

Asthma: medicines safety priorities

Key therapeutic topic

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www.nice.org.uk/guidance/ktt5

Key points

- Inhaled corticosteroids (ICS) are the first-choice regular preventer therapy for adults, young people and children with asthma.
- When long-acting beta agonists (LABAs) are prescribed for people with asthma, they should be prescribed with an ICS. LABAs should not be used without ICS.
- Respiratory disease features in the [NHS Long Term Plan](#) published in January 2019.
- **Options for local implementation:**
 - Review all people with asthma who have been prescribed a quantity of more than 12 short-acting reliever inhalers in the previous 12 months.
 - Monitor asthma control at every review. If control is suboptimal: confirm the person's adherence to prescribed treatment, review the person's inhaler technique, review if their treatment needs to be changed and ask about occupational asthma and/or other triggers, if relevant.
 - Adjust the dose of ICS over time, aiming for the lowest dose required for effective asthma control.
 - Consider decreasing maintenance therapy when a person's asthma has been controlled with their current maintenance therapy for at least 3 months.
 - Observe a person's inhaler technique and give advice when there is deterioration in their asthma control, when their inhaler device is changed, at every annual review, if the

- – person asks for it, and at every consultation relating to an asthma attack in all care settings.
- Offer a self-management programme, comprising a written personalised action plan and education to people with asthma.

Evidence context

The NICE guideline on [asthma: diagnosis, monitoring and chronic asthma management](#) was published in November 2017. The recommendations on pharmacological treatment are principally aimed at people whose asthma is newly diagnosed or uncontrolled on their current treatment. Where the recommendations represent a change from clinical practice, people whose asthma is well controlled should not have their treatment changed purely to follow guidance.

The NICE guideline recommends low-dose or paediatric low-dose inhaled corticosteroids (ICS) as first-line maintenance therapy for adults and children aged 5 and over who have asthma that is uncontrolled with a short-acting beta agonist (SABA) alone, or with symptoms at presentation that clearly indicate the need for maintenance therapy. For children aged under 5 years with suspected asthma that is uncontrolled with a SABA alone, or with equivalent symptoms at presentation that clearly indicate the need for maintenance therapy, the guideline recommends that an 8-week trial of a paediatric moderate dose ICS should be considered.

If asthma is uncontrolled with lower ICS doses, the guideline details when to offer or consider a leukotriene receptor antagonist (LTRA), a long-acting beta agonist (LABA), a maintenance and reliever therapy (MART) regimen, or an increase in the dose of ICS. If ICS maintenance therapy is needed, the guideline recommends offering regular daily ICS rather than intermittent or when required ICS therapy. It also advises adjusting the dose of ICS over time, aiming for the lowest dose required for effective asthma control.

Before starting or adjusting medicines, possible reasons for uncontrolled asthma should be considered, such as: alternative diagnoses, lack of adherence, suboptimal inhaler technique, smoking (active or passive), occupational exposures, psychosocial factors, and seasonal or environmental factors.

National review of asthma deaths

The Royal College of Physicians' [National review of asthma deaths](#) (NRAD) looked into the circumstances surrounding deaths from asthma in the UK for a 12-month period from February 2012 to January 2013. Data were available for analysis on 195 people who were thought to have

died from asthma during the review period. The NRAD had several key findings. For prescribing and medicines use, it found evidence of:

- **Excessive prescribing of reliever medication.** From 189 people who were on short-acting relievers at the time of death, the number of prescriptions was known for 165 people, and 65 of these (39%) had been prescribed more than 12 short-acting reliever inhalers in the year before they died, whereas 6 (4%) had been prescribed more than 50 reliever inhalers. Those prescribed more than 12 reliever inhalers were likely to have had poorly controlled asthma.
- **Under-prescribing of preventer medication.** To comply with recommendations, most people would usually need at least 12 preventer prescriptions per year. From 168 people on preventer inhalers at the time of death, either as stand-alone or in combination, the number of prescriptions was known for 128 people, and 49 of these (38%) were known to have been issued with fewer than 4 and 103 (80%) issued with fewer than 12 preventer inhalers in the previous year.
- **Inappropriate prescribing of LABA bronchodilator inhalers.** From available data, 27 (14%) of those who died were prescribed a single-component LABA bronchodilator at the time of death. At least 5 (3%) people were on LABA monotherapy without ICS preventer treatment.

A further study conducted by Asthma UK also found evidence that inhaled LABAs are being prescribed without an ICS and short-acting reliever inhalers are being prescribed excessively in some people with asthma. (See NICE's medicines evidence commentary on [asthma: new review of prescribing data highlights safety concerns](#).)

