COPD Inhaled Therapy Prescribing Guidance

For Basingstoke, Southampton and Winchester District Prescribing Committee

This guidance applies to patients with a COPD DIAGNOSIS CONFIRMED BY POSTBRONCHODILATOR SPIROMETRY:

Post bronchodilator FEV1/FVC of <0.7 (or below LLN) with symptoms consistent with COPD (exertional dyspnoea +/- cough productive of sputum) and risk factors (usually >20 pack years smoking history).

First and most cost effective steps in treatment include

- Annual flu and one off pneumococcal vaccination
- Smoking Cessation: best results with a combination of pharmacological therapy and psychological support
- Pulmonary Rehabilitation: best evidence for those scoring grade 3 and above on MRC score

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Key Principles and Definitions

Key Principles

- Recognition of EXACERBATION RISK requiring inhaled steroids by:
  - Documentation of Exacerbation History - both hospitalisation and home treated exacerbations relevant
  - % predicted FEV1 (risk increases with decreasing FEV1: GOLD Stage 3 and 4 ie FEV1<50% are at significantly increased risk)
  - Recognition of Asthma/COPD overlap and eosinophilic patients who require inhaled steroids as part of their treatment due to exacerbation risk
- Do not prescribe an inhaled without assessing INHALER TECHNIQUE and demonstrating use of the inhaler - Demonstration of device may be delegated to allied health care professionals including pharmacists
- Aim for device CONSISTENCY and use COMBINATIONS where possible to keep number of inhalers to a minimum

<table>
<thead>
<tr>
<th>GRADE OF OBSTRUCTION</th>
<th>Post bronchodilator %FEV1 (FEV1/FVC &lt;70%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>&gt;80%</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>50-80%</td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>30-49%</td>
</tr>
<tr>
<td>4</td>
<td>V severe</td>
</tr>
<tr>
<td></td>
<td>&lt;30%</td>
</tr>
</tbody>
</table>

MRC Breathlessness Scale

1. Not troubled by breathlessness except on strenuous exercise
2. Short of breath when hurrying on the level or walking up a slight hill
3. Walks slower than most people on the level, stops after a mile or so, or stops after 15 minutes walking at own pace
4. Stops for breath after walking about 100 yards or after a few minutes on level ground
5. Too breathless to leave the house, or breathless when undressing

ASTHMA-COPD OVERLAP (ACOS) – characterised by persistent airflow limitation with several features usually associated with asthma and with COPD

Best discriminating features listed below. 3 or more features below suggest disease; similar numbers in both asthma and COPD suggest presence of ACOS.

ASTHMA: onset<20yrs, symptom variability day to day, diurnal variation, recognised triggers, record of variable airflow obstruction (spirometry or PEF), normal lung function between symptoms, previous doctor diagnosis of asthma, family history of asthma or atopy, seasonal variation not progressive, spontaneous recovery or immediate/early response to BD or ICS, normal CXR.

COPD: onset >40yrs, symptoms persistent despite treatment, good/bad day variation only, chronic cough and sputum, record of persistent obstruction post bronchodilator, abnormal lung function, previous doctor diagnosis COPD/CB/emphysema, heavy exposure to risk factor (>20 pack yrs), slowly progressive, limited relief from rapid acting bronchodilators, severe hyperinflation
Step 1: Determine Inhaler Drug Class Indicated

NON EXACERBATOR PATHWAY (≠ No history of hospitalisation and 0-1 exacerbation per year)

LAMA or LABA Provide equivalent bronchodilation:
Better evidence for prevention of exacerbations by LAMA than LABA alone but caution advised in using LAMA if cardiac arrhythmia (excluding chronic AF) and NYHA class III/IV heart failure

If remain symptomatic progress to LAMA/LABA combination. Prescriber can consider starting with combination in preference to single agent in more symptomatic disease

EXACERBATOR PATHWAY = History of 1 hospitalisation or more than 1 exacerbation per year1

Features of Asthma/COPD Overlap Syndrome?

Evidence of severe obstruction on postbronchodilator spirometry (FEV1<50%)2

All patients also require a short acting beta2 agonist (SABA) as a reliever.

Reassessment following new medication required. If no improvement, review technique and consider alternative device, review diagnosis including secondary care referral if necessary and proceed to combination therapy for maximal clinical benefit.

1 ‘Exacerbator’ as per GOLD 2014 guideline review. If the patient is no longer exacerbating we do not currently recommend weaning steroids but this will be reviewed in future guidance as more evidence becomes available.

2 Current guidelines recommend giving patients with severe obstruction FEV1 <50% inhaled corticosteroids for additional bronchodilatation and exacerbation reduction. Note increased risk of non-fatal pneumonia with ICS (see note 2 p5) so consider individual risk/benefit ratio.
Step 2: Assess Inhaler Technique to determine if requires Dry Powder Inhaler (DPI) or Metered Dose Inhaler (pMDI)

Patient’s ability to use the device is essential - this will be determined by the inspiratory flow that they can achieve (which varies according to resistance of the device), manual dexterity, coordination and oral compatibility with mouthpiece. Patient preference around dosing schedule and device type will optimise compliance.

