Lancashire & South Cumbria Medicines Management Group

Asthma Treatment Guideline for Children

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VERSION CONTROL.

Please access via the LSCMMG website to ensure that the correct version is in use. http://www.lancsmmg.nhs.uk/

Version Number	Amendments made	Author	Date
1.0	Document to supersede LMMG Asthma summary guideline for adults and over 12s (March 2014) with regards to asthma treatment for children. Separate adult asthma guideline available.	Sharon Andrew	September 2019

Background Information and the Rationale for Guideline Development.

There have recently been developments in the treatment of Asthma with the publication of new national/international guidelines, the licensing of new drugs and devices and requests by clinicians to use new inhalers. As the developments affected the previous LMMG Asthma guideline, the LSCMMG requested a review and production of a separate Asthma Guideline for Children.

Acknowledgement: members of the Lancashire and South Cumbria Paediatric Clinical Asthma Group for their contributions.

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INTRODUCTION

Asthma guidelines authored jointly by The British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) were published in 2016.¹ Subsequently the National Institute for Health and Care Excellence (NICE) published guidelines for diagnosis, monitoring and chronic asthma management (NG80, 2017).² There are therefore two national guidelines for the treatment of asthma; these guidelines differ in some of their recommendations.

The evidence base considered by the BTS/SIGN and NICE guideline development groups is broadly the same for each guideline, but the methodology used to produce recommendations is significantly different:

- SIGN methodology is a multidisciplinary clinically led process which employs robust critical
 appraisal of the literature, coupled with consideration of pragmatic studies to ensure that
 guidelines provide clinically relevant recommendations.
- NICE methodology overlays critical appraisal of the literature with health economic modelling, with interpretation supported by advice from a multidisciplinary guideline development group

These different processes have resulted in some discrepancies in recommendations made by BTS/SIGN and NICE. However, it has been announced that future UK-wide guidance for the diagnosis and management of chronic asthma in adults, young people and children will be produced jointly by the British Thoracic Society (BTS), Scottish Intercollegiate Guideline Network (SIGN) and NICE.

PURPOSE AND SUMMARY

This asthma summary guideline has been created in collaboration with the Lancashire and South Cumbria Paediatric Clinical Asthma Group, with the aim to provide a consistent approach to asthma treatment for children within LSCMMG.

SCOPE

This guideline covers the chronic management of asthma only. These guidelines should **not** be referred to for the management of acute asthma.

This guidance does not override the individual responsibility of health professionals to make decisions in exercising their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Please note that **not** all ICS / LABAs have a UK marketing authorisation for use in young people aged under 16 for this indication.

For full prescribing information please refer to the BNF and SPC, ensuring correct SPC according to dose is consulted.

ADDITIONAL INFORMATION

- MART = Maintenance And Reliever Therapy. This is when a combination inhaler is to be used by a patient as both the maintenance and reliever therapy, as part of a specific treatment regime. A separate reliever inhaler is not needed. Not all inhalers are licensed for MART in children.
- ICS Doses for Children aged 16 and under, as per BTS / SIGN guidelines:
 ≤ 200mcg budesonide or equivalent considered a paediatric very low dose
 ≥ 200mcg to 400mcg budesonide or equivalent considered a paediatric low dose
 >400mcg budesonide or equivalent considered a paediatric medium dose (these should only be prescribed after referral of the patient to secondary care).
- The inhaler pathways included in this guideline are only **examples**. These have been designed to illustrate both device and drug continuity through the pathway, wherever possible.
- Clenil Modulite® must always be used with the Volumatic™ spacer device when administered to children and adolescents 15 years of age and under, whatever dose has been prescribed.
 NB. The Volumatic spacer device is the only spacer device licensed for use with the Clenil Modulite, however, other spacer devices are compatible.

PHARMACOLOGICAL TREATMENT PATHWAY FOR CHILDREN (AGED 5-16)

Note: Patient Compliance and Inhaler Technique should be checked at each visit, every step change in treatment and at least once a year.

Prescribe by brand to ensure device continuity.

