeholders (Respiratory Consultants, GPSi, Respiratory Nurses (primary and secondary care)), it was decided that device driven pathways were the most logical route. Each drug within the therapeutic classes were considered noninferior and therefore, the most important factor in optimising patient care would be the ability of patients to use an inhaler device correctly in order to gain maximal effect from the prescribed drug.

The new guideline incorporates guidance from GOLD and is mainly an outline of inhaled therapies available for COPD. A non-inhaler based guideline is currently in development; in the interim, for details on elements of treatment such as:

- Inspiratory flow rates for inhalers
- Use of corticosteroids
- Use of theophylline
- Short acting bronchodilators
- Lifestyle advice
- Advice on chronic cough assessment
- Specialist referral criteria
- Read code advice

Please refer to the previous guideline: COPD desktop guide (Version 1.4).pdf
**Diagnosis**
Consider diagnosis of COPD in anyone > 40 and who is a smoker / ex-smoker with any of the following symptoms:
- Chronic cough
- Breathlessness on exertion
- Regular sputum production
- Wheeze
- Frequent winter bronchitis

And no clinical features of asthma

**Tests**
Post-bronchodilator spirometry (absolute & % predicted)
Chest X-ray
Full blood count
BMI

**Assess airflow limitation**
In patients with post bronchodilator FEV₁/FVC <0.7 assess airflow limitation as per GOLD (2017)

<table>
<thead>
<tr>
<th>GOLD Grade</th>
<th>FEV₁ (% predicted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD 1</td>
<td>≥ 80</td>
</tr>
<tr>
<td>GOLD 2</td>
<td>50-79</td>
</tr>
<tr>
<td>GOLD 3</td>
<td>30-49</td>
</tr>
<tr>
<td>GOLD 4</td>
<td>&lt;30</td>
</tr>
</tbody>
</table>

**Assess patient exacerbation history and symptoms (mMRC and CAT scores)**

<table>
<thead>
<tr>
<th>Exacerbations per year</th>
<th>CAT</th>
<th>mMRC</th>
<th>Patient Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 1 not leading to hospital admission</td>
<td>&lt;10</td>
<td>0-1</td>
<td>A</td>
</tr>
<tr>
<td>≥ 1 not leading to hospital admission</td>
<td>≥10</td>
<td>≥2</td>
<td>B</td>
</tr>
<tr>
<td>≥ 2 or ≥ 1 leading to hospital admission</td>
<td>&lt;10</td>
<td>0-1</td>
<td>C</td>
</tr>
<tr>
<td>≥ 2 or ≥ 1 leading to hospital admission</td>
<td>≥10</td>
<td>≥2</td>
<td>D</td>
</tr>
</tbody>
</table>

This will provide a GOLD patient classification of both Grade and Group
Development of resistant organisms should be factored into decision making. The Global Initiative for Chronic Obstructive Lung Disease (GOLD 2017) strategy document recommends inhaled triple pharmacologic therapy (ICS/LAMA/LABA) ONLY for patients with advanced COPD with persistent symptoms and risk of exacerbations.

The current recommendation from the GOLD document for primary choice of a dual therapy, and their preferred route before escalation to triple therapy is a LABA /LAMA combination, citing that a LABA / LAMA combination was superior to a LABA / ICS combination in preventing exacerbations and other patient reported outcomes. A Cochrane review also recently concluded that for the treatment of COPD, LABA / LAMA has fewer exacerbations, a larger improvement of FEV1, a lower risk of pneumonia, and more frequent improvement in quality of life as measured by an increase over 4 units or more of the SGRQ when compared to LABA /ICS. Another randomised controlled trial did not demonstrate any benefit of adding an ICS to LABA plus LAMA on exacerbations. Therefore, when reviewing patients currently on a LABA / ICS combination it maybe more clinically appropriate for them to step treatment across to a LABA / LAMA combination before escalation of therapy to a triple combination.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD 2017) strategy document recommends inhaled triple pharmacologic therapy (ICS/LAMA/LABA) ONLY for patients with advanced COPD with persistent symptoms and risk of exacerbations.

The current recommendation from the GOLD document for primary choice of a dual therapy, and their preferred route before escalation to triple therapy is a LABA /LAMA combination, citing that a LABA / LAMA combination was superior to a LABA / ICS combination in preventing exacerbations and other patient reported outcomes. A Cochrane review also recently concluded that for the treatment of COPD, LABA / LAMA has fewer exacerbations, a larger improvement of FEV1, a lower risk of pneumonia, and more frequent improvement in quality of life as measured by an increase over 4 units or more of the SGRQ when compared to LABA /ICS. Another randomised controlled trial did not demonstrate any benefit of adding an ICS to LABA plus LAMA on exacerbations. Therefore, when reviewing patients currently on a LABA / ICS combination it maybe more clinically appropriate for them to step treatment across to a LABA / LAMA combination before escalation of therapy to a triple combination.

