NHS SCOTLAND

Respiratory Prescribing Strategy 2014 to 2016

Developed by the Respiratory MCN Working Group
Pharmacy and Medicines
Scottish Government Health and Social Care Directorates
The prescribing analysis included in this report has been quality assured by information services division (ISD) Scotland. While every effort has been made to ensure the accuracy of the data, it is possible that there are inaccuracies. It is essential that any data, table, graph contained within this document is not used for any other purpose than this respiratory prescribing strategy, and that is not passed on to any other person or organisation.

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Acknowledgements

This Respiratory Prescribing Strategy 2014 to 2016 has been achieved through a short life working group (SLWG) with membership from the NHS board Respiratory MCN teams. The resulting document has been informed by respiratory work undertaken by the boards.

Group members are shown below:

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<th>Position/Role</th>
<th>Organization</th>
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<tbody>
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<td>Peter Slane</td>
<td>General Practitioner</td>
<td>NHS Tayside</td>
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With thanks to the prescribing team at information services division (ISD) for providing additional expertise around the prescribing data. With special thanks to Fiona Eastop for pulling the report together and to Sean MacBride-Stewart for collated and presenting the prescribing data.
Foreword

This Respiratory Prescribing Strategy (2014 – 2016) has been written from a short life working group set up with the support and input of the lead clinicians of the Respiratory Managed Clinical networks in NHS Scotland.

It is designed to promote appropriate, evidence-based, cost-effective prescribing of treatment for asthma and COPD. This strategy is important, as currently NHS Scotland spends £125 million on respiratory medicines each year. The advice is based on clinical guidelines for COPD (NICE and GOLD) and asthma (SIGN 101). Cost-effective prescribing involves both the selection of therapies for an individual patient and consideration of when a treatment is no longer effective and should be stopped. When introducing a new therapy for an individual with COPD or asthma the prescriber needs to consider the advantages and disadvantages of any treatment and also to subsequently review whether or not that newly introduced therapy has been effective.

Management, choice of medication, and place in treatment of the medication differs for COPD and asthma. For example inhaled corticosteroids are used early on in asthma, but only for patients with severe COPD, and where other treatment options have been ineffective, as it carries the risk of pneumonia. Patients with asthma may develop COPD in later life. It is therefore important, but challenging, to regularly reassess the continued efficacy of any therapy used in order to avoid continuing medication that is no longer effective. Continued efficacy might be tested through temporary withdrawal of a therapy, with appropriate monitoring.

We recognise that the recommendations within this strategy cover the majority of prescribing in Scotland but there will be some individual patients who require treatment out-with formulary recommendations. When this is the case, those responsible for ongoing prescribing and monitoring should understand why this recommendation has been made.

Iain Small
Chair of Respiratory MCN

Bill Scott
Chief Pharmaceutical Officer

Aileen Keel, CBE
Acting Chief Medical Officer
Executive Summary

Respiratory disease in primary care comprises mainly of asthma (in adults and children) and Chronic Obstructive Pulmonary Disease (COPD). The incidence of asthma and COPD is increasing, with both potentially life-long conditions and therefore presenting a considerable challenge for NHS Boards in terms of optimising clinical outcomes and ensuring cost-effectiveness.

The total spend on respiratory medicines in 2012/13 was £125 million (i.e. 13% of the total expenditure on prescriptions dispensed in the community) with costs increasing year-on-year for the last 9 years. There is limited scope for prescribing efficiencies from the availability of generic products and an increasing number of newer agents, usually at greater costs. Analysis of Data suggests that there is prescribing out-with guidelines.

This prescribing strategy and review of current prescribing aims to provide NHS Boards with additional information to complement the existing guidelines and highlight key areas, in which patient safety and care can be optimised. It should be read alongside clinical guidelines and is not intended to replace these. Asthma guidelines state that therapy should be stepped-up, or stepped-down through the BTS/SIGN treatment steps where necessary, and regularly reviewed to ensure the lowest effective dose is prescribed. Treatment options are different for asthma and COPD with inhaled corticosteroid (ICS) use (in combination with LABA) restricted to those in COPD with severe disease (and frequent exacerbations) as ICS in COPD is associated with increased risk of pneumonia.

Review of inhaler technique is essential to ensure that the therapeutic agent is optimally delivered, prior to considering a change in therapy or dose.

Key messages

1. Local formulary review by NHS Boards and Respiratory MCNs should ensure clinical-effectiveness, patient safety and cost-effectiveness
2. Patient safety in respiratory prescribing is an area for concern where there is the risk of:
   a. higher than necessary doses of inhaled corticosteroids in asthma;
   b. unnecessary exposure to inhaled corticosteroid in mild COPD; and
   c. duplication of therapy
3. Patients should receive regular face-to-face review to ensure correct inhaler technique, self-management (where appropriate) and concordance with agreed treatment
4. Practices should review patient treatment according to disease stage and current guidelines, and consider audit to ensure patient therapy is appropriate
Section 1: General

1.1 Introduction

The main respiratory conditions treated in primary care are asthma (in adults and children) and Chronic Obstruction Pulmonary Disease (COPD). This prescribing strategy is limited to the chronic treatment of these two respiratory conditions.

The purpose of this strategy is to ensure person-centred, evidence-based, safe and cost-effective prescribing for people living with asthma and/or COPD. The strategy is based on current clinical guidance, mainly SIGN/BTS for asthma and GOLD/NICE\(^1\) for the treatment of COPD.

The prescribing strategy provides tools to review and assess current therapy. It focuses on areas of patient safety and the appropriateness of therapy.

Traditionally, asthma has been managed predominantly in primary care. COPD is increasingly being managed exclusively in primary care, especially with the widespread use of spirometry in GP practices.

Secondary care continues to have a vital role in the management of more complex patients, and those who require specialist advice. The strategy is intended for use by both primary and secondary care to ensure a consistent approach to patient care. Where specialist care of complex patients falls outside of the strategy recommendations it would be good clinical practice to clarify the rationale behind the decision making to primary care prescribers. The strategy does not include review of the long-term use of oral systemic corticosteroids. It is recognised that some patients with advanced COPD may require maintenance with oral corticosteroids, when the dose should be as low as possible and osteoporosis prophylaxis considered.

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\(^1\)The current clinical guidelines for COPD differ in some respects. Whilst NICE is primarily for the use in England, some elements are adopted for Scottish use, and it is in line with the QOF of the Scottish GP contract. However GOLD (2012) is more up-to-date, but its use has not been ratified, nor is it in line with QOF.
1.2 Demographics

1.2.1 Asthma– demographics

The 2011/12 Quality Outcomes Framework (QOF) reported that the prevalence of asthma was 6.0% of the population. This has increased from 5.4% in 2004/05. QOF prevalence data does not separate between adult and paediatric asthma. QOF prevalence reports are derived from a register of patients with asthma; excluding patients with asthma who have been prescribed no asthma-related drugs in the previous twelve months, which therefore may underestimate the overall prevalence of asthma. Recent analysis of prescribing data, hospital admissions and A&E data by the University of Aberdeen has indicated a higher prevalence of 8%.

