







NICE guideline

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# Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

# **Contents**

Overview	5
Who is it for?	6
Recommendations	7
1.1 Initial clinical assessment	9
1.2 Objective tests for diagnosing asthma in adults, young people and children aged 5 to 16 with a history suggestive of asthma	10
1.3 Diagnosing asthma in children under 5	14
1.4 Diagnosing occupational asthma	14
1.5 Monitoring asthma control	15
1.6 Principles of pharmacological treatment	16
1.7 Pharmacological management in people aged 12 and over	19
1.8 Pharmacological management in children aged 5 to 11	22
1.9 Pharmacological management in children under 5	25
1.10 Decreasing maintenance therapy	27
1.11 Adherence	27
1.12 Asthma in pregnancy and breastfeeding	28
1.13 Asthma in adolescents	29
1.14 Self-management	29
1.15 Risk-stratified care	31
1.16 Organisation and delivery of care	32
Terms used in this guideline	32
Recommendations for research	37
Key recommendations for research	37
Other recommendations for research	41
Rationale and impact	42
Objective tests for diagnosing asthma in adults, young people and children aged 5 to 16 with history suggestive of asthma	
Monitoring asthma control	47

	Principles of pharmacological treatment	50
	Digital inhalers	50
	Medicines for the initial management of newly diagnosed asthma in people aged 12 and over	51
	Medicine combination and sequencing in people aged 12 and over	52
	Transferring people aged 12 and over from other treatment pathways	55
	Medicines for initial management in children aged 5 to 11	55
	Medicine combination and sequencing in children aged 5 to 11	56
	Pharmacological management in children under 5	58
	Self-management	59
	Risk-stratified care	60
C	Context	62
F	inding more information and committee details	.63
l	Jodate information	64

This guideline replaces NG80.

This guideline is the basis of QS181 and QS25.

This guideline should be read in conjunction with NG244.

# Overview

This guideline covers diagnosing, monitoring and managing asthma in adults, young people and children. It aims to improve the accuracy of diagnosis, help people to control their asthma and reduce the risk of asthma attacks. It does not cover managing severe asthma or acute asthma attacks.

Last reviewed: 27 November 2024

This is a new collaborative guideline developed jointly by the British Thoracic Society (BTS), National Institute for Health and Care Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN).

It updates and replaces NICE guideline 80 (published November 2017) and parts of BTS/SIGN British guideline SIGN 158 (published July 2019). It also updates and replaces NICE technology appraisal guidance 10, 38,131 and 138, and NICE diagnostics guidance 12.

We reviewed the evidence and made new or updated recommendations on diagnosis, treatment and monitoring. We also updated some recommendations without an evidence review. For full details see update information.

**Next review:** This guidance will be reviewed if there is new evidence that is likely to change the recommendations.

BTS, NICE and SIGN have developed an asthma pathway, which brings together recommendations on diagnosing, monitoring and managing asthma in adults, young people and children. It aims to improve the accuracy of diagnosis, help people to control their asthma and reduce the risk of asthma attacks. It also covers managing difficult and severe asthma and acute asthma attacks.

# Who is it for?

- Healthcare professionals in primary care and the community, secondary care and tertiary asthma services
- · Commissioners and providers
- People with suspected or diagnosed asthma, their families and carers

# Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>NICE's information on making decisions about your</u> care. Information about decision making is also available from Realistic medicine.

<u>Making decisions using NICE guidelines</u> and <u>Using SIGN guidelines</u> explains how we use words to show the strength (or certainty) of our recommendations, information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

In this guideline, the NHS refers to NHS England and NHS Scotland unless stated otherwise. The recommendations are for all age groups unless indicated otherwise in the heading of the guideline section.

Health professionals should follow these NICE guidelines for people delivering care:

- Shared decision making
- Medicines adherence
- Multimorbidity.

