JAPC recognises this local asthma guidance (based on NICE NG80) differs from SIGN/BTS guidance. The evidence base considered by SIGN/BTS and NICE guideline group is broadly similar, but the methodology used to produce the guidance is significantly different.

- SIGN/BTS methodology is a multidisciplinary, clinically-led process which undertakes critical appraisal of the literature and provides clinically-relevant recommendations.
- NICE undertake critical appraisal of the literature with health economic modelling. These different processes have resulted in differing recommendations.

NICE recognise where the recommendations represent a change from traditional clinical practice, people whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow this guidance.

Uncontrolled asthma is defined as asthma that has an impact on a person’s lifestyle or restricts their normal activities.

Take into account the possible reasons for uncontrolled asthma, before starting or adjusting medicines. These may include:

- Alternative diagnosis
- Lack of adherence
- Suboptimal inhaler technique
- Smoking (active or passive)
- Occupational exposures
- Psychosocial factors
- Seasonal or environmental factors

After adjusting maintenance treatment, review the response to treatment changes in 4 to 8 weeks.

If asthma is uncontrolled reconsider the diagnosis, confirm avoidance of triggers, adherence and address comorbidities. If above is optimally controlled, for children on low dose inhaled corticosteroid (ICS) as maintenance therapy, consider a leukotriene receptor antagonist (LTRA) in addition to an ICS. If asthma is uncontrolled on ICS and LTRA combination, stop the LTRA and add a LABA. (The economic evaluation found that the most cost effective treatment option for patients uncontrolled on low dose ICS alone was to trial ICS+LTRA).

Monitor asthma control at every review. If control is suboptimal confirm the patient’s adherence to prescribed treatment. Patients do not always take their medicines exactly as prescribed. Recognise that non-adherence is common and that most patients are non-adherent sometimes. Routinely assess adherence in a non-judgemental way whenever you prescribe or review medicines.

Monitor the use of short-acting beta$_2$ agonist (SABA); patients requiring **more than 12** SABA’s a year should prompt an asthma review.

Clinician should ensure that patients receive the smallest dose of an ICS that provides optimal control of asthma, to reduce the risk of side-effects.

Inhalers should be prescribed by brand name to ensure the patient receives the device they are familiar with.

Consider referral to secondary care if more than 2 ED attendances or 1 or more attendances for exacerbation.

Pharmacological management of children less than 5 years is included towards the end of this guidance, as recommended by NICE NG80.
Diagnosis of asthma

Currently there is no gold standard test available to diagnose asthma. Both NICE and BTS/SIGN have tried to address the issue of over- and under-diagnosis of asthma.

Diagnosis should be based on clinical assessment supported by objective tests that seek to demonstrate variable airflow obstruction or the presence of airway inflammation. Objective tests include:

- Obstructive spirometry
- Bronchodilator reversibility test
- Peak flow variability
- FENO
- Direct bronchial challenge test with histamine or methacholine

The two guidance differ on the use of FENO:

- NICE places FENO testing in a prominent position in the diagnosis of asthma.
- BTS/SIGN - positive FeNO test indicates the presence of eosinophilic inflammation and increases the probability of asthma, where the structured clinical assessment suggests an intermediate probability

Full details regarding the diagnosis and monitoring of asthma can be found in NICE NG80 and BTS.
Pharmacological management of children and young people aged 5 to 16, with newly diagnosed asthma

A metred dose inhaler (MDI) plus a spacer device are recommended first line inhaler devices. Consider diagnosis review, adherence, avoidance of triggers, co morbidities addressed and ACT at each step prior to stepping up ICS.

For a small cohort of patients consider SABA for symptom relief for infrequent short-lived wheeze and normal lung function
(BTS/SIGN recommend initiation of treatment in association with an ICS)

Offer paediatric low dose of ICS, as first-line maintenance therapy

Consider paediatric low dose ICS plus LTRA as maintenance therapy

Consider paediatric low dose ICS plus LABA and stop LTRA treatment

If MART not considered appropriate for the patient

Consider paediatric moderate dose ICS plus a LABA as fixed dose regimen plus SABA as required

Consider paediatric moderate dose ICS plus a LABA within a MART regimen
(Currently only symbicort can be used in the MART regimen for children>12 yrs.)