Practice Team Information (PTI), provided by Information Services Scotland (ISD), shows there were approximately 0.25 million patients with a primary care consultation for asthma in 2011/12. This suggests that 1 in 6 patients with a recorded diagnosis for asthma are not being reviewed in primary care during that 12 month period. The asthma patients presenting in primary care accounted for approximately 0.5 million consultations – i.e. an average of 2 consultations per patient.

Figure 1: Asthma—estimated number of patients in Scotland consulting a GP or practice nurse at least once in the financial year 2011/12 per 1,000 patients registered; by age group

NOTES
a. Based on ISD's Read Code Grouping (RCG) "Asthma".
b. Based on 59 PTI practices that submitted complete GP and practice nurse data for the year ending 31 March 2012. Figures are standardised to the Scottish population by deprivation. For further information see
c. Population source: Community Health Index (CHI) record, as at 30 September 2011.

Figure 1 shows an increase in consultations for patients in their early thirties until early seventies.

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2 Data Source: QMAS Database/QOF Calculator - 2011/12 data as at 18th July 2012
3 Steiner M, Devereux G et al. University of Aberdeen Prevalence & treatment of Active Asthma in Scotland using the Prescribing Information System 2013
1.2.2 COPD - demographics

The 2011/12 QOF-reported prevalence of COPD was 2.1%. In 2006/07, the prevalence was 1.8% but there has been a change in the QOF definitions after 2010/11, so prevalence rates cannot be accurately compared.

Practice Team Information (PTI) provided by ISD shows there were approximately 0.1 million patients with a primary care consultation for COPD in 2011/12. This suggests that most registered COPD patients have at least one consultation in primary care in a year. COPD patients accounted for approximately 0.25 million consultations (i.e. an average 2.5 consultations per patient).

Figure 2: COPD\(^4\) – estimated number of patients in Scotland consulting a GP or practice nurse at least once in the financial year 2011/12\(^b\) per 1,000 patients registered\(^c\); by age group

NOTES
a. Based on ISD’s Read Code Grouping (RCG) ‘Bronchitis, emphysema & other chronic obstructive pulmonary diseases’.
b. Based on 59 PTI practices that submitted complete GP and practice nurse data for the year ending 31 March 2012. Figures are standardised to the Scottish population by deprivation. For further information see [http://www.isdscotland.org/Health-Topics/General-Practice/GP-Consultations/](http://www.isdscotland.org/Health-Topics/General-Practice/GP-Consultations/)
c. Population source: Community Health Index (CHI) record, as at 30 September 2011.

Figure 2 shows the rate of consultations across the ages, and as expected this increases with age.

\(^4\)Data Source: QMAS Database/QOF Calculator - 2011/12 data as at 18th July 2012
Section 2: Respiratory Prescribing

2.1 Overall costs

The total spend in Scotland for respiratory prescribing is around £125 million. It is not surprising that the majority of this occurs in primary care, with ICS &LABA combination products making the main contribution.

Figure 3: Table to show respiratory prescribing cost by class of medicine

<table>
<thead>
<tr>
<th>Class of Respiratory Medicine</th>
<th>Primary Care</th>
<th>Secondary Care</th>
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<tr>
<td>COMBINATION ICS &amp;LABA</td>
<td>£60,579,990</td>
<td>£2,283,883</td>
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<tr>
<td>LAMA</td>
<td>£23,849,873</td>
<td>£1,153,484</td>
</tr>
<tr>
<td>ICS</td>
<td>£10,244,069</td>
<td>£196,757</td>
</tr>
<tr>
<td>SABA</td>
<td>£9,113,153</td>
<td>£271,102</td>
</tr>
<tr>
<td>LRA</td>
<td>£7,505,915</td>
<td>£118,153</td>
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<tr>
<td>LABA</td>
<td>£3,991,138</td>
<td>£84,291</td>
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<tr>
<td>MUCOLYTICS</td>
<td>£3,197,293</td>
<td>£865,128</td>
</tr>
<tr>
<td>SAMA</td>
<td>£636,790</td>
<td>£54,196</td>
</tr>
<tr>
<td>THEOPHYLLINE</td>
<td>£403,468</td>
<td>£25,547</td>
</tr>
<tr>
<td>COMBINATION SABA&amp;SAMA</td>
<td>£317,353</td>
<td>£46,839</td>
</tr>
<tr>
<td>MISCELLANEOUS</td>
<td>£70,166</td>
<td>£57,501</td>
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<tr>
<td><strong>Sum:</strong></td>
<td><strong>£119,909,207</strong></td>
<td><strong>£5,156,882</strong></td>
</tr>
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NOTES

a. Classification based on SIGN/BTS and SIGN/GOLD guidelines (ICS = inhaled corticosteroid; LABA = long acting beta2 agonist; LAMA = long acting muscarinic antagonist; LRA = leukotriene receptor antagonist; SABA = short acting beta2 agonist; SAMA = short acting muscarinic antagonist)
b. From PRISMS, which details the prescriptions dispensed by community pharmacists and appliance contractors. Net Ingredient Cost = price paid by NHS Scotland for medicines dispensed by community pharmacies and refers the price after discounts and does not include any dispensing costs or fees.
c. From HMUD which details medicines supplied within hospitals. This data is incomplete because information from NHS Tayside is not currently available.

Figure 3 shows that the primary care spend on drugs used in respiratory medicines in 2012/13 was almost £120 million per annum, and currently accounts for more than 12.99% of the total expenditure on prescriptions dispensed in the community. This represents a 3.16% increase from the previous year, whereas the incidence of respiratory disease has not increased by the same amount. The spend in secondary care is over £5 million, which is approximately 1.51% of the total expenditure on medicines within hospitals.
2.2 Prescribing trends

Over the last nine years costs have increased with the greatest change being attributable to combination ICS and LABA products.

Figure 4: Primary Care Net ingredient costs\(^a\) within respiratory medicine\(^b\)

NOTES
\(a\). From PRISMS, which details the prescriptions dispensed by community pharmacists and appliance contractors. Net Ingredient Cost = price paid by NHS Scotland for medicines dispensed by community pharmacies and refers the price after discounts and does not include any dispensing costs or fees.
\(b\). Classification based on SIGN/BTS and SIGN/GOLD guidelines (ICS = inhaled corticosteroid; LABA = long acting beta\(_2\) agonist; LAMA = long acting muscarinic antagonist; LRA = leukotriene receptor antagonist; SABA = short acting beta\(_2\) agonist; SAMA = short acting muscarinic antagonist)
\(c\). Calendar Quarters: Q1 = January to March; Q2 = April to June; Q3 July to September; Q4 October to December

Further prescribing analysis and discussion is available in Appendix 1, and shows:
- Cost comparison: 30 days treatment of combination (ICS & LABA) inhalers (Fig. 5)
- Annual variations in prescribing respiratory items, with an increase in combination ICS & LABA and LAMA, but decreasing use of individual LABA and ICS from 2004/05 to 2012/13 (Fig. 6)
- Net ingredient cost of selected respiratory inhalers from 2004/5 to 2012/13 (Fig. 7)
- Number of patients prescribed selected classes of respiratory medicines showing a peak prescribing in the age 65 to 69 year group (Fig. 8)
- Comparison of prescribing rates of combination ICS & LABA by age and discussion on the effect of COPD on the prescribing rates (Fig. 9)
- Prescribing of combination inhalers in children, showing that prescribing out-with license indication occurs for some patients (Fig. 10)
- Prescription combinations out-with guidelines. The availability of the new Prescribing Information System (PIS) allows for more in-depth prescribing analysis and has highlighted some areas of prescribing out-with guidance.
Section 3: Clinical Guidelines

The prescribing for people with asthma is clearly defined in SIGN guideline 101: British Guideline on the Management of Asthma (produced jointly by SIGN and the British Thoracic Society (BTS)), which is currently subject to a regular update.