In addition, health professionals in England should follow these NICE guidelines for people delivering care:

- Medicines optimisation
- Patient experience in adult NHS services
- Babies, children and young people's experience of healthcare
- Decision making and mental capacity

In addition, health professionals in Scotland should follow Scottish Government guidance for people delivering care:

- Realistic Medicine
- Health and social care standards

- Mental health legislation and guidance
- Getting it right for every child.

# 1.1 Initial clinical assessment

# Clinical history

- 1.1.1 Obtain a structured clinical history in people with suspected asthma. Specifically, check for:
  - reported wheeze, noisy breathing, cough, breathlessness or chest tightness, and any variation (for example, worse during the night or early morning, or seasonal) in these symptoms
  - any triggers that make symptoms worse
  - a personal or family history of asthma or allergic rhinitis
  - symptoms to suggest alternative diagnoses (see the <u>tables on alternative</u> <u>diagnoses in wheezy children</u> and <u>alternative diagnoses in adults in the BTS/SIGN British guideline on the management of asthma SIGN 158.</u>) [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- Do not confirm a diagnosis of asthma without a suggestive clinical history and a supporting objective test. Code as suspected asthma until the diagnosis is confirmed. [NICE 2017, amended BTS/NICE/SIGN 2024]
- 1.1.3 If the diagnosis of asthma is confirmed, record the basis for this in the person's medical records, alongside the coded diagnostic entry. [NICE 2017, amended BTS/NICE/SIGN 2024]

# Physical examination

1.1.4 Examine people with suspected asthma to identify expiratory polyphonic wheeze and signs of other causes of respiratory symptoms but be aware that even if examination results are normal, the person may still have asthma. [NICE 2017]

# Initial treatment and objective tests for acute symptoms at presentation

- 1.1.5 Treat people immediately if they are acutely unwell or highly symptomatic at presentation, and perform objective tests that may help support a diagnosis of asthma (for example, <a href="eosinophil count">eosinophil count</a>, fractional exhaled nitric oxide [FeNO], spirometry or <a href="peak expiratory flow">peak expiratory flow</a> [PEF] before and after bronchodilator) if the equipment is available. [NICE 2017, amended BTS/NICE/SIGN 2024]
- 1.1.6 If objective tests for asthma cannot be done immediately for people who are acutely unwell or highly symptomatic at presentation, carry them out when acute symptoms have been controlled, and advise people to contact their healthcare professional immediately if they become unwell while waiting to have objective tests. [NICE 2017, amended BTS/NICE/SIGN 2024]
- 1.1.7 Be aware that the results of spirometry and <u>FeNO tests</u> may be affected in people who have been treated with inhaled corticosteroids (the test results are more likely to be normal). [NICE 2017]

# 1.2 Objective tests for diagnosing asthma in adults, young people and children aged 5 to 16 with a history suggestive of asthma

### **Adults**

See also <u>algorithm A for a summary of objective tests for diagnosing asthma in adults and</u> young people (aged over 16 years) with a history suggesting asthma.

- 1.2.1 Measure the blood <u>eosinophil count</u> or fractional exhaled nitric oxide (FeNO) level in adults with a history suggestive of asthma. Diagnose asthma if the eosinophil count is above the laboratory reference range or the FeNO level is 50 ppb or more. [BTS/NICE/SIGN 2024]
- 1.2.2 If asthma is not confirmed by eosinophil count or FeNO level, measure bronchodilator reversibility (BDR) with spirometry. Diagnose asthma if the FEV<sub>1</sub> increase is 12% or more and 200 ml or more from the pre-bronchodilator measurement (or if the FEV<sub>1</sub> increase is 10% or more of the predicted normal FEV<sub>1</sub>). [BTS/NICE/SIGN 2024]
- 1.2.3 If spirometry is not available or it is delayed, measure <u>peak expiratory flow</u> (PEF) twice daily for 2 weeks. Diagnose asthma if PEF variability (expressed as amplitude percentage mean) is 20% or more. **[BTS/NICE/SIGN 2024]**
- 1.2.4 If asthma is not confirmed by eosinophil count, FeNO, BDR or PEF variability but still suspected on clinical grounds, refer for consideration of a <u>bronchial challenge</u> <u>test</u>. Diagnose asthma if <u>bronchial hyper-responsiveness</u> is present. [BTS/NICE/SIGN 2024]

# Children aged 5 to 16

See also algorithm B for a summary of objective tests for diagnosing asthma in children aged 5 to 16 with a history suggesting asthma.

