Rescue/reliever inhalers in asthma

Primary Care Respiratory Society (PCRS) position statement

PCRS supports the pharmacological asthma management approaches recommended in the 2024 'Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN)'. The guidelines recommend that clinicians offer inhaled corticosteroids (ICS) to prevent and relieve symptoms in people diagnosed with asthma of all ages, and bronchodilator therapy should not be prescribed without a concomitant prescription of an ICS.

People aged 12 and above who are newly diagnosed with mild asthma with infrequent symptoms should be offered treatment with anti-inflammatory reliever therapy (AIR), a low-dose combination of ICS and formoterol to be taken as needed. In people presenting with frequent symptoms or an asthma exacerbation, low-dose maintenance and reliever therapy (MART) should be offered. For people not controlled on low-dose MART, moderate-dose MART should be offered. Once a person's asthma is better controlled, stepping down to low-dose MART or AIR, as appropriate, should be considered.

For people presenting with highly symptomatic asthma (for example, regular nocturnal waking) or with a severe exacerbation, they should commence treatment with low-dose MART (with or without a course of oral corticosteroids to treat the exacerbation as appropriate).

Children aged 5–11 years old who are newly diagnosed with asthma should be offered twice-daily paediatric low-dose ICS with a reliever inhaler. For children not controlled on this regimen, paediatric low-dose MART should be considered, but only if they are assessed to have the ability to manage a MART regimen.

Children under 5 years old with newly diagnosed or suspected asthma should be offered paediatric low-dose ICS with a reliever inhaler as needed.

Background

2024 marked a pivotal change in the management of asthma in the UK with the publication of a joint British Thoracic Society (BTS), National Institute for Health and Care Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN) guideline. This guideline, 'Asthma: diagnosis, monitoring and chronic asthma management',[1] has the potential to be the paradigm shift that is needed to improve asthma care in the UK. Prior to this guideline, the position for the UK was confusing.

The BTS/SIGN guideline (SIGN 158)[2] was first published in 2003 and last updated in July 2019. This was also the NICE-accredited asthma guideline until the publication of the NICE asthma guide (NG80) in 2017 (last updated March 2021).[3] The guidelines were not fundamentally different in that they all aimed to guide the user towards the correct approach to diagnosis and communicated that asthma treatment aimed to avoid attacks and control symptoms with as little use of rescue therapy as possible. However, they varied in their approach to initial and follow-on therapy as well as the position of maintenance and reliever therapy (MART). PCRS highlighted in 2018 that the two national guidelines were creating confusion for practitioners in primary care because of material differences in diagnosis and management.[4] As a result, PCRS provided a pragmatic guide to diagnosis and management of asthma to provide a clear primary care approach.[5] In relation to the use of short-acting bronchodilators (SABAs) alone, PCRS at that time aligned with the NICE and BTS/SIGN approaches in that, whilst confirmed asthma is likely to require a low-dose ICS, the use of a SABA twice a week or less and in the absence of symptoms was a reasonable initial step in asthma management. In addition, at the time the position of MART was a consideration for adults who have a history of asthma attacks despite regular medium-dose ICS or ICS/LABA (long-acting beta-agonist). This followed the BTS/SIGN evidence review and recommendation.

In 2019 the Global Initiative for Asthma (GINA) recommended a fundamental change in asthma management, recommending that treatment of asthma with SABA alone was no longer recommended for adults and adolescents.[6] GINA has published

its strategy in each of the intervening years with the latest in 2024.[7] With an annual update to its strategy, GINA is in the enviable position that it can publish up-to-date guidance informed by progress in evidence about how asthma should be managed.

In 2023 PCRS therefore reviewed the GINA strategy for asthma management and prevention and in spring 2023 updated their asthma resources.[8] These new resources recommended two treatment pathways for people with asthma aged 12 and over and reflected the GINA 2023[9] treatment tracks 1 and 2, where track 1, which uses ICS/formoterol as the preferred reliever throughout, was the preferred pathway and track 2 was the alternative pathway. The age cut-off was set at 12 because of limited evidence of efficacy and safety at the time for children below 12 to follow track 1. However, research is ongoing including UK-based research in children to assess an 'anti-inflammatory reliever' consisting of budesonide and formoterol in a single device,[10] and further studies are ongoing to assess the safety and efficacy of MART in younger children.

In 2019, BTS, SIGN and NICE announced that any future asthma guidance would be jointly developed. The publication was inevitably delayed by the COVID-19 pandemic, but this guideline was eventually published in November 2024. Since the previous iterations of national guidance, the thinking around asthma management has changed to limit the use of SABAs alone, given the risks associated with overreliance on SABA inhalers. The SABINA programme highlighted that overuse of SABAs in asthma is associated with an increased risk of exacerbation and mortality.[11]

