

### STEP 1 - MILD INTERMITTENT ASTHMA

Inhaled Salbutamol (MDI) 1-2 puffs as required, up to four times a day.

If symptomatic or using  $\beta_2$  agonist 3 times a week or more, waking one night a week or had an exacerbation requiring oral corticosteroids in the last 2 years proceed to next step.

### STEP 2 - REGULAR PREVENTER THERAPIES

Add Beclometasone: 200 - 800mcg daily Clenil® or 100 - 400mcg daily Qvar®.

Compliance, inhaler technique & elimination of trigger factors, should be checked before any increase in steroid dose or addition of other therapies.

### STEP 3 (a) - ADD ON THERAPY

Trial of Formoterol 12mcg twice daily for 2 – 4 weeks

(NB. Long acting  $\beta_2$  agonists (LABA) must not be used without concurrent use of an inhaled steroid)

- **Good response** - Combination device may be appropriate, go to 3(b)
- **No response** - Stop Formoterol, continue Beclometasone, go to 4

### STEP 3 (b) - CONSIDER USE OF A COMBINATION INHALER WHERE APPROPRIATE

**First Choice:** Fostair® - 100/6 MDI (100mcg Beclometasone / 6mcg Formoterol) Adults over 18. 1-2 puffs twice daily

**Second Choice:** Symbicort® Turbohaler (Budesonide with Formoterol)

**Third Choice:** Seretide® Evohaler (Fluticasone with Salmeterol) or Flutiform® (Fluticasone propionate with Formoterol)

If a patient's asthma is poorly controlled, ensure steroid therapy has been optimised and proceed to next step

### STEP 4 - PERSISTENT POOR CONTROL

- Consider trials of:
- Consider referral to specialist.
  - Up to 2000mcg per day of Clenil or 1000mcg per day of Qvar.
  - Uniphyllin Continus (theophylline MR)
  - Addition of montelukast.

### STEP 5 - CONTINUOUS OR FREQUENT USE OF ORAL STEROIDS

Refer patient for specialist care. Use daily steroid tablet (Prednisolone) in lowest dose giving adequate control.



## Notes

- All patients should be taught effective technique and regularly assessed by a competent healthcare professional.
- All patients should have a self management plan, including step up and step down advice.
- Good asthma control is based on a clinical assessment of the patient which may include the use of the Royal College of Physicians (RCP) Three Questions(1) and/or the Asthma Control Test™(2). It is usually associated with little or no need for short-acting  $\beta_2$  agonist.

### Inhaler devices

Choice of inhaler device (for example metered dose inhaler [MDI] or dry powder inhaler [DPI]) should be based on patient preference and assessment of correct use. If the patient is unable to use a device satisfactorily an alternative should be found. The choice of device may be determined by the choice of drug (3).

### Step 1

Prescribe an inhaled short-acting  $\beta_2$  agonist as short term reliever therapy for all patients with symptomatic asthma. Using short-acting inhaled  $\beta_2$  agonists as required is at least as good as regular (four times daily) administration. Unless individual patients are shown to benefit from regular use of inhaled short-acting  $\beta_2$  agonists then as required use is recommended.

Using two or more canisters of  $\beta_2$  agonists per month is a marker of poorly controlled asthma.

### Step 2

#### Use of inhaled steroids

Inhaled steroids are the most effective preventer drug for adults and children for achieving overall treatment goals. NHS Rotherhams first choice inhaled steroid is Beclometasone.

Beclometasone	Equivalent dose	UK licence covers			
		> 18 years	> 12 years	5-12 years	< 5 years
Clenil modulite	400mcg	✓	✓	✓	✓
Qvar	200mcg	✓	✓	x	x
Fostair	200mcg	✓	x	x	x

### Which inhaled steroid

There is little difference in efficacy between the respiratory steroids at equipotent doses. Fluticasone has twice the potency of Beclometasone and Budesonide (4). The relative safety of Mometasone is not fully established.

All steroids have the potential to cause dose related systemic adverse effects, particularly if high doses are used for long periods. Steroid cards should be given if patients are prescribed high doses.

### Fluticasone

Fluticasone provides equal clinical activity to BDP and Budesonide at half the dosage.

Committee on Safety of Medicines summary minutes - 29 September 2002 states that “contrary to previous belief, Fluticasone was not safer than other inhaled steroids.” Also, “although adrenal suppression is a well known adverse reaction to inhaled Fluticasone, it is under-recognised.”

Lipworth (5) showed that Fluticasone shows greater bioactivity for dose related adrenal suppression than Beclometasone or Budesonide (Arch Int Med 1999;159:941-955).

### Step 3a

#### Trial of a long acting beta<sub>2</sub> agonist (LABA) in addition to inhaled steroids

Trial of long acting beta agonist Formoterol Fumarate for 2 - 4 weeks. LABA's must not be used without regular respiratory steroids.