- 1.2.5 Measure the FeNO level in children with a history suggestive of asthma. Diagnose asthma if the FeNO level is 35 ppb or more. [BTS/NICE/SIGN 2024]
- 1.2.6 If the FeNO level is not raised, or if FeNO testing is not available, measure BDR with spirometry. Diagnose asthma if the FEV<sub>1</sub> increase is 12% or more from baseline (or if the FEV<sub>1</sub> increase is 10% or more of the predicted normal FEV<sub>1</sub>).

  [BTS/NICE/SIGN 2024]
- 1.2.7 If spirometry is not available or it is delayed, measure PEF twice daily for 2 weeks. Diagnose asthma if PEF variability (expressed as amplitude percentage mean) is 20% or more. [BTS/NICE/SIGN 2024]

- 1.2.8 If asthma is not confirmed by FeNO, BDR or PEF variability but still suspected on clinical grounds, either perform skin prick testing to house dust mite or measure total IqE level and blood eosinophil count.
  - Exclude asthma if there is no evidence of sensitisation to house dust mite on skin prick testing or if the total serum IgE is not raised.
  - Diagnose asthma if there is evidence of sensitisation or a raised total IgE level and the eosinophil count is more than 0.5 x 10<sup>9</sup> per litre. [BTS/NICE/SIGN 2024]
- 1.2.9 If there is still doubt about the diagnosis, refer to a paediatric specialist for a second opinion, including consideration of a bronchial challenge test. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on objective tests for diagnosing asthma in adults, young people and children aged 5 to 16 with a history suggestive of asthma.</u>

Full details of the evidence and the committee's discussion are in:

- evidence review A: diagnostic test accuracy of spirometry in people suspected of asthma
- evidence review B: diagnostic test accuracy for bronchodilator reversibility in people suspected of asthma
- evidence review C: diagnostic test accuracy of peak expiratory flow variability for the diagnosis of asthma
- evidence review D: accuracy of skin prick test in children for the diagnosis of asthma
- evidence review E: diagnostic test accuracy of IgE in children
- evidence review F: diagnostic accuracy of fractional exhaled nitric oxide (FeNO) measures
- evidence review G: diagnostic accuracy of eosinophil blood count measures in the diagnosis of asthma
- evidence review H: bronchial challenge with histamine and methacholine for the diagnosis of asthma
- evidence review I: bronchial challenge test with mannitol
- <u>evidence review J: bronchial challenge testing in response to exercise for the</u> diagnosis of asthma
- evidence review K: diagnostic accuracy of combination of tests.

# 1.3 Diagnosing asthma in children under 5

Diagnosis is hard in this age group because it is difficult to do the tests and there are no good reference standards.

- 1.3.1 For children under 5 with suspected asthma, treat with inhaled corticosteroids in line with the <u>recommendations on medicines for initial management in children under 5</u>, and review the child on a regular basis. If they still have symptoms when they reach 5 years, attempt objective tests (see the <u>section on objective tests for diagnosing asthma in adults, young people and children aged 5 to 16</u>). [NICE 2017]
- 1.3.2 If a child is unable to perform objective tests when they are aged 5:
  - try doing the tests again every 6 to 12 months until satisfactory results are obtained
  - refer for specialist assessment if the child's asthma is not responding to treatment. [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.3.3 Refer to a specialist respiratory paediatrician any preschool child with an admission to hospital, or 2 or more admissions to an emergency department, with wheeze in a 12-month period. [BTS/NICE/SIGN 2024]

# 1.4 Diagnosing occupational asthma

See the BTS clinical statement on occupational asthma.