The Medicines and Healthcare products Regulatory Agency (MHRA) recommends that LABAs should not be used without also taking regular corticosteroids. When used alone, LABAs have been associated with a worsening of asthma (sometimes severe) in some patients. NICE technology appraisal guidance on [inhaled corticosteroids for the treatment of chronic asthma in adults and in children aged 12 years and over](#) recommends a combination inhaler, within its marketing authorisation, as an option if treatment with an ICS and a LABA is considered appropriate.

The [NRAD](#) issued several recommendations. For prescribing and medicines use, these include the following:

- All people with asthma who have been prescribed more than 12 short-acting reliever inhalers in the previous 12 months should be invited for urgent review of their asthma control, with the aim of improving their asthma through education and change of treatment if required.
- An assessment of inhaler technique to ensure effectiveness should be routinely undertaken

- and formally documented at annual review, and also checked by the pharmacist when a new device is dispensed.
- Non-adherence to preventer ICS is associated with increased risk of poor asthma control and should be continually monitored.
- Use of combination inhalers should be encouraged. When LABAs are prescribed for people with asthma, they should be prescribed with an ICS in a single combination inhaler.

The Department of Health policy paper [Community pharmacy in 2016/17 and beyond](#) contains a measure that 'asthma patients dispensed more than 6 short-acting bronchodilator inhalers without any corticosteroid inhaler within a 6-month period are referred to an appropriate healthcare professional for an asthma review'.

Self-management and reviews

The NICE guideline on [asthma: diagnosis, monitoring and chronic asthma management](#) recommends that a self-management programme, comprising a written personalised action plan and education, is offered to adults, young people and children aged 5 and over with a diagnosis of asthma (and their families or carers, if appropriate). This should also be considered for the families or carers of children under 5 with suspected or confirmed asthma. The response to new or adjusted medicines for asthma should be reviewed after 4 to 8 weeks of treatment and, at every review, people should have their asthma control monitored. If control is suboptimal:

- confirm the person's adherence to prescribed treatment in line with the recommendations on assessing adherence in the NICE guideline on [medicines adherence](#)
- review the person's inhaler technique
- review if treatment needs to be changed
- ask about occupational asthma and/or other triggers, if relevant.

Using a validated questionnaire (the Asthma Control Questionnaire or Asthma Control Test) to monitor asthma control in adults (aged 17 and over) should be considered; and the guideline also gives recommendations on the use of spirometry, peak flow variability testing and fractional exhaled nitric oxide (FeNO) measurement.

The person should be observed for inhaler technique and given advice when there is deterioration in their asthma control, when their inhaler device is changed, at every annual review, if the person asks for it, and at every consultation relating to an asthma attack in all care settings.

A systematic review found that around 30% of people using inhalers had 'poor' inhaler technique, and that no appreciable change in this has occurred over the last 40 years. (See NICE's medicines evidence commentary on [inhaler use: has technique improved over time?](#))

In the July 2018 edition of Drug Safety Update, the MHRA issued advice to healthcare professionals about the [risk of airway obstruction from aspiration of loose objects with pressurised metered dose inhalers](#). This followed reports of accidental inhalation of the mouthpiece cover or objects that have become trapped in the inhaler. The advice includes telling people to remove the mouthpiece cover, shake the inhaler to remove loose objects that may not be visible, and check the inside and outside of the mouthpiece are clear before inhaling a dose.

The [annual asthma survey 2018 report](#) from Asthma UK has suggested that 3 out of 5 people with asthma do not receive basic asthma care. This was defined as meeting all of the following 3 standards:

- having an annual asthma review
- a written asthma action plan
- an inhaler technique check with a healthcare professional.

Out of 10,064 people who responded to the survey, 20% did not have an annual asthma review, 52% did not have an asthma action plan, and 19% did not have their inhaler technique checked.

Decreasing maintenance therapy

It is important to ensure that all people with asthma are treated optimally; this includes increasing and decreasing treatment appropriately by moving up and down the different treatment options. To minimise side effects from ICS in particular, the NICE guideline on [asthma: diagnosis, monitoring and chronic asthma management](#) recommends that, decreasing maintenance therapy can be considered when a person's asthma has been controlled with their current maintenance therapy for at least 3 months. This decision should be discussed with the person (or their family or carer, if appropriate) and the potential risks and benefits of decreasing maintenance therapy explained.

