Consensus recommendations for the practical application of the

# NICE/BTS/SIGN 2024 asthma guidance on MART therapy in children and young people

#### Introduction

The publication of the 2024 NICE/BTS/SIGN asthma guidance has brought about a stepwise change in the pharmacological approach to asthma management in children and young people (CYP), with the shift in emphasis away from conventional treatment and more towards anti-inflammatory reliever therapy (AIR) and maintenance and reliever therapy (MART).

Although welcomed as an approach due to its association with better outcomes and reduced exacerbation rates, the lack of evidence on dosing and safety in the CYP age group, lack of familiarity of some Health Care Professionals (HCPs) and patients with the regimen and lack of availability, particularly the 5-11 year olds, of licensed devices has led to challenges in the application of these changes to the real world.

Clinical trails are underway which hope to address some of these challenges in the future. Until the results of these trials are available, however, guidance is needed to ensure consistent and safe care can be delivered to CYP with asthma from primary to tertiary care.

This document outlines a consensus recommendation based on the best available evidence and expert opinion. Its purpose is to provide guidance on a safe approach within the limitations of the evidence and devices currently available. It will be important that these recommendations are regularly reviewed and there is careful and close monitoring of patients whose care is based on this guidance, especially in the younger age groups.

In addition, as with any guidance, these recommendations must be applied within the scope of the expertise and confidence of the clinician delivering the care, consideration of the informed opinions of the child, young person and care giver, and the ability of the patient to use a particular device.

# It is therefore recommended that MART should only be used in the 5-11 years age group if the following criteria are met:



1. The healthcare professional explaining, prescribing and implementing the MART regime is trained to tier 3 level or above according to the 'National Capabilities Framework for Professionals who Care for Children and Young People with Asthma'

2. If using a dry powder device, a formal assessment of the ability of the CYP to generate adequate inspiratory flow for the device to be used has been undertaken. (e.g. using the In-Check™ DIAL G16 Inhaler Technique Training and Assessment Tool or an inhaler device whistle)





3. Extra time has been allocated for the consultation to allow for adequate explanation and education of the MART regime and to complete and explain an associated MART Personalised Asthma Action Plan (PAAP): Find examples at: BeatAsthma, LALIG and ALUK

4. There is infrastructure to allow for closer monitoring and more regular surveillance than for those on conventional therapy e.g. capacity for more frequent follow up and prescribing alerts for higher-thanexpected use. This is to ensure patient understanding and adequate inhaler technique, effectiveness of the regime and review potential side effects of steroid toxicity or from higher dose formoterol use.





## **Conventional Pathway**

	pMDI and spacer	DPI	
Newly diagnosed: Paediatric Low dose ICS + SABA	Clenil 50 or Soprobec 50 1 or 2 inhalations twice daily	Pulmicort Turbohaler 100 or Budesonide easyhaler 100 1 inhalation once or twice per day or Flixotide Accuhaler 50 1 inhalation twice daily	
If uncontrolled: Paediatric Low dose ICS + LABA		ceptor antagonist eg montelukast neuropsychiatric side effects  Symbicort 100/6 or Fobumix 80/4.5  1 inhalation twice daily	
If uncontrolled: Paediatric Moderate dose ICS + LABA	Flutiform 50/5 or Combisal 25/50 or Avenor 50/25 or Seretide 50/25 2 inhalations twice daily	Symbicort 100/6 or Fobumix 80/4.5 2 inhalations twice daily	
Use SABA as reliever for all stages  Never use SABA as monotherapy			



## Suggested dosing and devices: Children (5 -11 Years)

#### **MART Pathway**

	pMDI and spacer	DPI		
Newly diagnosed Low dose ICS + SABA	Clenil 50 or Soprobec 50 1 or 2 inhalations twice daily + SABA for relief	Pulmicort Turbohaler 100: Budesonide easyhaler 100  1 inhalation once or twice per day or Flixotide Accuhaler 50  1 inhalation twice daily + SABA for relief		
If uncontrolled Low dose MART	Not Recommended*  If not able to use a DPI device either remain on the conventional pathway or refer to secondary care	Symbicort 100/6  Pobumix 80/4.5**  1 inhalation once or twice daily (maintenance) + 1 inhalation for relief (maximum 8 inhalations in total/24hrs, max 4 at any one time)***		
If uncontrolled Moderate dose MART	Not Recommended: REFER	Not Recommended: REFER		



This device is not licensed, either for the purpose listed or for that age group or both. The decision to use the device off lablel must be made in collaboration with the family/young person based on an informed discussion. If licensed options become available, these should be used in preference.