Whenever a change in medication / dose is made, consider 'diagnosis' In younger children a pMDI and spacer with mouthpiece are the preferred method of delivery of β2 agonists or inhaled corticosteroids

Short Acting Beta 2 Agonist (SABA) Reliever Therapy

(To be continued throughout pathway, but only to be used on MART regimen when advised by clinician / following review)

Inhaled Corticosteroid (ICS) Very Low Dose

1ST line Maintenance Therapy If still uncontrolled after 8 weeks, as per childhood ACT definition (An ACT score of ≤19 indicates uncontrolled asthma.) ICS (Very Low Dose) + Long Acting Beta 2 ICS (Very Low Dose) + LABA in MART agonist (LABA) in fixed dose regimen. regimen Note: If still uncontrolled, as per ACT definition, on fixed dose regimen, or Note: Not all inhalers are licensed for MART in compliance issues are suspected consider children. Consider patient preference and ability to changing to MART regimen with a understand and adhere to regime - inform patient of paediatric low ICS dose maximum dose If benefit from LABA, but control still inadequate If NO response to LABA ICS (Very Low Dose) + Long STOP LABA and consider ICS (Low Dose) + Long Acting Acting Beta 2 agonist (LABA) increasing dose of ICS to Low OR Beta 2 agonist (LABA) and consider addition of LTRA dose (review in 2-4 weeks) Note: LTRA (Montelukast) different doses for different ages If still uncontrolled after 8 weeks, as per childhood ACT definition (An ACT score of ≤19 indicates uncontrolled asthma.) **OR** if any concerns REFER TO SECONDARY CARE And consider trial of:

If a patient's asthma has been controlled for 3-6 months then consider decreasing current maintenance therapy. When reducing maintenance therapy, reduce dose of medicines in an order that takes into account the clinical effectiveness when introduced, side effects and the patient's preference e.g. consider stepping down by halving ICS dose i.e. reverse pathway. However, if control deteriorates then increase back to higher, previous maintenance dose.

Increasing ICS to Medium dose

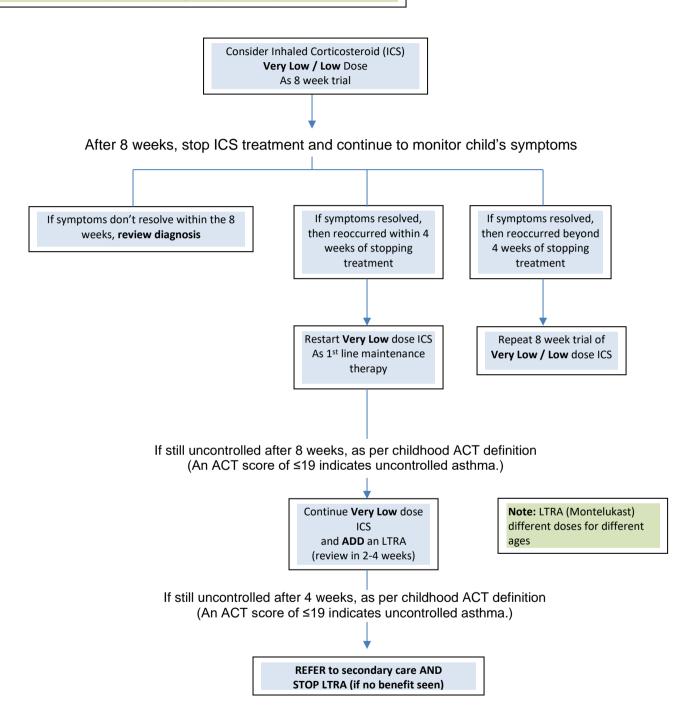
Minimum maintenance therapy is very low dose ICS

PHARMACOLOGICAL TREATMENT PATHWAY FOR CHILDREN (<5 YEARS)

Prescribe by brand to ensure device continuity.

Whenever a change in medication / dose is made, consider 'diagnosis' In children a pMDI and spacer with mouthpiece are the preferred method of delivery of $\beta 2$ agonists or inhaled corticosteroids. A face mask is required until the child can breathe reproducibly using the spacer mouthpiece.

Short Acting Beta 2 Agonist (SABA) Reliever
Therapy
(To be continued throughout pathway)



Note:

If a patient's asthma has been controlled for 3-6 months then consider decreasing current maintenance therapy.

When reducing maintenance therapy, reduce dose of medicines in an order that takes into account the clinical effectiveness when introduced, side effects and the patient's preference e.g. consider stepping down by halving ICS dose i.e. reverse pathway.