**No**

Determine if inspirational effort better suited to DPI or pMDI using in-check device on e.g. turbohaler vs. pmdi setting. Assess device suitability and teach technique as per DPI or pMDI guidance below including any use of spacer device.

**Inhaler already prescribed?**

**No**

Critical errors identified

**Yes**

Assess all aspects of technique as below

- If no, or easily correctable errors; demonstrate & re-inforce technique and re-assess.
- Discuss specifics, cleaning and replacement as per device information appendix.

**Dry Powder Inhaler (DPI)**

*DEEP FORCEFUL LONG inhalation*

**Dexterity Assessment:** Unwrapping Capsule /loading/piercing or twisting of device

**Mouthpiece profile:** Ability to lip purse, consider any weakness/dental problems or physiological problems

**Inspiration:** Can your patient reach & maintain a steady inspired flow over 5 seconds on a particular device?

**Ability to Breath hold:** 10 seconds where possible

Consider ability to use as required/reliever medication without carer support

**pMDI & Soft Mist**

*GENTLE SLOW LONG inhalation*

**Dexterity Assessment:** Hand strength to depress canister. Twisting of device, ability to handle size of spacer

**Mouthpiece profile:** Can your patient lip purse? Is there facial weakness/dental or physiological problems? Is a mask needed with spacer?

**Inspiration:** Patient preference on chamber size. Benefit of chamber coaching whistle. Can your patient maintain inspiration for 5 seconds and breath hold or better with tidal breathing technique?

**Co-ordination:** Advocate and demonstrate Spacer use. Teach and assess timing of dose release and breathing in.

Consider ability to use PRN medication without carer support

**Common Errors**

- Not removing cap, not loading/piercing capsule, not shaking/shake at wrong time, not breathing out, holding device at wrong angle, blocking vents, timing dose release & inspiration, too fast/slow, no breath hold

**Technique**

- Cap off, shake device &/or load the dose. Watch position.
- Gently breathe out then make good lip seal around mouthpiece.
- Breathe in & release the dose (if required) as per DPI or pMDI/soft mist technique.
- Remove inhaler from mouth & hold breath for 5-10 seconds. Replace cap, repeat if required

**Re-assessment**

- Exacerbation & recovery may affect ability & technique.
- Technique deteriorates 2-3 months after coaching so repeat.
- Keep device consistency where possible.
- Signpost pharmacist support & review service.

Videos; Asthma UK & wires.wessexahsn.org.uk/video-series/inhaler-technique/
Step 3: Combine Device Assessment and Inhaler Class and Educate Patient with chosen device

Identify the preferred inhaler by class and device (DPI/MDI). Where there is a choice of DPI available in drug class identify most suitable device (dexterity/oral compatibility). Prices are quoted to inform cost effective prescribing when a choice remains.

**DEVICE (BOLD); Trade name (italics), devices colour coded**

<table>
<thead>
<tr>
<th>Step 3: Combine Device Assessment and Inhaler Class and Educate Patient with chosen device</th>
<th>DPI – hard and fast and deep</th>
<th>pMDI – slow and gentle and long</th>
<th>Cost Per 30 days*</th>
<th>Cost Per 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SABA</strong>¹</td>
<td><strong>DPI</strong> – hard and fast and deep</td>
<td><strong>pMDI</strong> – slow and gentle and long</td>
<td><strong>Cost Per 30 days</strong></td>
<td><strong>Cost Per 30 days</strong></td>
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<td><strong>SABA</strong>¹</td>
<td><strong>DPI</strong> – hard and fast and deep</td>
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<td><strong>Cost Per 30 days</strong></td>
<td><strong>Cost Per 30 days</strong></td>
</tr>
</tbody>
</table>

1. All patients require SABA in addition to long acting therapy. Preferred SABA is pMDI through aerochamber due to cost and the ability to take multiple single actuations through aerochamber and tidal breath in exacerbation. However if patients are non compliant with an aerochamber then a DPI SABA should be considered as it may be more cost effective.

2. Patients should be warned of the increased risk of non-fatal pneumonia with use of any ICS. This risk appears to be dose related and related to type of steroid with fluticasone posing a greater risk than budesonide or beclomethasone.

3. All inhalers should be prescribed by brand name and device to avoid confusion. Prescribers must state Budesonide/Formoterol formulations by brand name and device or wrong inhaler may be dispensed.