The prescribing for people with COPD is defined in the GOLD guidelines (Global Initiative for Chronic Obstructive Lung Disease), which were updated in February 2013. Although more aligned to SMC recommendations, these are not yet ratified for use in NHS Scotland. Therefore NICE may also be referenced, but it is acknowledged that this was first issued in 2010.

Available at:
http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html
http://www.nice.org.uk/cg101
Section 4: The Prescribing Strategy

This prescribing guidance does not supersede either SIGN/BTS 101 or GOLD clinical guidelines. It provides further direction on the selection of therapeutic agent. Primary focus is on patient safety and the appropriateness of therapy. Cost-effectiveness is considered as a secondary concern.

The prescribing strategy also takes account of recommendations from the Scottish Medicines Consortium (SMC).
Available at: http://www.scottishmedicines.org.uk/Home

It is recognised that it may be easier to follow the prescribing strategy when initiating treatment for new patients. However, it is just as important to review existing patients to ensure safety and appropriateness of therapy.

The use of audit is recommended in the implementation of the strategy, both in primary and secondary care, and for both non-medical and medical prescribers.
Section 5: Inhaler technique & monitoring

5.1 Inhaler technique

The correct inhaler technique is fundamental for the therapeutic benefit of inhaled respiratory medicines because it ensures correct drug delivery and improves disease control. Poor inhaler technique increases the risk of poor disease control, adverse effects, inappropriate escalations in therapy and unnecessary increased cost.

It is important that every opportunity should be taken to review inhaler technique, and if necessary re-educate the patient on the correct technique. If the patient can still not operate or use the device effectively, it is necessary to change to a more suitable device. The traditional view that a metered dose inhaler (MDI) is the most cost-effective option may not be valid if the patient is unable to operate it correctly, due to the opportunity cost of poorly controlled disease.

The inhaler device should be age appropriate according to license, and the use of spacers is recommended in children.

When a prescriber is considering an increase in dose/treatment step, particular consideration should be given to assessing inhaler technique and compliance. This should be done in conjunction with review of peak flow readings, which can be reduced due to poor drug delivery.

A recent project, the Inhaler Technique Improvement Project, (delivered in the South Central Region of England between April 2011 and June 2012) has demonstrated that correct inhaler technique produces improvements in: patient outcomes; a positive association with changes in emergency hospital admissions; improved asthma control and COPD symptom management. Full outcomes of the project can be accessed at: http://www.networks.nhs.uk/nhs-networks/south-east-coast-respiratory-programme/documents/120904%20CIREM_ITIP_HIEC_Evaluation.pdf

The project also recommends that clinical staff have their teaching technique appraised regularly to ensure correct demonstration.

5.2 Peak Expiratory Flow (PEF) monitoring in Asthma

SIGN/BTS (2011 update) states that the use of PEF monitoring is not of proven benefit in the improving symptom control in adults and children. However there may be some benefit in adults with severe disease; those with poor perception of bronchoconstriction and the assessment of an acute exacerbation.

As with other respiratory therapies, NHS boards should consider their preferred choice of PEF meters.
Section 6: Asthma – adults

6.1 Assessment of therapy

- **Assessment** of therapy indicates whether a step-up, maintenance or step-down of treatment is required
- **Adherence to therapy** and the dose the patient is taking should be checked, prior to considering a step-up. The importance of preventative medication should be explained to the patient
- **Exacerbation** advice should include appropriate treatment of the exacerbation, e.g. systemic corticosteroids and not a step-up in inhaler treatment
- **Measurement** of asthma control should be using a recognised method

The recommended assessment is the Asthma Control Test\(^5\), (which can be read-coded on GP computer systems) available at: [http://www.asthma.com/resources/asthma-control-test.html](http://www.asthma.com/resources/asthma-control-test.html)

6.2 Therapeutic principles

- **SIGN/BTS guidelines** recommend that asthma is treated in a stepwise manner, where the patient is moved up, maintained or moved down the BTS/SIGN steps dependent on the control of asthma
- Patients should have an asthma self-management plan in place
- Smoking cessation is important, and continued smoking reduces the response to ICS
- Patients should be started on the lowest appropriate dose of inhaled corticosteroid (SIGN/BTS recommend 400 micrograms beclometasone per day in adults, and 200 micrograms beclometasone per day in children)
- The maximal effect to inhaled corticosteroid therapy is generally achieved with low to moderate doses (200-800 micrograms beclometasone per day). Doses above this increase the risk of adverse effects
- Leukotriene receptor antagonists or sustained release theophylline can be considered as alternatives to increasing steroid dose
- Patients at Step 4 of the BTS/SIGN guideline require high-dose corticosteroids and regular bronchodilators due to persistent poor control
- Prescribing data suggests that there are more patients being treated at Step 4 than would be expected from prevalence data. Over treatment exposes the patient to increased risk of adverse effects
- The British National Formulary (BNF) recommends that patients receiving >800 micrograms of beclometasone (or equivalent, e.g. fluticasone propionate 500 microgram or 800 microgram budesonide) per day should be issued with a steroid card. See Appendix 1 for dose equivalence chart
- Consider osteoporosis screening in patients maintained on inhaled steroid dose >800 micrograms per day beclometasone (or equivalent) for 10 years and a 10 year risk of major fracture >10% (use WHO FRAX): [www.sheffield.ac.uk/frax](http://www.sheffield.ac.uk/frax)

\(^5\) Currently QOF requires the completion of the RCP questions, rather than the ACT
• SIGN/BTS provides guidance on inhaler devices, to ensure that patients have demonstrated satisfactory technique prior to supply, as discussed previously

• Whilst a metered-dose inhaler (MDI), with or without a spacer, may be as effective as any other hand held device, patients may prefer some types of dry powder inhaler (DPI). See Section 5.1 on inhaler technique

• See chart for suggested inhaler choice, treatment steps and rationale (Appendix 2)

• Historically, pressurised meter dose inhalers (pMDIs) were generally the most cost-effective devices, however there are exceptions (e.g. Seretide 250 evohaler® 30 days treatment - £59.48; Seretide 500 accuhaler® 30 days treatment - £40.92). See Appendix 3 for NHS board variation in use

Section 7: Asthma – children

7.1 Assessment of Therapy

- **Assessment** of therapy indicates whether a step-up, maintenance or step-down of treatment is required.
- **Adherence to therapy** and the dose the patient is taking should be checked, prior to considering a step-up. The importance of preventative medication should be explained to the patient/parent/carer.
- **Exacerbation** advice should include appropriate treatment of the exacerbation, e.g. systemic corticosteroids and not a step-up in inhaler treatment.
- **Measurement** of asthma control should be using a recognised method. SIGN/BTS suggests a variety of measurements to assess asthma control in children.