However, if control deteriorates then increase back to higher, previous maintenance dose

Minimum maintenance therapy is very low dose ICS

Before referral to Secondary Care

Please consider common causes of poor asthma control:

- Incorrect diagnosis, or co-morbidity that has been missed
- Lack of medication adherence
- Current treatment is unsuitable
- Under-use of ICS or overuse of SABAs
- Inappropriate inhaler technique
- Failure to use a spacer with medication delivered by a metered dose inhaler
- Smoking (active or passive)
- Exposure to occupational triggers
- Seasonal or environmental factors
- Psychosocial reasons, including ideas and concerns about asthma/treatment

Further information on Pharmacological Treatment

Leukotriene Receptor Antagonists (LTRAs)

Montelukast 3 4 5 6

This is currently the only licensed LTRA.

Dosage:

- Adults and adolescents 15 years of age and older, 10 mg daily to be taken in the evening.
- Paediatric patients 6 to 14 years of age 5 mg daily to be taken in the evening (chewable tablets are available).
- Paediatric patients 2 to 5 years of age 4 mg daily to be taken in the evening (chewable tablets are available).
- Paediatric patients 6 months to 5 years of age 4 mg daily to be taken in the evening (sachets
 of granules are available). The diagnosis of persistent asthma in very young children (6
 months 2 years) should be established by a paediatrician or pulmonologist.

Tabulated list of Adverse reactions (this is not an exclusive list please consult individual products SPC)

Frequency	Adverse experience	
Very Common	Upper respiratory infection,	
Common	Diarrhoea, nausea, vomiting, elevated levels of serum transaminases, rash, pyrexia	
Uncommon	Hypersensitivity reactions, dream abnormalities, anxiety, agitation, depression, psychomotor hyperactivity, dizziness, drowsiness, paraesthesia/hypoesthesia, seizure, epistaxis, dry mouth, dyspepsia, bruising, urticaria, pruritus, arthralgia, myalgia, enuresis, asthenia/fatigue, malaise, oedema.	
Rare	Increased bleeding tendency, disturbance in attention, memory impairment, tic, palpitations, angioedema	
Very Rare	Thrombocytopenia, hepatic eosinophilic infiltration, hallucinations, disorientation, suicidality, Churg-Strauss Syndrome, pulmonary eosinophilia, hepatitis, erythema nodusum, erythema multiforme.	

Frequency Category: Very Common (\geq 1/10), Common (\geq 1/100 to <1/10), Uncommon (\geq 1/1000 to <1/100), Rare (\geq 1/10,000 to <1/1000), Very Rare (<1/10,000).

Suggested Clinical Practical Solutions

• If a child on Montelukast suffers from 'night terrors' then suggest that they take the medication in a morning rather than in the evening

Inhaled Corticosteroids (ICS)

Different corticosteroid products and doses are licensed for different age groups and some are not licensed for use in children. Prior to prescribing, the relevant summary of product characteristics (SPC) should be consulted. https://www.medicines.org.uk/emc

Tabulated list of Adverse reactions (this is not an exclusive list please consult individual products SPC)

Frequency	Adverse experience
Very Common	Oropharyngeal candidiasis
Common	Cough, throat irritation, difficulty in swallowing, hoarseness.
Uncommon	Anxiety, depression, cataract, blurred vision, muscle spasm, tremor, rash, pruritus, erythema,urticaria
Rare	Hypersensitivity reactions, hypocorticism, hypercorticism, signs /symptoms of systemic corticosteroid effects, behavioural changes, restlessness, nervousness, dysphoria, bronchospasm, bruising,
Very Rare	Glaucoma, decreased bone density, oedema of the eyes, face, lips and throat, adrenal suppression, growth retardation

Frequency Category: Very Common (\geq 1/10), Common (\geq 1/100 to <1/10), Uncommon (\geq 1/1000 to <1/100), Rare (\geq 1/10,000 to <1/1000), Very Rare (<1/10,000).

NB: Due to the risk of growth retardation in the paediatric population, growth should be regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled corticosteroid, if possible, to the lowest dose at which effective control of asthma is maintained.

In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.

