

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Asthma management for children and young people aged 5-16 years and children < 5 years

This guideline is based on NICE NG80, November 2017, March 2021

- 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

- Occupational exposures
- Psychosocial factors
- Seasonal or environmental factors

- Smoking (active or passive)
- 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. 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 beta₂ agonist (SABA); patients requiring **more than** 6 ^{1,2}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.
- Consider referral to secondary care if >2 ED attendances or \geq 1 attendance for exacerbation.
- Pharmacological management of children less than 5 years is included towards the end of this guidance, as recommended by NICE NG80.
- <u>MHRA Aug 2022</u>: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists (under a treatment plan). Use of a nebuliser purchased independently of medical advice for use in the home to deliver nebulised asthma rescue medications to children can mask a deterioration in the underlying disease and may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates.

- Metered dose inhalers (MDI), including breath-actuated MDIs, contain propellants hydrofluorocarbons (HFCs) which are powerful greenhouse gases and can contribute to global warming. Dry powder inhalers (DPIs) do not contain propellant, so they have a lower carbon footprint. All inhaler prescriptions, Structured Medication Reviews or planned Asthma Reviews taking place in primary care should consider moving or facilitating patients to lower carbon options where it is clinically appropriate to do so.
- All formulary dry powder inhalers contain lactose and are contraindicated in patients with hypersensitivity to lactose or milk proteins. Refer to the SmPC for full prescribing information.
- Inhalers should be prescribed by brand name to ensure the patient receives the device they are familiar with.

Document Control	Date
MART treatment option for WockAIR added to p5	June 2023
MART/SMART regimes table updated as per SPCs	April 2024
Table on page 4- DuoResp Spiromax 160/4.5 added for Asthma (adults & now children ≥12yrs)	August 2024

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Abbreviations

SABA	Short-acting beta ₂ agonist			
ICS	Inhaled corticosteroid			
LTRA	Leukotriene receptor antagonist			
LABA	Long-acting beta agonist			
MART	Maintenance and reliever therapy			
SMART	Symbicort maintenance and reliever therapy			
FENO	Fractional Exhaled Nitric Oxide			
MDI	Metered dose inhaler			
Offer	A strong recommendation usually where there is clear evidence of benefit			
Consider	A recommendation for which the evidence of benefit is less certain.			

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:

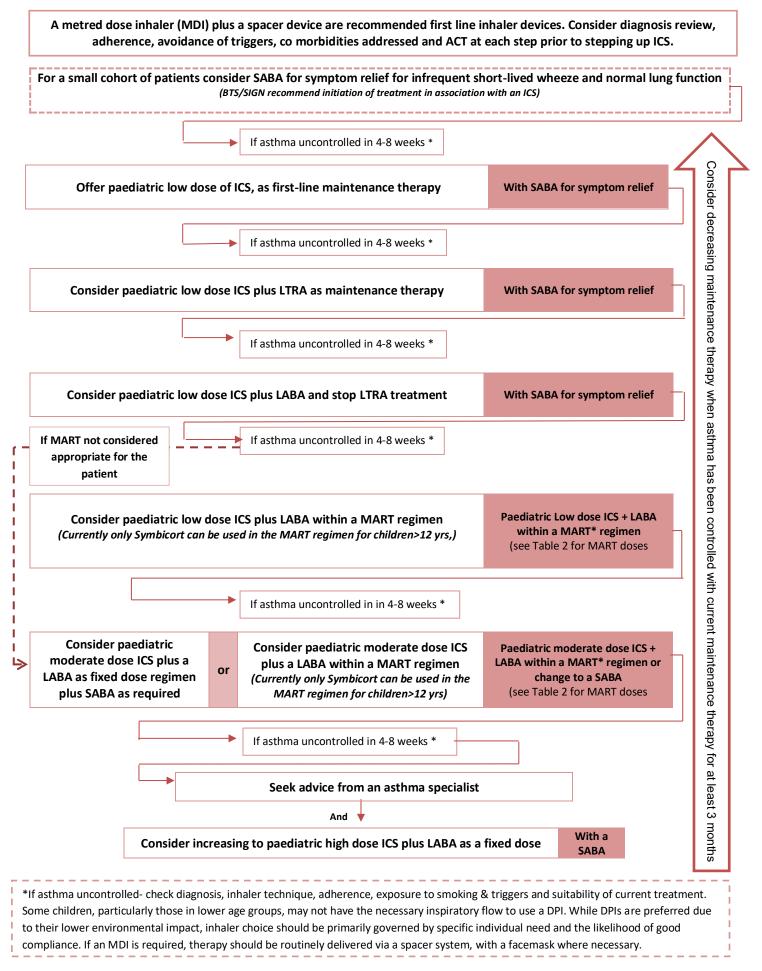
- Obstructive spirometry
- Bronchodilator reversibility test
- Peak flow variability
- FeNO
- Direct bronchial challenge test with histamine or methacholine

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 <u>NICE NG80</u> and <u>BTS</u>.