The recommended assessment is the Asthma Control Test (children aged 4-11 years), available at: [http://www.asthma.com/resources/childhood-asthma-control-test.html](http://www.asthma.com/resources/childhood-asthma-control-test.html)

7.2 Therapeutic principles

- SIGN/BTS guidelines recommend that asthma is treated in a stepwise manner, where the patient is moved up, maintained or moved down dependent on the control of asthma.
- Response to treatment should be undertaken at initiation and at review.
- Patients should have an asthma self-management plan in place and this should be shared with all involved in the child’s care.
- An appropriate low dose of inhaled corticosteroid can control asthma symptoms, whilst minimising the incidence of side effects.
- Children receiving >400 micrograms of beclometasone (or equivalent, e.g. fluticasone propionate 200 microgram or 400 microgram budesonide) per day should be issued with a steroid card. See Appendix 1 for dose equivalence chart.
- Children should be prescribed asthma medication within the licensed ages and doses. The appropriateness of off-label use of respiratory medicines in children should be reviewed, and where necessary referred to secondary care for further specialist input.
- See Appendix 4 for a summary of licensed devices, age ranges and doses.
- Devices should be suitable for age, and may require the use of a spacer.
- See chart for suggested inhaler choice, treatment steps and rationale (Appendix 5).

7.3 Monitoring principles

- Doses of ≥400 micrograms beclometasone (or equivalent) per day have been associated with systemic side effects in children.

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6 Currently QOF requires the completion of the RCP questions, rather than the ACT.
• Consideration should be given to any concomitantly administered steroids, e.g. topical, nasal, which may increase overall steroid dose
• Paediatric patients prescribed ≥800 micrograms beclometasone (or equivalent) per day should be under the care of paediatric specialist services\(^7\) for the duration of treatment, as highlighted in Appendix 4
• ACTH test can be considered to assess adrenal responsiveness (but may not be able to accurately predict clinical relevant adrenal insufficiency)
• Paediatric patients should have their weight and height centile recorded annually to detect any significant changes in growth

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\(^7\) Paediatric specialist services, as defined by Healthcare Improvement Scotland (HIS) as, within healthcare services there are staff trained to meet the special requirements of children.
Section 8: COPD

8.1 Assessment of Therapy

- Inhaler technique; patient compliance and the dose the patient is taking should be checked, prior to considering a change in therapy
- The recommended assessment is the COPD Assessment Test (CAT), available at: http://www.catestonline.co.uk/test/index.htm
- Assessment of FEV$_1$ should always be post-bronchodilator therapy

8.2 Therapeutic principles

- Drug treatment should be commenced in line with national guidelines, which are based on symptoms and disease severity
- The therapeutic goals for COPD treatment are to reduce symptoms, improve quality of life and reduce exacerbations
- All treatments require to be assessed against these goals to determine efficacy and treatment discontinued if no benefit is seen
- Long-acting anti-muscarinics and long-acting β-agonists have similar evidence for their use in therapy and either can be started after the use of short-acting β-agonists
- Smoking cessation is the most important intervention for patients with COPD in reducing disease progression

8.2.1 Long-acting anti-muscarinic therapy (LAMA) (Appendix 5)

- Long-acting anti-muscarinic agents (LAMA) improve symptoms and reduce exacerbations and hospitalisations
- Therapeutic response to the chosen LAMA should be reviewed within 3 months to ensure that symptomatic control has improved using the CAT assessment questions. However, the impact on exacerbation rates may not be evident by then.
- If the LAMA has not produced a symptomatic response, then it should be stopped and the patient commenced on a long-acting β-agonist (LABA), if not previously tried.
- If the LAMA has produced a therapeutic response, but adverse effects, such as dry mouth, constipation cannot be tolerated, then an alternative LAMA can be tried.
- Until recently tiotropium was the only long-acting agent available. However glycopyrronium bromide and aclidinium bromide are now licensed for use in COPD
- The two newer agents are more cost-effective than tiotropium; however they have been subject to fewer clinical/safety trials and will be subject to a longer period of time before generic versions are available

8.2.2 Long-acting β-agonists (LABA) (Appendix 5)

- There is evidence that long-acting β-agonists (LABA) reduce exacerbations and improve symptom control
- LABAs should be used in patients who:
  o are intolerant/unresponsive to LAMAs, or
  o are still symptomatic with a LAMA to improve symptomatic relief
LABAs currently available are formoterol and salmeterol (both twice daily dosing regimen), and indacaterol (once daily dosing regimen).

If the LABA has not produced a symptomatic response, then it should be stopped and the patient commenced on a long-acting anti-muscarinic agents (LAMA), if not previously tried.

Choice of LABA should be based on patient inhaler technique; devices available and health board formulary preferences.

8.2.3 Appropriateness of inhaled corticosteroid (ICS) in COPD

Benefits of ICS/LABA combination:
- Treatment with ICS in combination with LABAs has been shown to reduce symptoms, improve quality of life and reduce exacerbations
- There is no single agent ICS licensed in COPD
- Only three ICS/LABA combination products are licensed for the treatment of COPD – Seretide 500/50 accuhaler®; Symbicort 400/12 turbohaler® and Symbicort 200/6 turbohaler®

Point of note: There is discrepancy between the current GOLD guidelines which recommend the use of ICS/LABA combination when FEV₁<60% predicted, however SMC has recommended their use when FEV₁<50% predicted

Limitations/restrictions
- ICS treatment in COPD is associated with increased risk of pneumonia, in addition to other adverse effects. Therefore, the place of ICS in COPD is limited to those patients with more severe disease, and those having two or more exacerbations over a 12 month period
- Due to this risk of adverse effects (especially pneumonia), in patients whose FEV₁ is greater than 50% predicted (and not exacerbating regularly), consideration should be given to withdrawing the ICS

Good practice
- Patients with FEV₁<50% predicted and currently prescribed an ICS which is not licensed for COPD (e.g. beclometasone 200 micrograms twice daily), should be changed to a licensed product with consideration of the lowest steroid dose (to minimise side-effects) and the most cost-effective preparation
- If a patient has a dual-diagnosis of asthma and COPD, but their FEV₁ is greater than 50% predicted, there should be no change of inhaled corticosteroid, because the control of asthma should be maintained