Suggested Clinical Practical Solutions

• If a child is prescribed an ICS, advise child / parent / carer to rinse the mouth and / or brush teeth after every use in order to reduce the risk of oropharyngeal candidiasis

Long Acting Beta 2 Agonists (LABA)

N.B. LABAs should always be prescribed and used in conjunction with an ICS, therefore, where possible combination inhalers should be used.

Different LABA products and doses are licensed for different age groups and some are not licensed for use in children. Prior to prescribing, the relevant summary of product characteristics (SPC) should be consulted. https://www.medicines.org.uk/emc

Tabulated list of Adverse reactions (this is not an exclusive list please consult individual products SPC)

Frequency	Adverse experience
Very Common	
Common	Headache, tremor, palpitations, muscle cramps, cough,
Uncommon	Rash, nervousness, tachycardia, agitation, restlessness, sleep disorder, dizziness, taste disturbances, throat irritation, nausea,
Rare	Hypokalaemia, insomnia, hypersensitivity reactions,
Very Rare	Anaphylatic reactions, hyperglycaemia, cardiac arrythmias, oropharyngeal irritation, paradoxical bronchospasm, arthralgia, non specific chest pain, thrombopenia,

Frequency Category: Very Common (\geq 1/10), Common (\geq 1/100 to <1/10), Uncommon (\geq 1/1000 to <1/100), Rare (\geq 1/10,000 to <1/1000), Very Rare (<1/10,000).

Example Inhaler Pathways for children (aged 5-16)

Pathway Example 1. For MDI

Very Low Dose ICS

still

Clenil Modulite 50mcg / dose inhaler

(Beclometasone) 2 puffs twice daily Use Volumatic™ spacer device

Low Dose ICS

Clenil Modulite 100mcg / dose inhaler

If no

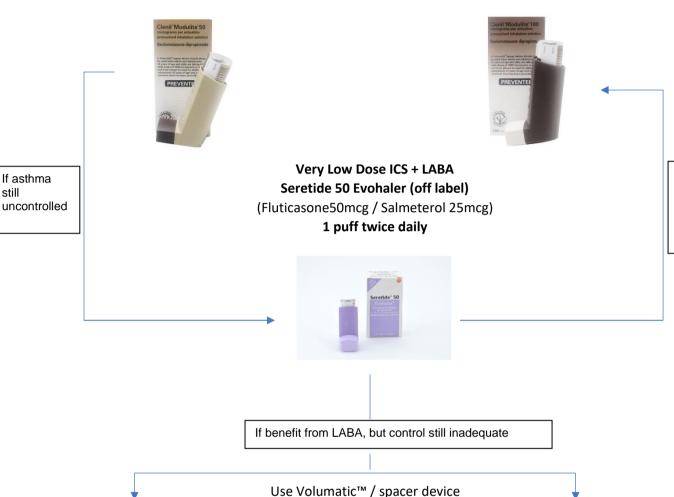
response to

LABA and

asthma still

uncontrolled

(Beclometasone) 2 puffs twice daily Use Volumatic™ spacer device



Low Dose ICS + LABA Seretide 50 Evohaler (Fluticasone 50mcg / Salmeterol 25mcg) 2 puffs twice daily

OR

Very Low Dose ICS + LABA + LTRA Seretide 50 Evohaler (off label)

(Fluticasone 50mcg / Salmeterol 25mcg)

1 puff twice daily

+ Monteleukast





+ Montelukast

NB: There is no Beclometasone + LABA combination inhaler licensed for use in paediatric asthma. For children ≤ 15 years a Clenil Modulite must always be used with a Volumatic™ spacer device (licensed).

Pathway Example 2. For MDI

Very Low Dose ICS
Flixotide 50mcg / dose Evohaler
(Fluticasone) 1 puff twice a day

Low Dose ICS
Flixotide 50mcg/dose Evohaler
(Fluticasone) 2 puffs twice a day
Use spacer device



If asthma

uncontrolled

still



Very Low Dose ICS + LABA

Seretide 50 Evohaler (off label)
(Fluticasone50mcg / Salmeterol 25mcg)
1 puff twice daily

If no response to LABA and asthma still uncontrolled



If benefit from LABA, but control still inadequate

Use spacer device

Low Dose ICS + LABA
Seretide Evohaler
Fluticasone 50mcg / Salmeterol 25mcg)
2 puffs twice daily