Paediatric low dose ICS + LABA within a MART* regimen
(see Table 2 for MART doses)

Paediatric moderate dose ICS + LABA within a MART* regimen or change to a SABA
(see Table 2 for MART doses)

Seek advice from an asthma specialist

And

Consider increasing to paediatric high dose ICS plus LABA as a fixed dose

With a SABA

*If asthma uncontrolled- check diagnosis, inhaler technique, adherence, exposure to smoking & triggers and suitability of current treatment
<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand name</th>
<th>Device</th>
<th>Traffic light classification</th>
<th>Licensed indication</th>
<th>Daily dose range</th>
<th>Cost per device*</th>
<th>30 day cost</th>
<th>Annual cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SABA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salbutamol 100mcg</td>
<td>Salbutamol MDI</td>
<td>MDI</td>
<td>Green</td>
<td>Asthma (children)</td>
<td>2 puffs as required</td>
<td>£1.50 (200 dose)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Salbutamol easyhaler 100mcg</td>
<td>Easyhaler salbutamol</td>
<td>DPI</td>
<td>Green</td>
<td>Asthma (children &gt; 4 yrs)</td>
<td>2 puffs as required</td>
<td>£3.31 (200 dose)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Salbutamol Easi-breathe 100mcg</td>
<td>Salamol Easi-breathe</td>
<td>Breathe actuated inhaler</td>
<td>Green</td>
<td>Asthma (children)</td>
<td>2 puff as required</td>
<td>£6.30 (200 dose)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>LTRA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Montelukast tablets</td>
<td>Montelukast</td>
<td>Oral tablet</td>
<td>Green</td>
<td>Asthma (adults &amp; children &gt;15 yrs)</td>
<td>10mg ON</td>
<td>£1.87 x 28</td>
<td>£2.00</td>
<td>£24</td>
</tr>
<tr>
<td>Montelukast chewable tablets 5mg</td>
<td>Montelukast</td>
<td>Chewable tablet</td>
<td>Green</td>
<td>Asthma (Children &gt; 6-14 yrs)</td>
<td>5mg ON</td>
<td>£1.21x28</td>
<td>£1.30</td>
<td>£16</td>
</tr>
<tr>
<td>Montelukast chewable tablets 4mg</td>
<td>Montelukast</td>
<td>Chewable tablet</td>
<td>Green</td>
<td>Asthma (Children &gt; 2-5 yrs)</td>
<td>4mg ON</td>
<td>£1.08 x28</td>
<td>£1.16</td>
<td>£14</td>
</tr>
<tr>
<td><strong>Inhaled Corticosteroid</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Beclometasone 50mcg MDI</td>
<td>Clenil modulite 50mcg</td>
<td>MDI</td>
<td>Green</td>
<td>Asthma (adults &amp; children)</td>
<td>2 puffs BD</td>
<td>£3.70 (200 dose)</td>
<td>£2.22</td>
<td>£27</td>
</tr>
<tr>
<td>Beclometasone 100mcg MDI</td>
<td>Clenil modulite 100mcg</td>
<td>MDI</td>
<td>Green</td>
<td>Asthma (adults &amp; children)</td>
<td>1 puff BD</td>
<td>£7.42 (200 dose)</td>
<td>£2.22</td>
<td>£27</td>
</tr>
<tr>
<td>Budesonide 100mcg</td>
<td>Easyhaler budesonide 100mcg</td>
<td>Breath-actuated DPI</td>
<td>Green</td>
<td>Asthma (adults &amp; children &gt;6 yrs)</td>
<td>1 puffs BD</td>
<td>£8.86 (200 dose)</td>
<td>£2.66</td>
<td>£32</td>
</tr>
<tr>
<td>Fluticasone 50mcg MDI</td>
<td>Flixotide evohaler</td>
<td>MDI</td>
<td>Green</td>
<td>Asthma (adults &amp; children &gt;4 yrs)</td>
<td>1 puff BD</td>
<td>£5.44 (120 dose)</td>
<td>£2.72</td>
<td>£33</td>
</tr>
<tr>
<td>Fluticasone 100mcg DPI</td>
<td>Flixotide accuhaler</td>
<td>DPI</td>
<td>Green</td>
<td>Asthma (adults &amp; children &gt;4 yrs)</td>
<td>1 puff BD</td>
<td>£8.00 (60 dose)</td>
<td>£8.00</td>
<td>£96</td>
</tr>
<tr>
<td><strong>LABA/ICS combination products</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluticasone /Salmeterol 50/25mcg</td>
<td>Seretide evohaler 50</td>
<td>MDI</td>
<td>Green for children</td>
<td>Asthma (adults &amp; children &gt;4 yrs)</td>
<td>1 puff BD</td>
<td>£18.00 (120 dose)</td>
<td>£9.00</td>
<td>£108</td>
</tr>
<tr>
<td>Fluticasone /Salmeterol 50/25mcg</td>
<td>Seretide evohaler 50</td>
<td>MDI</td>
<td>Green for children</td>
<td>Asthma (adults &amp; children &gt;4 yrs)</td>
<td>2 puffs BD</td>
<td>£18.00 (120 dose)</td>
<td>£18</td>
<td>£216</td>
</tr>
<tr>
<td>Fluticasone /Salmeterol 1000/50mcg</td>
<td>Seretide accuhaler 100</td>
<td>Breathe actuated DPI</td>
<td>Green for children</td>
<td>Asthma (adults &amp; children &gt;4 yrs)</td>
<td>1 puff BD</td>
<td>£18.00 (60 dose)</td>
<td>£18</td>
<td>£216</td>
</tr>
<tr>
<td>Budesonide/formoterol 100/6mcg turbohaler</td>
<td>Symbicort 100/6 turbohaler</td>
<td>Breath-actuated DPI</td>
<td>Green</td>
<td>Asthma (adults &amp; children &gt;6yrs)</td>
<td>1 puff BD</td>
<td>£28 (120 dose)</td>
<td>£14</td>
<td>£168</td>
</tr>
<tr>
<td>Budesonide/formoterol 200/6 turbohaler</td>
<td>Symbicort 200/6 turbohaler</td>
<td>Breath-actuated DPI</td>
<td>Green</td>
<td>Asthma (adults &amp; children &gt;12yrs)</td>
<td>2 puffs BD</td>
<td>£28 (120 dose)</td>
<td>£28</td>
<td>£336</td>
</tr>
</tbody>
</table>