---

Glossary

ACT  asthma control test
ACTH  adrenocorticotropic hormone
BNF  British national formulary
BTS  British thoracic society
CAT  COPD assessment test
CFC  chlorofluorocarbon
CHI  community health index
COPD  chronic obstructive pulmonary disease
DPI  dry powder inhaler
GOLD  global initiative for chronic obstructive lung disease
HMUD  hospital medicines use database
ICS  inhaled corticosteroid
ISD  information services division
LABA  long-acting beta-agonist
LAMA  long-acting muscarinic antagonist
LRA  leukotriene receptor antagonist
MCN  managed clinical network
MDI  metered dose inhaler
PIS  prescribing information system
pMDI  pressurised metered dose inhaler
PRISMS  prescribing information system for Scotland
PTI  practice team information
QMAS  quality management and analysis system
QOF  quality outcomes framework
RCG  read code grouping
SABA  short-acting beta-agonist
SAMA  short-acting muscarinic antagonist
SMC  Scottish medicines consortium
SIGN  Scottish intercollegiate guidelines network
WHO  world health organisation
Appendix 1: Prescribing trends, costs & variation

In many therapeutic areas, there are potential savings to be acquired over time, when medicines are no longer under patent and more cost-effective generic equivalents are available. This is not likely in respiratory medicine as many of the inhaler devices are under patent (following the restriction on the use of CFCs, and newer devices were required). Therefore cost-effective products should be considered by boards for inclusion in their formulary, and reviewed regularly as new products are available.

Figure 5: Cost of 30 days treatment with combination (ICS & LABA) inhalers

<table>
<thead>
<tr>
<th>COMBINATION ICS &amp; LABA</th>
<th>Equivalent BDP Dose Per Day (mcg)</th>
<th>Cost per 30 days treatment (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYMPTOMATIC TURBOLIZER 400 mcg/12 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>76.00</td>
<td></td>
</tr>
<tr>
<td>SERETIDE EVOCALM 250 mcg/25 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>59.48</td>
<td></td>
</tr>
<tr>
<td>FLUTIFORM INH 250/10 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>45.56</td>
<td></td>
</tr>
<tr>
<td>SERETIDE ACCUHALER 500 mcg/50 mcg (2 INHAL DAILY) greater than 1000 mcg</td>
<td>40.92</td>
<td></td>
</tr>
<tr>
<td>SERETIDE EVOCALM 250 mcg/25 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>35.00</td>
<td></td>
</tr>
<tr>
<td>SERETIDE EVOCALM 125 mcg/25 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>35.00</td>
<td></td>
</tr>
<tr>
<td>FOSTAIR INH 100 mcg/8 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>29.32</td>
<td></td>
</tr>
<tr>
<td>FLUTIFORM INH 125/5 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>19.26</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 400 mcg/12 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>38.00</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 200 mcg/8 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>38.00</td>
<td></td>
</tr>
<tr>
<td>FOSTAIR INH 100 mcg/8 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>14.66</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 100 mcg/5 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>33.00</td>
<td></td>
</tr>
<tr>
<td>SERETIDE ACCUHALER 100 mcg/5 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>31.19</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 400 mcg/12 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>19.00</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 400 mcg/12 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>19.00</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 400 mcg/12 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>18.00</td>
<td></td>
</tr>
<tr>
<td>FLUTIFORM INH 50/5 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>18.00</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 100 mcg/8 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>26.50</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 200 mcg/8 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>9.50</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMATIC TURBOLIZER 100 mcg/8 mcg (1 INHAL DAILY) greater than 1000 mcg</td>
<td>8.25</td>
<td></td>
</tr>
</tbody>
</table>

NOTES:

a. Prices and dose details from BNF 65 Mar-Sep 2013
b. Potency equivalence from SIGN/BTS Asthma Guideline and/or Summary of Product Characteristics (the dose ratio with beclometasone dipropionate for budesonide is 1:1, for fluticasone propionate it is 2:1 and for Fostair® it is 5:2 due to the extra-fine particles of beclometasone dipropionate created by the hydrofluoroalkane propelled metered dose inhaler, i.e. 400 mcg extra-fine beclometasone equivalent to 1000 mcg beclometasone:).

The dose of inhaled corticosteroid with Symbicort® and Fostair® is controlled by increasing or decreasing the number of inhalations rather than changing to a higher or lower potency inhaler, as is the case with Flutiform® and Seretide® which is why the Symbicort® and Fostair® inhalers appear more than once in the table.

Figure 5 lists all of the combination ICS & LABA inhalers currently available, and the cost of 30 days treatment for a range of steroid equivalent doses. Please note that device costs may have subsequently changed, e.g. Seretide 100 Accuhaler® is now £18.00 for 30 days treatment.
Figure 6: Annual variation in prescribing of major classes of inhalers (items)

NOTES:

a. From PRISMS, which details the prescriptions dispensed by community pharmacists and appliance contractors.

b. Prescription items = number of times a medicine is dispensed by community pharmacies and refers to the frequency of prescribing but not the quantity of each dispensing.

c. Classification based on SIGN/BTS and SIGN/GOLD guidelines (ICS = inhaled corticosteroid; LABA = long acting beta\(_2\) agonist; LAMA = long acting muscarinic antagonist)

Figure 6 shows the increased use of combination inhalers over the previous 9 years, whilst the use of individual ICS and individual LABA has decreased. The net effect over time is that more prescriptions for inhaled corticosteroids and long-acting beta\(_2\)-agonists, either separately or combined into a single inhaler, are being prescribed. Guidelines recommend these treatments for the treatment of stage 3-4 asthma or management of moderate to severe COPD.

It may be that patients’ therapies are being stepped up sooner, and so reliever therapy is being required less. However the implication is that patients are being stepped up to combination therapy sooner than the BTS/SIGN 101 guidelines recommend with the potential risk of being over treated.
Figure 7: Net ingredient cost of selected respiratory inhalers

Figure 7 shows net ingredient costs for all major classes of inhalers in primary care over the last 9 financial years divided into the individual therapeutic agents. The table clearly demonstrates the trend in cost for the use of fluticasone propionate & salmeterol combination inhalers. The relative cost of these products can be seen in figure 5.

NOTES:

a. From PRISMS which details the prescriptions dispensed by community pharmacists and appliance contractors. Prescription items = number of times a medicine is dispensed by community pharmacies and refers the frequency of prescribing but not the quantity of each dispensing.
Figure 8: Number of patients, by age range, prescribed selected classes of respiratory medicines

![Graphs showing number of patients, by age range, prescribed selected classes of respiratory medicines.](image)

**NOTES**
- a. From PIS, which details the prescriptions dispensed by community pharmacists and appliance contractors, including the unique patient identifier CHI
- b. (CHI) was recorded from 96.2% of the prescription items for the selected medicines in the time period
- c. Count of distinct patients dispensed respiratory medicines in each class of respiratory medicine within the months January 2013, February 2013 and March 2013
- d. Patient age calculated at 1 February 2013
- e. Classification based on SIGN/BTS and SIGN/GOLD guidelines (ICS = inhaled corticosteroid; LABA = long acting beta_2 agonist; LAMA = long acting muscarinic antagonist; SABA = short acting beta_2 agonist)