Pharmacological management of children and young people aged 5 to 16, with newly diagnosed asthma



Drug	Brand name	Device	TLC	Licensed indication	Daily dose range	Cost per device*	30day cost	Annual cost	
SABA									
Salbutamol 100microg	Salamol MDI	MDI	Green	Asthma (children)	2 puffs as required	£1.46 (200 dose)	NA	NA]
Salbutamol Easyhaler 100microg	Easyhaler salbutamol	DPI	Green	Asthma (children > 4 yrs)	2 puffs as required	£3.31 (200 dose)	NA	NA	
Salbutamol Accuhaler 200microg	Ventolin	DPI	Green	Asthma (children >4 yrs)	1 puff as required	£1.99 (60 doses)	NA	NA	
Salbutamol Easi-breathe 100microg	Salamol Easi-breathe	Breath actuated inhaler	Green	Asthma (children)	2 puff as required	£6.30 (200 dose)	NA	NA	
LTRA									
Montelukast 10mg tablets	Montelukast	Oral tablet	Green	Asthma (adults & children >15 yrs)	10mg ON	£ 1.34 x 28	£1.44	£17	
Montelukast chewable tablets 5mg	Montelukast	Chewable tablet	Green	Asthma (Children > 6-14 yrs)	5mg ON	£1.15x28	£1.23	£15	
Montelukast chewable tablets 4mg	Montelukast	Chewable tablet	Green	Asthma (Children > 2-5 yrs)	4mg ON	£1.08 x28	£1.16	£14	
Inhaled Corticosteroid	• •	• 		• •	•				ICS dose
Beclometasone 50mcg MDI	Soprobec 50mcg	MDI	Green	Asthma (adults & children)	2 puffs BD	£2.78 (200 dose)	£1.67	£20	200mcg bec
Beclometasone 100mcg MDI	Soprobec 100mcg	MDI	Green	Asthma (adults & children)	1 puff BD	£5.57 (200 dose)	£1.67	£20	200mcg bec
Beclometaone 50mcg MDI	QVAR 50mcg	MDI	Green	Asthma (adults &	1 puff BD	£7.87 (200 dose)	£2.36	£28	100mcg extrafine
extrafine particle size	_			children >5 yrs)	2 puffs BD	£7.87 (200 dose)	£4.72	£57	200mcg extrafine
Budesonide 100mcg	Easyhaler budesonide	Breath-actuated DPI	Green	Asthma (adults &	1 puff BD	£8.86 (200 dose)	£2.66	£32	200mcg bud
-	100mcg			children >6 yrs)	2 puffs BD	£8.86 (200 dose)	£5.32	£64	400mcg bud
Fluticasone 50mcg MDI	Flixotide evohaler	MDI	Green for children	Asthma (adults & children >4 yrs)	1 puff BD	£6.53 (120 dose)	£3.26	£40	100mcg flut
Fluticasone 100mcg DPI	Flixotide accuhaler	DPI	Green for children	Asthma (adults & children >4 yrs)	1 puff BD	£4.02 (60 dose)	£4.02	£48	200mcg flut
LABA/ICS combination products ~			- crimer cri	onnor en e r y o y					
Budesonide/formoterol 100/6mcg	Symbicort 100/6	Breath-actuated DPI.	Green	Asthma (adults &	1 puff BD	£28 (120 dose)	£14	£168	200mcg bud
turbohaler	turbohaler			children > 6yrs)	2 puffs BD	£28 (120 dose)	£28	£336	400mcg bud
Budesonide/formoterol 200/6	Symbicort 200/6	Breath-actuated DPI.	Green	Asthma (adults &	1 puff BD	£28 (120 dose)	£14	£168	400mcg bud
turbohaler	turbohaler			children > 12yrs)	2 puffs BD	£28 (120 dose)	£28	£336	800mcg bud
Budesonide/formoterol 200/6	WockAIR 160/4.5	Breath-actuated DPI.	Green	Asthma ≥12yrs (& COPD)	1 puffs BD	£19 (120 dose)	£9.50	£114	400mcg bud
	, -			, , , , , , , , , , , , , , , , , , , ,	2 puffs BD	£19 (120 dose)	£19	£228	800mcg bud
Budesonide/formoterol 200/6mcg	DuoResp Spiromax	DPI	Green	Asthma (adults &	1 puffs BD	£27.97 (120 dose)	£13.99	£168	400mcg bud
	160/4.5		alternative ICS/LABA	children ≥12yrs)	2 puffs BD	£27.97 (120 dose)	£27.97	£336	800mcg bud
Fluticasone /Salmeterol	Seretide accuhaler	Breath actuated DPI	Green for	Asthma (adults &	1 puff BD	£17.46 (60 dose)	£17.46	£210	200mcg flut
100/50mcg	100		children	children >4 yrs)					
Fluticasone/Salmeterol 100/50mcg	Fixkoh Airmaster 50/100	Breath-actuated DPI.	Green for children	Asthma (adults & children ≥12 yrs)	1 puff BD	£14.47 (60 dose)	£14.47	£174	200mcg flut
Fluticasone /Salmeterol 50/25mcg	Seretide evohaler 50	MDI	Green for children	Asthma (adults & children >4 yrs)	1 puff BD	£17.46 (120 dose)	£8.73	£105	100mcg flut
Fluticasone/Salmeterol 50/25mcg	Combisal 25/50	MDI	Green for children	Asthma (adults & children >4 yrs)	2 puffs BD	£13.50 (120 dose)	£13.50	£162	100mcg flut
Fluticasone /Salmeterol 50/25mcg	Seretide evohaler 50	MDI	Green for children	Asthma (adults & children >4 yrs)	2 puffs BD	£17.46 (120 dose)	£17.46	£210	200mcg flut