<sup>\*</sup> Due to a lack of evidence on the safety of using Symbicort 100/3 for MART therapy in this age group, a child using this device in this way requires careful monitoring to ensure high doses of steroids are not being used regularly and to ensure efficacy. Its use should be limited to asthma clinics run by health care professionals (HCPs) practicing at tier 4 or above according to the national CYP asthma capabilities framework and with the capacity to review 3 monthly at least initially. If this can be achieved in a primary care setting this may be an appropriate treatment regime for primary care. Personalised asthma action plans (PAAPs) should highlight the need to contact a HCP if close to maximum doses are being used regularly. Regular use of >800mcg per day needs consideration for tertiary referral.

<sup>\*\*</sup> the delivered dose of Fobumix 80/4.5 is equivalent to 100/6 of Symbicort

<sup>\*\*\*</sup> A total daily dose of more than 6 inhalations is not normally needed; however, a total daily dose of up to 8 inhalations could be used for 2 days. Patients regularly using more than 6 inhalations daily should seek medical advice.

### **Secondary Care**

#### **MART Pathway**

	pMDI and spacer	DPI		
Newly diagnosed: Paediatric Low dose ICS + SABA	Clenil 50 or Soprobec 50 1 or 2 inhalations twice daily + SABA for relief	Pulmicort Turbohaler 100: Budesonide easyhaler 100  1 inhalation once or twice per day or Flixotide Accuhaler 50  1 inhalation twice daily + SABA for relief		
If uncontrolled: Paediatric Low dose MART	Symbicort 100/3*  1 inhalation twice daily or 2 inhalations once daily Plus 2 inhalations for relief	Symbicort 100/6 Fobumix 80/4.5**  1 inhalation once or twice daily (maintenance) + 1 inhalation for relief (maximum 8 inhalations in total/24hrs, max 4 at any one time)***		
If uncontrolled: Paediatric Moderate dose MART	Symbicort 100/3* 2 inhalations twice daily (maintenance)	Symbicort 100/6* or or Fobumix 80/4.5*  2 inhalations twice daily (maintenance)		
	+ 2 inhalations for relief (maximum 16 inhalations in total/24hrs, max 8 at any one time)	+ 1 inhalation for relief (maximum 8 inhalations in total/24hrs, max 4 at any one time) ***		



These are not licensed, either for the purpose listed or for that age group or both. The decision to use the device must be made in collaboration with the family/young person based on an informed discussion

\*A child using this formulation for MART requires careful monitoring to ensure high doses of steroids are not being used regularly. Its use should be limited to asthma clinics run by HCPs practicing at tier 4 or above according to the national CYP asthma capabilities framework and with the capacity to review 3 monthly at least initially. PAAPs should highlight the need to contact a HCP if close to maximum doses are being used regularly. Regular use of >800mcg per day needs consideration for tertiary referral.

A total daily dose of more than 12 inhalations is not normally needed; however, a total daily dose of up to 16 inhalations could be used for 2 days. Patients regularly using more than 12 inhalations daily should seek medical advice.

<sup>\*\*</sup> the delivered dose of Fobumix 80/4.5 is equivalent to 100/6 of Symbicort

<sup>\*\*\*</sup> A total daily dose of more than 6 inhalations is not normally needed; however, a total daily dose of up to 8 inhalations could be used for 2 days. Patients regularly using more than 6 inhalations daily should seek medical advice.



	pMDI and spacer	DPI		
AIR	Symbicort 100/3	Symbicort 200/6 or DuoResp Spiromax 160/4.5 or Wockair 160/4.5 Fobumix 160/4.5		
Low dose MART	Symbicort 100/3 2 inhalations once or twice daily (maintenance)	Symbicort 100/6 Fobumix 80/4.5  1 inhalation twice daily (maintenance)  Symbicort 200/6 or Fobumix 160/4.5 or Duoresp Spiromax 160/4.5 or Wockair 160/4.5  1 inhalation once or twice daily (maintenance)		
Mod dose MART	Symbicort 100/3 4 inhalations twice daily (maintenance)	Symbicort 200/6 or Fobumix 160/4.5 or Duoresp Spiromax 160/4.5 or Wockair 160/4.5 2 inhalations twice daily (maintenance)		
	+2 inhalations for relief, Max 24 in one day, max 12 at any one time*	+ 1inhalation for relief, max 12 in one day, max 6 at any one time**		



These are not licensed, either for the purpose listed or for that age group or both. The decision to use the device must be made in collaboration with the family/young person based on an informed discussion

<sup>\*</sup> A total daily dose of more than 16 inhalations is not normally needed; however, a total daily dose of up to 24 inhalations could be used for 2 days. Patients regularly using more than 16 inhalations daily should seek medical advice.