Figure 8 shows the increase in prescribing respiratory items by age until a peak in the 65-69 year group. Note the difference in the scale for patient count between the charts due to different levels of prescribing. Although the treatment of all respiratory disease is included in this figure, the effect of COPD diagnosis is evident from the age of 40-45 with the introduction of LAMA prescribing, and subsequently mucolytics. The prescribing of LABA & ICS combination also increases at this age but it is not possible to determine if this is due to COPD.
Figure 9: Comparison of prescribing rates of combination ICS & LABA by age

NOTES:

a. From PIS which details the prescriptions dispensed by community pharmacists and appliance contractors, including the unique patient identifier CHI

b. (CHI) was recorded from 96.2% of the prescription items for the selected medicines in the time period

c. Count of distinct patients dispensed combination ICS and LABA inhalers within the months January 2013, February 2013 and March 2013. Flutiform® is not included in the graph due to low levels of prescribing (fewer than 150 patients in total for all three Flutiform inhalers).

d. Patient age calculated at 1 February 2013

Figure 9 provides more detail than the chart in figure 8, by defining the combination inhalers prescribed for each age group. An increase in licensed combinations for COPD (Seretide 500 accuhaler®, Symbicort 200/6 turbohaler® and Symbicort 400/12 turbohaler®) is expected as COPD progresses, however the increase from 50-54 age group may again be suggesting that patients are being treated with this combination earlier than the disease progression warrants. It may also be that products not licensed for use in COPD are also being prescribed.
NOTES:

a. From PIS, which details the prescriptions dispensed by community pharmacists and appliance contractors, including the unique patient identifier CHI.

b. CHI was recorded from 96.8% of the prescription items for the selected medicines in the time period.

c. Count of distinct patients dispensed combination ICS and LABA inhalers within the months January 2013, February 2013 and March 2013. There were 128 patients aged between 0 and 4 years dispensed a combination inhaler and 1,847 aged between 5 and 11 years.

d. Patient age calculated at 1 February 2013.

Figure 10 examines the prescribing of combination inhalers in children, where there is an increased restriction of licensed dose and device approval. The data shows that children are being prescribed combination inhalers off-label for their age range, although the number of patients will be small per board it may be that these patients, whose device is out-with license, are under the care of a specialist and that higher doses are required. However, the prescribing out-with license should be undertaken with caution, especially when a higher than recommended dose is prescribed.
Figure: 11 Prescription combinations out-with guidelines

The availability of Prescribing Information System (PIS) data allows for more in-depth prescribing analysis. This suggests some areas of prescribing out-with guidance.

**Asthma therapy (SIGN/BTS)**

Patients prescribed a combination inhaler and no other inhaler in the same time period, i.e. no SABA. This may indicate that: there is no requirement for SABA due to good control; the patient is using SMART or treatment is at a higher step than actually required.

**Asthma therapy (SIGN/BTS)**

Patients prescribed a LABA inhaler and no other inhaler in the same time period. Salmeterol is not licensed for immediate symptomatic relief in asthma, whereas formoterol is, but there is the possibility that some patients may not have a SABA when they should.

**Asthma therapy (SIGN/BTS)**

Patients prescribed a combination of LAMA, LABA and ICS inhaler in the same time period. Whilst this is expected in some patients with moderate/severe COPD, it is not recommended in the management of mild COPD or asthma and therefore unexpected in the ages of 15-39 years.

**Asthma (SIGN/BTS) or COPD (GOLD)**

Patients prescribed a combination inhaler and another LABA inhaler in the same time period. This suggests that either the patient has moved between the steps of treatment for asthma, or COPD, which would be appropriate. However there is the possibility that patients are prescribed both with an increased cardiovascular risk.

**NOTES:**

a. From PIS which details the prescriptions dispensed by community pharmacists and appliance contractors, including the unique patient identifier CHI.

b. (CHI) was recorded from 96.4% of the prescription items for the selected medicines in the time period.

c. Count of distinct patients dispensed respiratory medicines in each class of respiratory medicine between the months December 2011 and May 2013.

d. Patient age calculated at 1 May 2013.
Appendix 2: Inhaled corticosteroid equivalence chart

<table>
<thead>
<tr>
<th>Standard beclometasone (micrograms)</th>
<th>Approved name</th>
<th>Brand name&lt;sup&gt;10&lt;/sup&gt;</th>
<th>Combination brand</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regular Standard Dose - BTS Steps 2 and 3 - when combined with Long Acting Beta Agonist (LABA)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'100 bd'</td>
<td>beclometasone 100 bd</td>
<td>Clenil® 100 bd</td>
<td>Qvar® 50 bd</td>
</tr>
<tr>
<td></td>
<td>budesonide 100 bd</td>
<td>Pulmicort® 100 bd</td>
<td>Symbicort® 100/6 bd</td>
</tr>
<tr>
<td>'200 bd'</td>
<td>fluticasone prop. 50 bd</td>
<td>Flixotide® 50 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>beclometasone 200 bd</td>
<td>Clenil® 200 bd; Qvar® 100 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>budesonide 200 bd</td>
<td>Pulmicort® 200 bd</td>
<td>Symbicort® 200/6 bd</td>
</tr>
<tr>
<td></td>
<td>fluticasone prop. 100 bd</td>
<td>Flixotide® 100 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mometasone 200 od *</td>
<td>Asmanex® 200 od</td>
<td></td>
</tr>
<tr>
<td><strong>PAEDIATRIC Regular High Dose - BTS Step 4 - STEROID CARD REQUIRED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'250 bd'</td>
<td>beclometasone 250 bd</td>
<td>Clenil® 250 bd</td>
<td>Fostair® 100/6 bd (&gt;18y)</td>
</tr>
<tr>
<td>'400 bd'</td>
<td>beclometasone 400 bd</td>
<td>Clenil® 200 X2 bd</td>
<td>Qvar® 100 X2 bd</td>
</tr>
<tr>
<td></td>
<td>budesonide 400 bd</td>
<td>Pulmicort® 400 bd</td>
<td>Symbicort® 400/12 bd</td>
</tr>
<tr>
<td></td>
<td>fluticasone prop. 200 bd</td>
<td>Flixotide® 100 X2 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mometasone 200 X2 od *</td>
<td>Asmanex® 200 X2 od</td>
<td></td>
</tr>
<tr>
<td><strong>ADULT Regular High Dose - BTS Step 4 - STEROID CARD REQUIRED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PAEDIATRIC ADRENAL SUPPRESSION can occur from this dose</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'500 bd'</td>
<td>beclometasone 250 X2 bd</td>
<td>Clenil® 250 X2 bd</td>
<td>Fostair® 100/6 X2 bd (&gt;18y)</td>
</tr>
<tr>
<td></td>
<td>fluticasone prop. 250 bd</td>
<td>Flixotide® 250 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seretide® A 250/50 X2 bd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seretide® E 125/25 X2 bd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flutiform® 125/5 X2 bd</td>
</tr>
<tr>
<td>'600 bd'</td>
<td>beclometasone 200 X3 bd</td>
<td>Clenil® 200 X3 bd; Qvar® 100 X3 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>budesonide 200 X3 bd</td>
<td>Pulmicort® 200 X3 bd</td>
<td>Symbicort® 200/6 X3 bd</td>
</tr>
<tr>
<td></td>
<td>fluticasone prop. 100 X3 bd</td>
<td>Flixotide® 100 X3 bd</td>
<td></td>
</tr>
<tr>
<td><strong>ADULT ADRENAL SUPPRESSION can occur from this dose</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'750 bd'</td>
<td>beclometasone 250 X3 bd</td>
<td>Clenil® 250 X3 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>fluticasone prop. 125 X3 bd</td>
<td>Flixotide® 125 X3 bd</td>
<td></td>
</tr>
<tr>
<td>'800 bd'</td>
<td>beclometasone 400 X2 bd</td>
<td>Clenil® 200 X4 bd; Qvar® 100 X4 bd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>budesonide 400 X2 bd</td>
<td>Pulmicort® 400 X2 bd</td>
<td>Symbicort® 400/12 X2 bd</td>
</tr>
<tr>
<td></td>
<td>fluticasone prop. 200 X2 bd</td>
<td>Flixotide® 100 X4 bd</td>
<td></td>
</tr>
<tr>
<td>'1,000 bd'</td>
<td>fluticasone prop. 500 bd</td>
<td>Flixotide® 500 bd</td>
<td>Seretide® A 500/50 bd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seretide® E 250/25 X2 bd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flutiform® 250/10 X2 bd</td>
</tr>
</tbody>
</table>