(*Price per MIMS online Jan 2018 and DT)
**Inhaled corticosteroid dose regimens for children**

The doses in this table should be used as a guide and should not be interpreted as a definitive statement of the relative potencies of the different inhaled steroids.

<table>
<thead>
<tr>
<th></th>
<th>Paediatric low dose</th>
<th>Paediatric moderate dose</th>
<th>Paediatric high dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paediatric low dose</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Budesonide</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry powder inhalers</td>
<td>100 - 200 micrograms per day in 2 divided doses</td>
<td>300 - 400 micrograms per day in 2 divided doses</td>
<td>500 - 800 micrograms per day in 2 divided doses</td>
</tr>
<tr>
<td><strong>Budesonide</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fluticasone propionate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metered dose and dry powder inhalers</td>
<td>100 micrograms per day in 2 divided doses</td>
<td>150 - 200 micrograms per day in 2 divided doses</td>
<td>250 - 400 micrograms per day in 2 divided doses</td>
</tr>
<tr>
<td><strong>Ciclesonide</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metered dose inhaler</td>
<td>80 micrograms per day as a single dose</td>
<td>160 micrograms per day as a single dose or in 2 divided doses</td>
<td>240 – 320 micrograms per day in 2 divided doses</td>
</tr>
</tbody>
</table>

1 CFC-containing beclometasone dipropionate MDIs are no longer available, so are not included. The MHRA advises that beclometasone dipropionate CFC-free inhalers should be prescribed by brand name (Drug safety update, July 2008).