Key issues

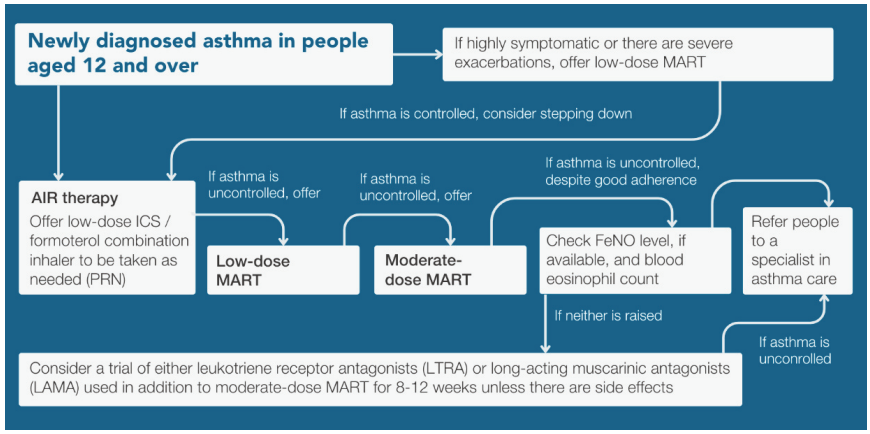
BTS/NICE/SIGN 2024

In the 2024 BTS/NICE/SIGN guideline1 there is a clear statement that says:

"Do not prescribe short-acting beta-agonists to people of any age with asthma without a concomitant prescription for ICS".

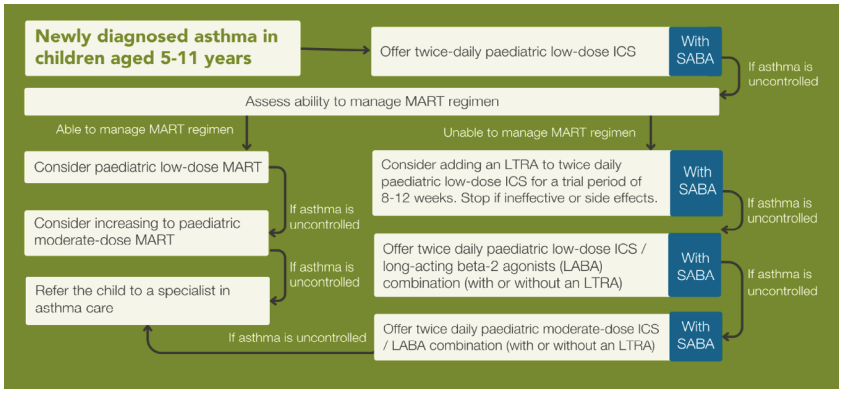
For adults and adolescents aged 12 and over the guidelines now recommend one pathway which is similar to GINA track 1 and recommends a low-dose ICS/formoterol combination inhaler to be taken as needed (AIR therapy) as the first step or low-dose ICS/formoterol as MART for those who are highly symptomatic or exacerbating at presentation. There is no alternative treatment pathway recommended for this age group and therefore no recommendation for treatment regimens using SABA as a rescue/reliever inhaler. The guideline committee highlighted that this decision was due to the clear evidence for exacerbation reduction using strategies where ICS/formoterol is the reliever/rescue inhaler.[1]

The guideline also highlights that any adult or adolescent aged 12 and over currently on a SABA-only regime should be offered AIR therapy and, if they are uncontrolled on their current traditional treatment regime, switching to a MART regime should be considered.



There are now a few branded products with a UK AIR licence from 12 years of age that contain budesonide 200 µg and formoterol 6 µg (not all budesonide/formoterol-containing inhalers have an AIR licence at the time of writing). There is a wider choice of inhalers available for MART therapy with the addition of low-dose extra-fine beclometasone 100 µg/formoterol 6 µg; however, only the budesonide/formoterol-containing inhalers are licensed from 12 years of age. (Always check a product summary of characteristics for specific licensing details https://www.medicines.org.uk/emc)