When reducing maintenance therapy:

- Stop or reduce the dose of medicines in an order, taking into account the clinical effectiveness when introduced, side effects and the person's preference.
- Only consider stopping ICS treatment completely for people who are using low-dose ICS alone

- as maintenance therapy and are symptom-free.
- Agree with the person (or their family or carer, if appropriate) how the effects of decreasing maintenance therapy will be monitored and reviewed, including self-monitoring and a follow-up with a healthcare professional.
- Review and update the person's asthma action plan when decreasing maintenance therapy.

Prolonged use of high doses of ICS (as with the use of oral corticosteroids) carries a risk of systemic side effects, including adrenal suppression, growth retardation in children and young people, decreased bone mineral density, cataracts, glaucoma, and psychological or behavioural effects. (See the following links for more details: [MHRA 2006](#); [MHRA 2010](#); NICE medicines evidence commentaries [March 2013](#) and [November 2014](#).)

In the [August 2017](#) edition of [Drug Safety Update](#), the MHRA also issued advice on the rare risk of central serous chorioretinopathy with local as well as systemic administration of corticosteroids. The BTS/SIGN guideline on the [management of asthma](#) recommends that reductions in ICS dose should be slow because people deteriorate at different rates. Reductions should be considered every 3 months, decreasing the dose by approximately 25% to 50% each time. Data suggest that this is realistic and possible without compromising patient care (see [Hawkins et al. 2003](#)).

The MHRA advises that corticosteroid treatment cards should be routinely provided for people (or their parents or carers, if appropriate) who need prolonged treatment with high doses of ICS (see the [May 2006](#) edition of [current problems in pharmacovigilance](#) for more information). The London Respiratory Network has produced a [corticosteroid card](#) that is specifically tailored for people who are using high doses of ICS. The Committee on Safety of Medicines has issued warnings about the use of high doses of ICS, particularly in [children](#) and in relation to [fluticasone propionate](#).

The BTS/SIGN guideline on the management of asthma recommends that children prescribed ICS should have their growth monitored annually (although isolated growth failure is not a reliable indicator of adrenal suppression). Two Cochrane reviews, which are discussed in NICE's medicines evidence commentary on [asthma in children and young people: effects of inhaled corticosteroids on growth](#), found that ICS use in children was associated with a reduction in linear growth velocity, and higher doses of ICS were associated with a greater reduction in growth. These findings support the NICE guideline, which recommends using the smallest doses of ICS that provide optimal asthma control, in order to reduce the risk of side effects.

A Scottish retrospective database analysis, reported in NICE's medicines evidence commentary on [ICS dose changes in people with asthma](#), found that initiating combination ICS plus LABA therapy

resulted in widespread increases in ICS dose. The average increase was about 50%, and was substantially greater among people previously on lower ICS doses. This raises questions around the awareness of ICS doses in different preparations, and suggests that an evaluation of the appropriateness of high-dose combination inhaler therapy in primary care is needed.

The NICE Pathway on [asthma](#) brings together all related NICE guidance and associated products in a set of interactive flowcharts. The NICE quality standard on [asthma](#) (updated in 2018) describes concise sets of prioritised statements designed to drive measurable quality improvements within these areas.

Practice examples and shared learning

There are several NICE [shared learning case studies](#) relating to asthma, showing how NICE guidance and standards have been put into practice by some NHS organisations:

- [Modern innovative solutions improving outcomes in asthma breathlessness and COPD \(MISSION ABC\)](#).
- [Impact of a pharmacist-led asthma and COPD respiratory clinic in general practice](#).
- [Integrated 24-hour children and young people's asthma service: reducing unnecessary hospital attendance](#).

Prescribing data, metrics or supporting resources

At this point, the following metrics have been identified to support this topic.

Several respiratory metrics related to this key therapeutic topic are included in the NHS England [medicines optimisation dashboard](#), which brings together a range of medicines-related metrics from across sectors. These include:

- Asthma (AST003) % achieving upper threshold or above, which is the percentage of practices in a clinical commissioning group (CCG) that achieve upper threshold or above (70% or more, inclusive of exceptions) for quality and outcomes framework (QOF) indicator AST003.
- Asthma (AST003) % underlying achievement, which is the percentage underlying achievement at CCG level for QOF indicator AST003, inclusive of exceptions.
- Emergency asthma admissions, which is the number of emergency attendances for asthma per 100 patients on the practice asthma disease register.

Update information

September 2019: This topic was retained for the 2019 rapid update of medicines optimisation: key therapeutic topics. Minor editorial changes have been completed but no new content has been added.

About this key therapeutic topic

This document summarises the evidence base on this key therapeutic topic that has been identified to support medicines optimisation. **It is not formal NICE guidance.**

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