4. Prices correct at time of finalisation.
Appendix 1: Dry Powder Inhaler Devices

All DPI’s require a **DEEP, FORCEFUL AND LONG** inhalation

Consider dexterity, mouthpiece, dose delivery indication and carer support. Assess inspiratory effort on in-check, whistle or placebo

<table>
<thead>
<tr>
<th>Inhaler Device</th>
<th>Dexterity Required</th>
<th>Confirmation of Actuation</th>
<th>Loading required</th>
<th>Considerations for device use</th>
<th>Assessment tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>BREEZHALER</td>
<td>Required</td>
<td>Capsule cleared.</td>
<td>Foil protected capsule</td>
<td>Pierce capsule firmly but once only. Take 2 inhalations from 1 capsule. Do not wash device LAMA, LABA, LAMA/LABA</td>
<td>Placebo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Capsule vibration.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lactose taste.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EASYHALER</td>
<td>Minimal</td>
<td>Lactose taste.</td>
<td>No</td>
<td>Requires shaking. Dose counter decreases in 5’s triggered on depressing top section of device. ICS, SABA, LABA</td>
<td>Empty device placebo/mouthpieces</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Possibly no taste</td>
<td>No</td>
<td>Large dose counter decreases each time lid is opened. 6-week shelf life on opening foil cover. Do not block vents ICS/LABA, LAMA, LAMA/LABA</td>
<td>Whistle and placebo</td>
</tr>
<tr>
<td>ELLIPTA</td>
<td>Minimal</td>
<td></td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Possibly no taste</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lactose taste.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GENUAIR</td>
<td>Minimal</td>
<td>Colour indicator/Audible click/Lactose taste</td>
<td>No</td>
<td>Dose counter (in 10's) plus separate lock out mechanism when empty. Keep breathing in after click heard to receive full dose. Indicator changes on successful actuation only LAMA, LAMA/LABA</td>
<td>Placebo/disposable mouthpieces</td>
</tr>
<tr>
<td>HANDIHALER</td>
<td>Required</td>
<td>Capsule vibration during inhalation</td>
<td>Foil protected capsule</td>
<td>Pierce capsule firmly, once only. Take 2 inhalations from 1 capsule. Device should be washed monthly and left to air-dry for 24 hours LAMA</td>
<td>Placebo</td>
</tr>
<tr>
<td>TURBOHALER</td>
<td>Minimal. Base gripper from AZ</td>
<td>Lactose taste</td>
<td>No</td>
<td>Dose counter decreases on turning base. SABA, LABA, ICS/LABA</td>
<td>Whistle/placebo/in-check</td>
</tr>
<tr>
<td>SPIROMAX</td>
<td>Minimal</td>
<td>Lactose taste</td>
<td>No</td>
<td>Dose counter decreases when lid is opened. Drops in &quot;2's&quot;. 6-month shelf life on opening foil cover. Do not block vents ICS/LABA</td>
<td>Placebo</td>
</tr>
</tbody>
</table>
**Appendix 2: MDI and Soft Mist Devices**

All Metered Dose and soft mist inhalers require a **SLOW, GENTLE and LONG** inhalation

Consider spacer, dexterity, mouthpiece and carer support. Assess inspiratory effort using an assessment tool (in-check, flo-tone or placebo)

<table>
<thead>
<tr>
<th>Device</th>
<th>Hand strength</th>
<th>Co-ordination required</th>
<th>Confirmation of Actuation</th>
<th>Spacer</th>
<th>Considerations for device use</th>
<th>Assessment tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>pMDI</td>
<td>Required. Haleraid available OTC</td>
<td>Required</td>
<td>Taste, Dose counters often on device</td>
<td>Yes</td>
<td>Device re-priming maybe needed as early as after 3 days of no use. SABA, SAMA, LABA, ICS, ICS/LABA</td>
<td>In-check, flo-tone and trainer, placebo</td>
</tr>
<tr>
<td>Ba-pMDI</td>
<td>Minimal</td>
<td>Reduced</td>
<td>Taste, audible click</td>
<td>No</td>
<td>Device re-priming required after 5 days of no use. Close lid/lower lever to prime for 2nd dose when required.</td>
<td>In-check, Easi-breathe disposable mouthpieces from TEVA, placebo</td>
</tr>
<tr>
<td>RESPIMAT</td>
<td>Required</td>
<td>Required</td>
<td>Click from spring on dose release. Dose counter on side</td>
<td>Off license but can be considered where absolutely necessary</td>
<td>Soft mist released over &lt;2 seconds. Keep inhalation going for at least 4 seconds. Needs priming after 7 days of no activity. Do not cover air vent</td>
<td>Placebo</td>
</tr>
</tbody>
</table>
Appendix 3: Spacer Devices

Spacer choice should be driven by device compatibility and patient preference.

Spacers with whistles maybe a useful adjunct to inhaler technique

Face Masks maybe appropriate for some adults

- The spacer should be compatible with the pMDI being used.
- The drug is administered by repeated single actuations of the metered-dose inhaler into the spacer, with each actuation followed by inhalation.
- There should be minimal delay between pMDI actuation and inhalation.
- Tidal breathing is as effective as single breaths.
- Spacers should be cleaned monthly rather than weekly as per manufacturer’s recommendations or performance is adversely affected. They should be washed in detergent and allowed to dry in air. The mouthpiece should be wiped clean of detergent before use.
- Drug delivery via a spacer may vary significantly due to static charge. Metal and other antistatic spacers are not affected in this way.
- Plastic spacers should be replaced at least every 12 months but some may need changing at six months.