(*Price per MIMs online April 23and DT) ∞ Some children, particularly those in lower age groups, may not have the necessary inspiratory flow to use a DPI. While DPIs are preferred due to their lower environmental impact, inhaler choice should be primarily governed by specific individual need and the likelihood of good compliance. If an MDI is required, therapy should be routinely delivered via a spacer with a facemask where necessary.

Inhaled corticosteroid dose regimens for children (NICE NG80)

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

	Paediatric low dose	Paediatric moderate dose	Paediatric high dose
Beclometasone diprop	ionate ¹	4000	
Standard particle CFC- free inhalers	100 - 200micrograms per day in 2 divided doses	300 - 400 micrograms per day in 2 divided doses	500 - 800 micrograms per day in 2 divided doses.
Extra-fine particle CFC- free inhalers ²	100 micrograms per day in 2 divided doses	150 - 200micrograms per day in 2 divided doses	300 - 400 micrograms per day in 2 divided doses
Budesonide			
Dry powder inhalers	100 - 200 micrograms per day as a single dose or in 2 divided doses	300 - 400 micrograms per day as a single dose or in 2 divided doses	500 - 800 micrograms per day in 2 divided doses
Fluticasone propionate	•		
Metered dose and dry powder inhalers ⁴	100 micrograms per day in 2 divided doses	150 - 200 micrograms per day in 2 divided doses	250 - 400 micrograms per day in 2 divided doses
Ciclesonide			
Metered dose inhaler ³	80 micrograms per day as a single dose	160 micrograms per day as a single dose or in 2 divided doses	240 – 320 micrograms per day in 2 divided doses

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.

Regimen	Symbicort Turbohaler SMART Licenced adults and children <u>></u> 12 years	DuoResp Spiromax Licenced for children ≥12years	WockAIR Licenced for children ≥ 12 years
Device	Budesonide/formoterol 100/6 or 200/6	Budesonide/formoterol 160/4.5 only	Budesonide/formoterol 160/4.5 only
Maintenance dose	100/6 strength- 2 puffs daily 200/6 strength - 2 puffs daily, increased if necessary to 2 puffs twice a day for some patients.	2 puffs daily - increased if necessary to 2 puffs twice a day for some patients.	2 puffs daily - increased if necessary to 2 puffs twice a day for some patients
As required dose	1 additional puff as needed. If symptoms persist after a few	1 additional puff as needed. If symptoms persist after a few	1 additional puff as needed. If symptoms persist after a few