OR

Very Low Dose ICS + LABA + LTRA Seretide 50 Evohaler (off label) Fluticasone 50mcg / Salmeterol 25mcg 1 puff twice daily + Monteleukast



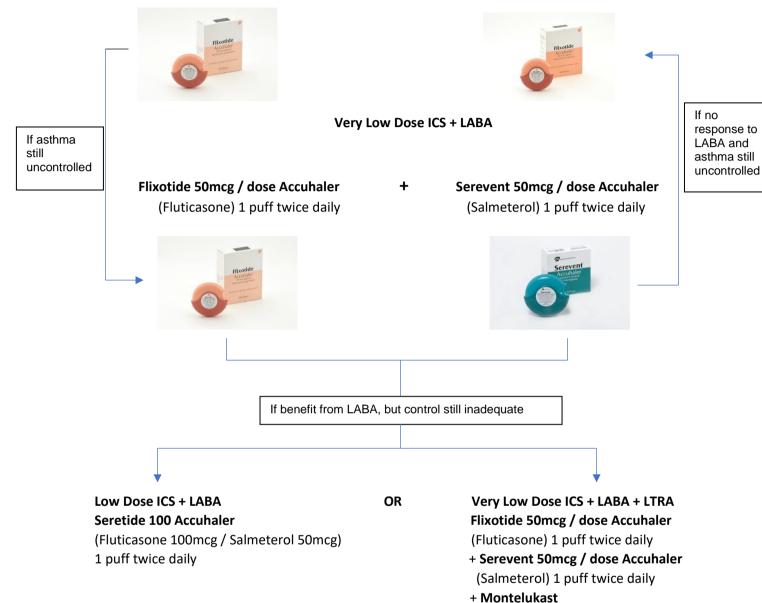


+ Montelukast

Pathway Example 3. For Accuhaler

Very Low Dose ICS
Flixotide 50mcg / dose Accuhaler
(Fluticasone) 1 puff twice daily

Low Dose ICS
Flixotide 100mcg / dose Accuhaler
(Fluticasone) 1 puff twice daily









+ Montelukast

Pathway Example 4. For Turbohaler

Very Low Dose ICS

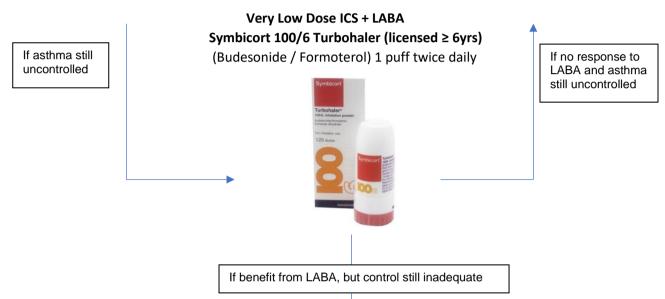
Pulmicort 100mcg / dose Turbohaler
(Budesonide) 1 puff twice daily

Low Dose ICS

Pulmicort 200mcg/dose Turbohaler
(Budesonide) 1 puff twice daily







OR

Low Dose ICS*+ LABA

Symbicort 100/6 Turbohaler (licensed ≥ 6yrs)
(Budesonide Formoterol) 2 puffs twice daily

Very Low Dose ICS + LABA + LTRA

Symbicort 100/6 Turbohaler (licensed ≥ 6yrs)

(Budesonide Formoterol) 1 puff twice daily





+ Montelukast

NB Symbicort 100/6 Turbohaler is licensed for MART but $\underline{\text{only}}$ in children \geq 12 years of age.

REFERENCES

¹ Health improvement Scotland. BTS/SIGN British Guideline for the management of asthma. 2016. SIGN 153.

² Asthma: diagnosis, monitoring and chronic asthma management, NICE NG80, November 2017. https://www.nice.org.uk/guidance/ng80

Montelukast 4mg Chewable Tablets SPC https://www.medicines.org.uk/emc/product/6098/smpc
 Montelukast 5mg Chewable Tablets SPC https://www.medicines.org.uk/emc/product/6098/smpc

⁵ Montelukast 10 mg film coated tablets SPC https://www.medicines.org.uk/emc/product/1243/smpc

⁶ Montelukast Sodium 4 mg Oral Granules SPC https://www.medicines.org.uk/emc/product/3043/smpc