Formoterol Fumarate was chosen as it effect sets in rapidly (within 1–3 minutes) and is still significant 12 hours after inhalation. There are only limited data available on the pharmacokinetics of salmeterol because of the technical difficulty of assaying the active substance in plasma due to the low plasma concentrations at therapeutic doses achieved after inhaled dosing.

Formoterol	Delivery Device	Dose per metered inhalation	UK licence > 12 years	Adult dose regime
Atimos	MDI	12mcg	✓	12mcg BD, increased to max. 24mcg BD
Foradil	Dry Powder	12mcg	✓	12mcg BD, increased to max. 24mcg BD
Oxis	Dry Powder	6mcg 12mcg	✓	<b>Adults over 18 yrs:</b> 6–12 mcg 1–2 times daily, increased up to 24 mcg BD if necessary; occasionally up to 72 micrograms daily may be needed (max. single dose 36 mcg) <b>Child 6-18 yrs:</b> 6–12 mcg 1–2 times daily; occasionally up to 48 mcg daily may be needed (max. single dose 12 mcg)

### Step 3b

#### Use of combination inhalers

There is no difference in efficacy in giving inhaled steroid and long-acting  $\beta_2$  agonist in combination or in separate inhalers. However once a patient is on stable therapy, combination inhalers have the advantage of guaranteeing that the long-acting  $\beta_2$  agonist is not taken without inhaled steroid.

Combination Device	Delivery Device	Dose per metered inhalation	UK licence	Adult dose regime
<b>Fostair</b> (Beclometasone/Formoterol)	MDI	100/6mcg	> 18 yrs	1–2 puffs BD; max. 4 puffs daily
<b>Symbicort</b> (Budesonide/Formoterol)	DPI	100/6 mcg 200/6 mcg 400/6 mcg	> 6yrs > 12 yrs > 12 yrs	1–2 puffs BD; max. 4 puffs twice daily 1–2 puffs BD; max. 4 puffs twice daily 1 puff BD; max. 2 puffs twice daily
<b>Seretide Evohaler</b> (Fluticasone/Salmeterol)	MDI	50/25 125/25 250/25	> 5 yrs > 12 yrs > 12 yrs	2 puffs twice daily 2 puffs twice daily 2 puffs twice daily
<b>Flutiform</b> (Fluticasone/Formoterol)	MDI	50/5 125/5 250/10	> 12 yrs > 12 yrs > 18 yrs	2 puffs twice daily 2 puffs twice daily 2 puffs twice daily

#### Symbicort Turbohaler as maintenance and rescue medication.

In selected adult patients (> 18 yrs) at step 3 who are poorly controlled or in selected adult patients at step 2 (**above** BDP 400 mcg/day who are poorly controlled), the use of Symbicort as rescue medication instead of a short-acting  $\beta_2$  agonist, in addition to its regular use has been shown to be an effective treatment regimen. When this management option is introduced the total regular dose of daily inhaled corticosteroids should not be decreased. The regular maintenance dose of inhaled steroids may be budesonide 200 mcg twice daily or budesonide 400 mcg twice daily. Patients taking rescue budesonide/formoterol once a day or more should have their treatment reviewed. **Careful education of patients about the specific issues around this management strategy is required.**

If the patient is atopic and there is some response to the addition of a LABA, but control is still inadequate consider trialling a leukotriene antagonist (Montelukast) before moving to Step 4.

### Step 4

Consider referral to specialist.

Increase steroid dose to 2000mcg/day Clenil, (1000mcg QVAR or equivalent) and trial other therapies. If this provides no improvement, then stop additional the drugs which have provided no benefit.

A steroid card is needed for those patients on high dose steroid therapy (more than 1500mcg/day BDP or equivalent)

### Step 5

Refer to Specialist.

#### Refs.

- Pearson MG, CE B, editors. Measuring clinical outcome in asthma : a patient-focused approach London: Royal College of Physicians; 1999. ([http://www.rcplondon.ac.uk/news/news.asp?PR\\_id=70](http://www.rcplondon.ac.uk/news/news.asp?PR_id=70))
- Nathan RA, Sorkness CA, Kosinski M, Schatz M, Li JT, Marcus P, et al. Development of the asthma control test: a survey for assessing asthma control. J Allergy Clin Immunol. 2004;113(1):59-65. ([http://www.asthma.org.uk/applications/control\\_test/](http://www.asthma.org.uk/applications/control_test/))
- BTS /SIGN British Guideline on the Management of Asthma revised June 2009
- Drug & Therapeutics Bulletin Vol 38:1 January 2000
- Brian J. Lipworth; Systemic Adverse Effects of Inhaled Corticosteroid Therapy: A Systematic Review and Meta-analysis; *Arch Intern Med.* 1999;159:941-955.