<sup>10</sup> Correct at date of publication

### Appendix3 – Adult Asthma - chart for treatment steps and inhaler choice\textsuperscript{11,12}

<table>
<thead>
<tr>
<th>BTS/SIGN Step</th>
<th>Metered Dose Inhaler Options (+/- spacer)</th>
<th>Dry Powder Device Options</th>
<th>Breath-Actuated Device Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1:</strong> Short-acting ( \beta_2 )-agonist as required</td>
<td>Salbutamol 100mcg p1-2:prn</td>
<td>1\textsuperscript{st}: Salbutamol 100mcg p1-2:prn 2\textsuperscript{nd}: Terbutaline 500mcg p1:prn</td>
<td>Salbutamol 100mcg p1-2:prn</td>
</tr>
<tr>
<td><strong>Step 2:</strong> Add regular ICS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• BDP100mcg (Clenil\textsuperscript{®}) p2:bd, or  • Flut50mcg p2:bd</td>
<td>• BDP100mcg p2:bd, or  • Bud100mcg p2:bd, or  • Flut100mcg p1:bd</td>
<td>• BDP50mcg (Qvar\textsuperscript{®}) p2:bd</td>
</tr>
<tr>
<td><strong>Step 3:</strong> Add LABA, ↑ ICS dose to 800mcg/d</td>
<td>Combination device  • BDP/formoterol 100/6mcg (Fostair\textsuperscript{®}) p1:bd (↑ to p2:bd*, or  • Flut/formoterol 50/5mcg (Flutiform\textsuperscript{®}) p2:bd, or  • Flut/salmeterol 50/25mcg (Seretide\textsuperscript{®}) p2:bd</td>
<td>Combination device  • Bud/formoterol 200/6mcg (Symbicort\textsuperscript{®}) p1:bd, or  • Flut/salmeterol 100/50mcg (Seretide\textsuperscript{®}) p1:bd</td>
<td>Individual devices  • BDP 50-100mcg (Qvar\textsuperscript{®}) p2:bd, However no breath-actuated LABA – refer to other device options</td>
</tr>
<tr>
<td><strong>Step 4:</strong> ↑ ICS up to 2000mcg/d (high strength)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• BDP/formoterol 100/6mcg (Fostair\textsuperscript{®}) p2:bd*,  • Flut/formoterol 125/5mcg (Flutiform\textsuperscript{®}) p2:bd*, ↑ to 250/10mcg p2:bd*, or  • Flut/salmeterol 125/25mcg (Seretide\textsuperscript{®}) p2:bd*, ↑ to 250/25mcg p2:bd*</td>
<td>• Bud/formoterol 400/12mcg (Symbicort\textsuperscript{®}) p1:bd*, or  • Flut/salmeterol 250/50mcg (Seretide\textsuperscript{®}) p1:bd*, ↑ to 500/50 p1:bd*</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Step 5:</strong> Maintain high dose ICS at 2000mcg/d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Flut/formoterol 250/10mcg (Flutiform\textsuperscript{®}) p2:bd*, or  • Flut/salmeterol 250/50mcg (Seretide\textsuperscript{®}) p2:bd*</td>
<td>Flut/salmeterol 500/50mcg (Seretide\textsuperscript{®}) p1:bd*</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**plus low dose daily steroid tablets plus specialist referral/care**

BDP - Beclometasone dipropionate; Bud – Budesonide; Flut – fluticasone propionate; *Steroid card required

\textsuperscript{11} Correct at date of publication

\textsuperscript{12} All inhaler choices listed alphabetically.

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Cost comparison chart (provided by Tayside) available at [http://www.nhstayside.scot.nhs.uk/RMCN/c\backslash
clinical_protocols/docs\_167839\_Adult\%20Asthma\%20Inhaled\%20Medicine\%20Chart.pdf](http://www.nhstayside.scot.nhs.uk/RMCN/c\backslash
clinical_protocols/docs\_167839\_Adult\%20Asthma\%20Inhaled\%20Medicine\%20Chart.pdf)

Appendix 4: Licensed inhaled products in children, with licensed doses with respect to age ranges