Date: October 2017

Pharmacologic treatment algorithms by GOLD grading - Thick red boxes and arrows indicate the preferred GOLD treatment pathways

**Group A**
- Continue, stop or try alternative class of bronchodilator
- Evaluate effect
- A bronchodilator (short or long acting)

**Group B**
- LAMA + LABA
- Persistent symptoms
- Long acting bronchodilator (LABA or LAMA)

**Group C**
- LAMA + LABA
- LABA + ICS
- Persistent symptoms / further exacerbations

**Group D**
- Consider roflumilast if FEV1<50% predicted and patient has chronic bronchitis (to be initiated by secondary care) TA461
- Consider macrolide (in former smokers for up to 12 months) to be initiated in secondary care
- Further exacerbations
- LAMA + LABA + ICS
- LAMA + LABA
- LABA + ICS
- Persistent symptoms / further exacerbations

If still symptomatic and severe:
- Refer for pulmonary rehabilitation
- Consider referral to respiratory physician
- Consider referral for O2 assessment
- Consider nebuliser assessment
- Consider palliative care issues

For stable patients review:
- annually for mild to moderate;
- at least 6 monthly for severe and very severe
Reviews should include spirometry.
Ensure recall date is highlighted to patient and coded on system.
Choose devices the patient can and will use effectively; train the patient to use the device; check the patient's inhaler technique regularly at each visit; try to use same delivery device for each inhaled drug

**ELLIPTA strategy** (for LAMA, LABA+LAMA and LAMA plus LABA+ICS)

**Inspiratory Flow Rate Required:** Ellipta – MEDIUM/HIGH

**INCRUSE ELLIPTA (LAMA)** (Umeclidinium)

**ANORO ELLIPTA (LABA+LAMA)** (Umeclidinium + Vilanterol)

**INCRUSE ELLIPTA (LAMA)** (Umeclidinium)

**PLUS**

**RELVAR ELLIPTA 92/22 (ICS+LABA)** (Fluticasone + Vilanterol)
Choose devices the patient can and will use effectively; train the patient to use the device; check the patient’s inhaler technique regularly at each visit; try to use same delivery device for each inhaled drug.

**RESPIMAT strategy** (for LABA, LAMA, LABA+LAMA) plus **FOSTAIR MDI** for (ICS +LABA)

**Inspiratory Flow Rate Required:** Respimat – LOW, MDI - LOW

**SPIRIVA** Respimat (LAMA) **OR** **STRIVERDI** Respimat (LABA) (Tiotropium) (Olodaterol)

**SPIOLTO** Respimat (LABA+LAMA) (Tiotropium + Olodaterol)

**SPIRIVA** Respimat (LAMA) **PLUS** **FOSTAIR MDI** (ICS+LABA) (Beclometasone + Formoterol)

**OR**

**TRIMBOW** (LABA/LAMA/ICS) (Formoterol, Glycopyrronium, Beclometasone)
Choose devices the patient can and will use effectively; train the patient to use the device; check the patient’s inhaler technique regularly at each visit; try to use same delivery device for each inhaled drug.

**GENUAIR strategy** (for LAMA and LABA+LAMA), **OXIS Turbohaler** (for LABA), and **SYMBICORT Turbohaler** or **FOSTAIR Nexthaler** (for ICS+LABA).

**Inspiratory Flow Rate Required:** Genuair and Turbohaler MEDIUM / HIGH, Nexthaler – MEDIUM

- **EKLIRA Genuair** (LAMA) (Aclidinium)
- **OXIS Turbohaler** (LABA) (Formoterol)
- **DUAKLIR Genuair** (LABA+LAMA) (Aclidinium + Formoterol)
- **EKLIRA Genuair** (LAMA) (Aclidinium) **PLUS** **SYMBICORT Turbohaler** (ICS+LABA) (Budesonide + Formoterol)
- **OR** **FOSTAIR Nexthaler** (ICS+LABA) (Beclometasone + Formoterol)
1 Chronic obstructive pulmonary disease in over 16s: diagnosis and management Clinical guideline [CG101] Published date: June 2010 https://www.nice.org.uk/guidance/cg101