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	minutes, an additional puff	minutes, an additional puff	minutes, an additional puff
	should be taken. Not more	should be taken. Not more	should be taken. Not more
	than 6 puffs on any single	than 6 puffs on any single	than 6 puffs on any single
	occasion.	occasion	occasion.
Maximum in 24	Normally 8 puffs in 24	Normally 8 puffs in 24	Normally 8 puffs in
hours	hours.12 puffs in 24 hours for	hours.12 puffs in 24 hours for	24hours.12 puffs in
	a limited period	a limited period.	24hours for a limited period.
Maximum			
cost per 24	£1.87 - £2.80	£2.80	£1.26- £1.90
hours			

Asthma self-management plan

All patients (including young people and children aged ≥5 years) with asthma should receive selfmanagement 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
 - \circ < 2 years prednisolone 10mg daily for up to 3 days
 - $\circ~2-5$ 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

Consider decreasing maintenance treatment when a person's asthma has been controlled with their current maintenance therapy <u>for at least</u> 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 Good building blocks of an asthma review | Primary Care Respiratory Society (pcrsuk.org)

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

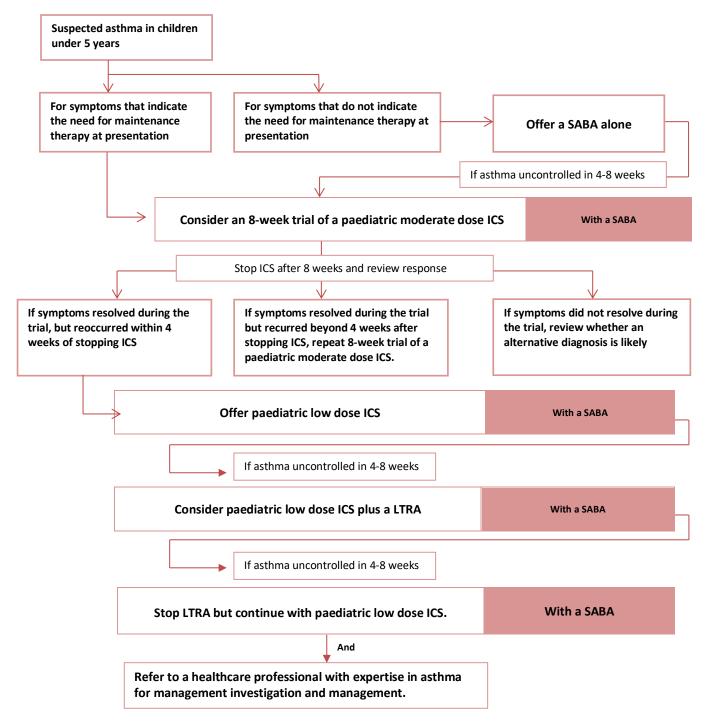
Assessment of asthma control

- 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.

Asthma control questionnaire (ACQ)	Well validated in adults and children>5 years. A composite scoring system with a strong bias to symptoms.	NICE NG80 –recommended
Asthma control test or children's asthma control test (ACT)	Validated in adults and children ≥4 years. 95% range for repeat measure and minimally clinically important difference not defined	NICE NG80 –recommended
Mini asthma quality of life questionnaire or paediatric asthma quality of life questionnaire	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.	
Royal College of Physicians () 3 questions ⁴ (<u>CKS</u>)	Not well validated in adults or children, but simple to use	 Have you had difficulty sleeping because of asthma symptoms (including cough)? Have you had your usual asthma symptoms during the day (cough, wheeze, chest tightness or breathlessness)? Has your asthma interfered with your usual activities (e.g. housework, work, school, etc.)? Yes to any of these questions implies uncontrolled asthma.

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

Pharmacological management of patients under 5 years old.



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.

References

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- 2. <u>https://www.pcrs-uk.org/sites/default/files/2021-Dec-Issue-23-BuildingBricksAsthma_0.pdf</u> (Accessed 9/3/23)
- 3. NICE NG80 Asthma: diagnosis, monitoring and chronic asthma management.
- 4. Pearson MG, Bucknall CE, eds. Measuring clinical outcome in asthma: a patient-focused approach. London: Royal College of Physicians, 1999. [Google Scholar]