2 Extra-fine particle CFC-free inhalers include brands such as Qvar, which are more potent than standard particle CFC-free inhalers. 100 micrograms of beclometasone dipropionate via Qvar products are approximately equivalent to 200 micrograms of beclometasone dipropionate in standard particle CFC-free inhalers. At the time of publication (February 2018), Qvar products did not have UK marketing authorisations for use in children aged under 12 years. Dosages in this table are based on Global Initiative for Asthma 2017 recommendations for children aged 6 to 11 years.

3 At the time of publication (February 2018), ciclesonide (Alvesco) did not have UK marketing authorisation for use in children aged under 12 years (see notes on page 1). Dosages in this table are based on Global Initiative for Asthma 2017 recommendations for children aged 6 to 11 years.

4 At the time of publication (February 2018), the only licensed dosage of fluticasone propionate for children aged 4 to 11 years via the combination products Seretide Accuhaler and Seretide Evohaler (fluticasone propionate with salmeterol) was 200 micrograms per day in 2 divided doses.
Maintenance and Reliever therapies (MART) for children
NICE recommends use of MART in children aged 5-16 (evidence was sufficient to recommend its use, despite lack of licensing). At the time of publication (November 2017), MART regimens did not have a UK marketing authorisation for use in children and young people (aged under 12) for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision.

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Symbicort SMART Licensed adults and children &gt;12 years</th>
<th>Fostair MART Licensed for adults ≥ 18 years</th>
<th>DuoResp Spiromax Licensed for adults ≥ 18 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>Budesonide/formoterol 100/6 or budesonide/formoterol 200/6</td>
<td>Not licenced in children</td>
<td>Not licenced in children</td>
</tr>
<tr>
<td>Maintenance dose</td>
<td>100/6 strength - 2 puffs daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>200/6 strength - 2 puffs daily, For some patients 2 puffs twice daily may be appropriate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>As required dose</td>
<td>1 puff as required, if symptoms persist an additional puff can be taken. No more than 6 puffs on any single occasion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum in 24 hours</td>
<td>Normally 8 puffs in 24 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 puffs in 24 hours for a limited period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum cost per 24 hours</td>
<td>£1.87 - £2.80</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Asthma self-management plan
All patients (including young people and children aged ≥5 years) with asthma should receive self-management education and a written personalised asthma plan. However remember some patients will have specific needs. Less than 50% of people use their medicines as prescribed. Advise on:
- When and how to take their medicines
- Correct inhaler technique
- Avoidance of known trigger factors
- Recognising poor control.

For an acute asthma attack in children, BTS/SIGN recommend:
Use a SABA (Salbutamol) via a large-volume spacer to relieve acute symptoms.
- For a child, give a puff every 30–60 seconds, up to 10 puffs. Each puff should be given one at a time and inhaled with five tidal breaths. Repeat every 10–20 minutes according to clinical response.
- Prescribe a short course of oral prednisolone
  - < 2 years: prednisolone 10mg daily for up to 3 days
  - 2 – 5 years: 20mg daily for up to 3 days is usually sufficient
  - 5 years: 30mg – 40mg daily, up to 3 days is usually sufficient

Decreasing maintenance treatment
(See local step down guidance for further details)
Consider decreasing maintenance treatment when a person’s asthma has been controlled with their current maintenance therapy for at least 3 months

Criteria for stepping down
- Doses of medication can be reduced by 25-50% every 3 months for stable patients while maintaining symptom control.
- After treatment is stepped down the patient should have their treatment reviewed within 4-8 weeks.
- Stepping down should be explained to the patient and be part of their personalised asthma action plan.
- Only consider stopping ICS treatment completely for people who are using low dose ICS alone as maintenance therapy and are symptom-free.
Uncontrolled asthma
Uncontrolled asthma is defined as
• 3 or more days a week with symptoms or
• 3 or more days a week requiring use of a SABA or
• 1 or more nights a week with awakening due to asthma.