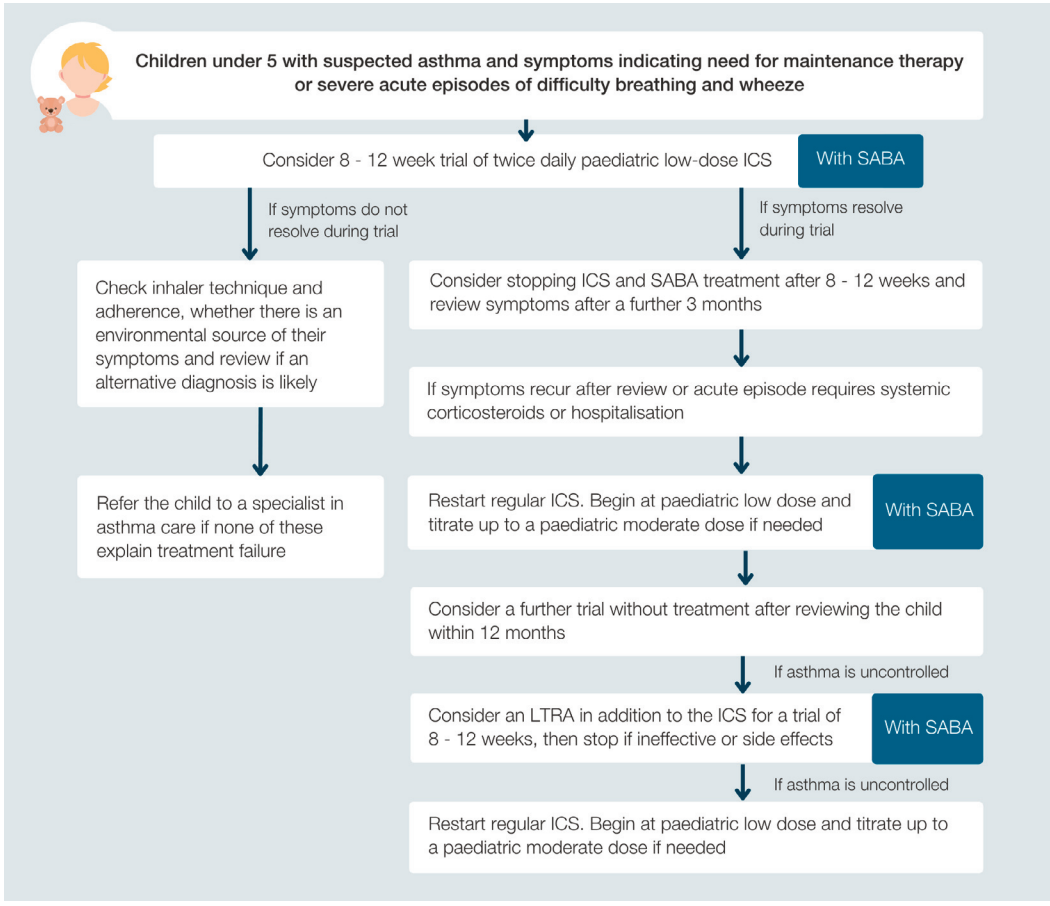
In November 24 PCRS produced a 'First Steps to Implement the New BTS/NICE/SIGN guideline' document[12] to support primary care to implement some of the significant changes seen within the new guideline. The document contains summary algorithms for the management of each age group.



The first step of management for all children aged 5–11 is paediatric low-dose ICS plus SABA as rescue/reliever because the evidence for this was superior to SABA alone and there is no evidence for the use of AIR in this age group.[1] However, if the child remains uncontrolled at this step, the guideline recommends assessing the child's ability to use a MART regime and considering a MART pathway with paediatric low-dose MART. This is a significant change from previous guidance for children in this age group. This decision was based on the evidence from one study of MART in children which showed superiority of MART vs other treatment options.[1] SABA remains the rescue/reliever of choice if the child cannot use a MART regime; however, this must be alongside an ICS-containing controller treatment. At the time of writing there is no licensed paediatric low-dose ICS/formoterol for use as MART in children aged 5–11 in the UK and therefore clinicians must consider the implications of this.

For children under 5 years old with asthma or suspected asthma, there is also no place for the management of asthma with SABA rescue/reliever alone within the 2024 BTS/NICE/SIGN guidance,[1] although SABA is the rescue/reliever inhaler of choice throughout the pathway. Initial treatment with paediatric low-dose ICS with SABA rescue/reliever is recommended because the evidence for ICS-containing treatment options clearly showed greater benefits than those without ICS.[1]

Therefore, as a result of the publication of the 2024 BTS/NICE/SIGN guideline, PCRS wishes to state its position on the use of rescue/reliever inhalers in asthma.



PCRS position

- Bronchodilator therapy alone is not recommended for people with asthma of any age.
- Inhaled corticosteroid (ICS)-containing medication should be prescribed to all people with asthma.
- In adults and adolescents aged 12 and above with mild asthma with infrequent symptoms, initial treatment should be anti-inflammatory reliever therapy (AIR) with an appropriately licensed ICS/formoterol-containing inhaler (where symptoms are infrequent). If a patient presents as highly symptomatic, low-dose maintenance and reliever therapy (MART) should be prescribed.
- Single inhaler therapy is associated with better adherence. Using ICS/formoterol as the preferred rescue/reliever inhaler ensures anti-inflammatory treatment is provided each time bronchodilation is required and is an effective management approach.
- AIR and MART approaches using dry powder inhalers, where appropriate, will support the government's target of achieving a net zero NHS by 2040.
- Asthma care should be individualised by making decisions with the patient. Although PCRS supports the use of AIR and MART, there may be occasional instances where these regimes may be unacceptable to the patient. Consider if an alternative treatment regime may be appropriate for the patient, but this should never be SABA alone.
- Children aged 5–11 should be offered paediatric low-dose ICS as the initial controller therapy with SABA as a rescue/reliever.
- Paediatric low-dose MART should be considered if the child is uncontrolled on paediatric low-dose ICS plus SABA if the child is assessed as able to use a MART regime. At the time of writing this option is off-label and clinicians are reminded to consider the implications of this.
- Children aged under 5 with asthma or suspected asthma should be prescribed a paediatric low-dose ICS as initial controlled therapy with SABA as rescue/reliever.

PCRS would like to thank the National Guideline Committee for their hard work in developing a joint national guidance and would like to highlight the importance of the clarity given within the guideline. PCRS implores Integrated Care Boards to take on the recommendations within the guideline and make available appropriate treatment regimes in local formularies.

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