<table>
<thead>
<tr>
<th>Drug/ Brand Name</th>
<th>Age Range</th>
<th>Max Daily Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1(a) Beclometasone</strong> – Standard dose inhaler. e.g. Asmabec (&gt;6yrs), Clenil (any age), Pulvinal Beclometasone (&gt;5yrs), Qvar</td>
<td>&lt;12 yrs</td>
<td>400mcg/day*</td>
<td>VFA is not recommended for use in children under 12 years. *(800mcg/day where add on therapy fails to control – age 5-12) 800mcg/day</td>
</tr>
<tr>
<td></td>
<td>&gt;12 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1(b) Beclometasone</strong> – High dose inhaler. i.e. 250mcg/dose and above. Asmabec Clickhaler, Clenil Modulite Pulvinal,</td>
<td>&lt;12 yrs</td>
<td>Not recommended</td>
<td>This includes Clenil 200 inhaler</td>
</tr>
<tr>
<td></td>
<td>&gt;12 yrs</td>
<td>2000mcg/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;12 yrs</td>
<td>1600mcg/day</td>
<td></td>
</tr>
<tr>
<td><strong>2 Budesonide</strong> i.e. Budesonide Easyhaler, Pulmicort, Novolizer.</td>
<td>&lt;12 yrs</td>
<td>800mcg/day</td>
<td>Novolizer – child must be &gt; 6 yrs. Pulmicort – child must be &gt;5yrs.</td>
</tr>
<tr>
<td></td>
<td>&gt;12 yrs</td>
<td>1600mcg/day</td>
<td></td>
</tr>
<tr>
<td><strong>3 Ciclesonide</strong> i.e. Alvesco.</td>
<td>&gt;12 yrs</td>
<td>160mcg/day</td>
<td>Not recommended in children &lt;12yrs</td>
</tr>
<tr>
<td><strong>4 Fluticasone propionate</strong> i.e. Flixotide.</td>
<td>5 – 16 yrs Evohaler &gt;4yrs</td>
<td>400mcg/day</td>
<td>50mcg Evohaler ONLY 50mcg and 100mcg Accuhaler and Diskhaler ONLY</td>
</tr>
<tr>
<td><strong>5 Mometasone Furoate</strong> i.e. Asmanex.</td>
<td>&gt;12 yrs</td>
<td>800mcg/day</td>
<td>Not recommended in children &lt;12yrs</td>
</tr>
<tr>
<td><strong>6 Budesonide + Formoterol</strong> i.e. Symbicort</td>
<td>6 – 12 yrs</td>
<td>400mcg/day</td>
<td>Symbicort 100/6 ONLY</td>
</tr>
<tr>
<td></td>
<td>12 – 17 yrs</td>
<td>400mcg/day</td>
<td>Symbicort 100/6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>800mcg/day</td>
<td>Symbicort 200/6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>800mcg/day</td>
<td>Symbicort 400/12</td>
</tr>
<tr>
<td><strong>7 Fluticasone propionate + Salmeterol</strong> i.e. Seretide</td>
<td>&gt;4 yrs</td>
<td>200mcg/day</td>
<td>Seretide 50 Evohaler/</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seretide 100 Accuhaler ONLY</td>
</tr>
<tr>
<td></td>
<td>&gt;12 yrs</td>
<td>1000mcg/day</td>
<td>All preparations suitable.</td>
</tr>
<tr>
<td><strong>8 Fluticasone propionate + formoterol</strong></td>
<td>&gt;12 yrs</td>
<td>500mcg/day</td>
<td>Flutiform 50/5</td>
</tr>
</tbody>
</table>

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13 Inhalers detailed in alphabetical order.
14 Correct at date of publication
Appendix 5: Variation of device usage between mainland boards - Seretide 500 Accuhaler® as a percentage of Accuhaler 500® and Evohaler 250® (GIC/1,000pts)

[Graph showing percentage usage over time for different mainland boards]

Percentage usage of devices for various mainland boards, showing a rise in Seretide 500 Accuhaler® usage as a percentage of Accuhaler 500® and Evohaler 250®.

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### Appendix 6: Asthma Children (aged 5-12 years) - chart for treatment steps and suggested inhaler choice

<table>
<thead>
<tr>
<th>BTS/SIGN Step</th>
<th>Metered Dose Inhaler Options (+/- spacer)</th>
<th>Dry Powder Device Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1:</strong> Short-acting β₂-agonist as required</td>
<td>Salbutamol 100mcg p1-2:prn</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: Salbutamol 100mcg p1-2:prn</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2&lt;sup&gt;nd&lt;/sup&gt;: Terbutaline 500mcg p1:prn</td>
</tr>
</tbody>
</table>
| **Step 2:** Add regular ICS | • BDP50mcg p2:bd, or  
|               | • Flut50mcg p2:bd | • BDP100mcg p2:bd (>6yrs), or  
|               |                                         | • Bud100mcg p1:bd, or  
|               |                                         | • Flut 50-100mcg p1:bd |
| **Step 3:** Add LABA, ↑ ICS dose to 400mcg/d, or if no response to LABA trial other therapies. | **Individual devices**  
|               | • Salmeterol 25mcg (>4yrs)p2:bd + ICS  
|               | • Flut/salmeterol 50/25mcg (Seretide®>4yrs) p2:bd | **Combination device**  
|               |                                         | • Formoterol 6mcg (>6yrs)p1:bd + ICS, or  
|               |                                         | • Salmeterol 50mcg (>4yrs)p1:bd + ICS  
|               |                                         | **Combination device**  
|               |                                         | • Bud/formoterol 100/6mcg (Symbicort®>6yrs) |
|               |                                         | p1:bd, ↑ to p2:bd* or  
|               |                                         | • Flut/salmeterol 100/50mcg (Seretide®>4yrs) p1:bd |
| **Step 4:** ↑ ICS up to 800mcg/d (high strength) | Salmeterol 25mcg (>4yrs) p2:bd plus  
|               | • BDP 100-200mcg p2:bd*, or  
|               | • Flut50mcg p2:bd, ↑ to p4:bd* | Salmeterol 25mcg (>4yrs) p2:bd, or  
|               |                                         | Formoterol 6mcg (>6yrs) p1:bd plus  
|               |                                         | • Bud 100-200mcg p2:bd*, or  
|               |                                         | • Flut50mcg p2:bd, ↑ to p4:bd* |
| **Step 5:** Maintain high dose ICS at 800mcg/d | **Individual devices**  
|               | Salmeterol 25mcg (>4yrs) p2:bd plus  
|               | • BDP 200mcg p2:bd*, or  
|               | • Flut50mcg p4:bd* | **Individual devices**  
|               |                                         | Salmeterol 25mcg (>4yrs) p2:bd, or  
|               |                                         | Formoterol 6mcg (>6yrs) p1:bd plus  
|               |                                         | • Bud 200mcg p2:bd*, or  
|               |                                         | • Flut50mcg p4:bd*  

*plus low dose daily steroid tablets plus specialist referral/care

**BDP- Beclometasone dipropionate; Bud – Budesonide; Flut – fluticasone propionate; *Steroid card required**

15 Correct at date of publication  
16 All inhaler choices listed alphabetically.
## Appendix 7: COPD - Therapy selection guidance

<table>
<thead>
<tr>
<th>Short acting β₂ agonist</th>
<th>Long acting β₂ agonist</th>
<th>Long-acting anti-muscarinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salbutamol 100mcg p1-2:prn (pMDI, DPI, BA), or Terbutaline 500mcg p1:prn</td>
<td>Formoterol DPI 12mcg p1:bd, or Salmeterol pMDI 25 mcg p2:bd, or DPI 50mcg p1:bd, or Indacaterol DPI 150-300mcg p1:daily</td>
<td>Tiotropium Handihaler® + refill caps 18mcg: daily, or Tiotropium Respimat® 2.5mcg: daily or Aclidinium 322mcg p1:bd, or Glycopyrronium bromide 44mg daily</td>
</tr>
</tbody>
</table>

Add, if FEV1<50% predicted** (or 2 or more exacerbations in a year)

** post bronchodilator

*Steroid card required

- Two formulations of tiotropium are available:
  - The Handihaler with refill capsules. This requires manual dexterity to use, but the refill capsules only are required on a regular basis, which is a more cost-effective method, than prescribing the combinhaler (handihaler and capsules) on every occasion.
  - The Respimat® is suitable for those with dexterity problems, as recommended by SMC.

- Newer LAMAs:
  - Glycopyrronium bromide is administered once daily, however its device requires some manual dexterity.
  - Aclidinium bromide is administered twice daily; however its device is straightforward to use.

- Combined inhaled corticosteroid and LABA:
  - Only the 3 devices listed are licensed for COPD.

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17 All inhaler choices listed alphabetically.