Monitoring asthma control [http://www.pcrs-uk.org/opinions/asthma_review_final.pdf]
If there is evidence of poorly controlled asthma the following should be considered and addressed appropriately:
• Review/confirm asthma diagnosis
• Check inhaler technique at every review and ask the patient to demonstrate.
• Check medication adherence. Is the patient taking the medicines as prescribed? Look at prescribing history to see if it is consistent with the amount the patient should have taken.
• Always ask about the child’s exposure to smoking. Offer smoking cessation advice to patients/parents/carers. Advocate a smoke-free home and car. Smoking reduces the effect of inhaled steroids and increased doses may be needed in current and ex-smokers.
• Link with rhinitis. Asthma and rhinitis co-exist in the majority of patients. Diagnosis of co-morbid rhinitis should be actively pursued in all patients with uncontrolled asthma.
• Adjusting therapy. After consideration of diagnosis, adherence, inhaler technique, smoking status, triggers and concomitant rhinitis, patients with poorly controlled asthma should be advised to step-up their medication. It is equally important to consider stepping down treatment in patients who are consistently well controlled.
• After adjusting maintenance treatment, review the response to treatment changes in 4 to 8 weeks

The RCP three questions to assess asthma control in the last month:
1. Have you had difficulty sleeping because of asthma symptoms (including cough)?
2. Have you had your usual asthma symptoms during the day (cough, wheeze, chest tightness or breathlessness)?
3. Has your asthma interfered with your usual activities (e.g. housework, work, school, etc.)?
Yes to any of these questions implies uncontrolled asthma. [http://www.pcrs-uk.org/opinions/asthma_review_final.pdf]

Assessment of asthma control
Various tools are available for use to assess asthma control. Examples of available tools include:

<table>
<thead>
<tr>
<th>Asthma control measure</th>
<th>Description</th>
<th>Validity</th>
<th>NICE guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma control questionnaire (ACQ)</td>
<td>Well validated in adults and children &gt; 5 years. A composite scoring system with a strong bias to symptoms.</td>
<td></td>
<td>NICE NG80 – recommended</td>
</tr>
<tr>
<td>Asthma control test or children's asthma control test (ACT)</td>
<td>Validated in adults and children ≥ 4 years. 95% range for repeat measure and minimally clinically important difference not defined</td>
<td></td>
<td>NICE NG80 – recommended</td>
</tr>
<tr>
<td>Mini asthma quality of life questionnaire or paediatric asthma quality of life questionnaire</td>
<td>Well validated quality of life questionnaire. Scores usually reported as the mean of responses across the four domains with values lying between 1 and 7. Higher scores indicate better quality of life.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Royal College of Physicians (RCP) 3 questions</td>
<td>Not well validated in adults or children, but simple to use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Adapted from BTS/SIGN 2016)

- Monitor asthma control at each review in young people and children aged 5 and over using either spirometry or peak flow variability testing.
- NICE state, do not use FENO or challenge testing to monitor asthma control.
Pharmacological management of patients under 5 years old.

Suspected asthma in children under 5 years

For symptoms that indicate the need for maintenance therapy at presentation

For symptoms that do not indicate the need for maintenance therapy at presentation

Offer a SABA alone

If asthma uncontrolled in 4-8 weeks

Consider an 8-week trial of a paediatric moderate dose ICS

Stop ICS after 8 weeks and review response

If symptoms resolved during the trial, but reoccurred within 4 weeks of stopping ICS

If symptoms resolved during the trial but recurred beyond 4 weeks after stopping ICS, repeat 8-week trial of a paediatric moderate dose ICS.

If symptoms did not resolve during the trial, review whether an alternative diagnosis is likely

Offer paediatric low dose ICS

With a SABA

If asthma uncontrolled in 4-8 weeks

Consider paediatric low dose ICS plus a LTRA

With a SABA

If asthma uncontrolled in 4-8 weeks

Stop LTRA but continue with paediatric low dose ICS.

With a SABA

And

Refer to a healthcare professional with expertise in asthma for management investigation and management.

Where the recommendations represent a change from traditional clinical practice, children whose asthma is well controlled on their current treatment should not have their treatment changed purely to follow this guidance.