<sup>\*\*</sup> A total daily dose of more than 8 inhalations is not normally needed; however, a total daily dose of up to 12 inhalations could be used for 2 days. Patients regularly using more than 8 inhalations daily should seek medical advice.

# Air and MART budesonide with formoterol combination inhaler choices for children age 6 to 17 years

Medi- cation	Picture	Туре	Age 6-11 years		Age 12-17 years			
			AIR	Paediatric Low dose MART	Paediatric Mod dose MART	AIR	Low dose MART	Mod dose MART
Symbicort 100/3	0	MDI	Not licensed Not recom- mended	Not licensed Recommend- ed according to HCP competencies	Not licensed Recommend- ed according to HCP competencies	Not licensed Recommend- ed according to HCP com- petencies	Licensed	Licensed
Symbicort turbohaler 100/6		Dry powder inhaler	Not licensed Not recom- mended	Not licensed Recommend- ed according to HCP competencies	Not licensed Recommend- ed according to HCP competencies	Not licensed Not recommend- ed	Licensed	Licensed
Fobumix Easyhaler 80/4.5*		Dry powder inhaler	Not licensed Not recom- mended	Not licensed Recommend- ed according to HCP competencies	Not licensed Recommend- ed according to HCP competencies	Not licensed Not recommend- ed	Licensed	Licensed
Fobumix Easyhaler 160/4.5		Dry powder inhaler	Not licensed Not recom- mended	Not licensed Not recommended	Not licensed Recommend- ed according to HCP competencies	Licensed	Licensed	Licensed
Symbicort turbohaler 200/6		Dry powder inhaler	Not licensed Not recom- mended	Not licensed Not recommended	Not licensed Not recommended	Licensed	Licensed	Licensed
Duoresp spiromax 160/4.5	in this control of the control of th	Dry powder inhaler	Not licensed Not recom- mended	Not licensed Not recommended	Not licensed Not recommended	Licensed	Licensed	Licensed
WokAir 200/6	The state of the s	Dry powder inhaler	Not licensed Not recom- mended	Not licensed Not recommended	Not licensed Not recommended	Licensed	Licensed	Licensed

The decision to use a device off label must be made in collaboration with the family/young person based on an informed discussion. If licensed options become available, these should be used in preference.

# **MART Emergency Management:**

Any CYP on an AIR or MART regime should have corresponding personalised asthma action plan (PAAP).

This plan should outline the number of doses a CYP can have in the different zones, the maximum dose they can have at any one time and the maximum total dose they can have in a 24-hour period. Patients should be advised to seek an urgent medical review if they are regularly using close to their maximum doses.

If a child/young person in the 'red zone' remains symptomatic having used their max dose of MART at any one time, they should call 999.

If needed, they can repeat their 'maximum set of doses at any one time' whilst waiting for the ambulance to come.

There is no role for the use of SABA in an AIR or MART PAAP. The one exception to this is if the child/young person is in a situation where their MART inhaler is not available (E.g in school) treatment should be with SABA in the conventional way.

If a child/young person on a MART regime has had SABA treatment as part of an emergency hospital admission for an acute exacerbation, they should be transferred back from SABA to their MART regime according to their MART PAAP where possible before discharge so as to allow treatment to be gradually reduced at home according to their MART PAAP/symptoms.

#### **References:**

- 1. Asthma: diagnosis, monitoring and chronic asthma management (BTS/NICE/SIGN) NICE Guideline NG245. https://www.nice.org.uk/guidance/NG245 (2024).
- 2. Global Strategy for Asthma Management and Prevention: GINA Main Report. <a href="https://ginasthma.org/2024-report/">https://ginasthma.org/2024-report/</a> (2024).
- 3. Bisgaard H, Le Roux P, Bjåmer D, Dymek A, Vermeulen JH, Hultquist C. Budesonide/formoterol maintenance plus reliever therapy: a new strategy in pediatric asthma. Chest. 2006 Dec 1;130(6):1733-43.
- 4. Symbicort 100/6 inhalation powder Summary of product characteristics (SmPC) (emc) (medicines.org.uk) Available at: <a href="https://www.medicines.org.uk/emc/product/1326/smpc">https://www.medicines.org.uk/emc/product/1326/smpc</a> [Accessed 24 April 2025]

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