- 1.4.1 In people with adult-onset asthma, poorly controlled established asthma, or reappearance of childhood asthma, check for a possible occupational component by asking:
  - Are symptoms the same, better or worse on days away from work?
  - Are symptoms the same, better or worse when on holiday (time away from work, longer than usual breaks, at weekends or between shifts)?

Make sure all answers are recorded for later review. [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]

1.4.2 Refer people with suspected occupational asthma to an occupational asthma specialist. [NICE 2017]

# 1.5 Monitoring asthma control

- 1.5.1 Monitor <u>asthma control</u> at every review. In addition to asking about symptoms, check:
  - · time off work or school due to asthma
  - amount of reliever inhaler used, including a check of the prescription record
  - number of courses of oral corticosteroids
  - any admissions to hospital or attendance at an emergency department due to asthma.

If control is suboptimal, see <u>recommendation 1.6.1 in the section on principles</u> <u>of pharmacological treatment</u>. **[BTS/NICE/SIGN 2024]** 

- 1.5.2 Consider using a validated symptom questionnaire (for example, the Asthma Control Questionnaire, the Asthma Control Test or the Childhood Asthma Control Test) at any asthma review. [BTS/NICE/SIGN 2024]
- 1.5.3 Do not use regular peak expiratory flow (PEF) monitoring to assess asthma control unless there are person-specific reasons for doing so (for example, when PEF measurement is part of the personalised asthma action plan). [BTS/NICE/SIGN 2024]
- 1.5.4 Consider fractional exhaled nitric oxide (FeNO) monitoring for adults with asthma:
  - at their regular review, and
  - before and after changing their asthma therapy. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on monitoring asthma</u> control.

Full details of the evidence and the committee's discussion are in:

- evidence review L: symptom diary for monitoring asthma
- evidence review M: pulmonary function monitoring in asthma
- evidence review N: FeNO measures to monitor asthma.

# 1.6 Principles of pharmacological treatment

Licensed indications for asthma inhalers vary between different medicines, different doses and different devices. Not all asthma inhalers are licensed for use in line with the recommendations in this guideline. See <a href="NICE's information on prescribing medicines">NICE's information on prescribing medicines</a> or <a href="SIGN's information on prescribing licensed medicines out with their marketing authorisation">NICE's information on prescribing licensed medicines out with their marketing authorisation</a> and refer to the summary of product characteristics for individual products.

- 1.6.1 Take into account and try to address the possible reasons for <u>uncontrolled</u>

  <u>asthma</u> before starting or adjusting medicines for asthma in adults, young people and children. These may include:
  - alternative diagnoses or comorbidities
  - suboptimal adherence (see the recommendation on adherence)
  - suboptimal inhaler technique
  - smoking (active or passive), including vaping using e-cigarettes
  - occupational exposures (see the <u>recommendation on checking for possible</u> <u>occupational asthma</u>).
  - psychosocial factors (for example, anxiety and depression, relationships and social networks)

- seasonal factors
- environmental factors (for example, air pollution, indoor mould exposure).
   [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- If possible, check the fractional exhaled nitric oxide (FeNO) level when asthma is uncontrolled. If it is raised this may indicate poor adherence to treatment or the need for an increased dose of inhaled corticosteroid (ICS). [BTS/NICE/SIGN 2024]
- Do not prescribe short-acting beta<sub>2</sub> agonists to people of any age with asthma without a concomitant prescription of an ICS. [BTS/NICE/SIGN 2024]
- 1.6.4 After starting or adjusting medicines for asthma, review the response to treatment in 8 to 12 weeks (see the recommendations on monitoring asthma control). [NICE 2017, amended BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these 2024 recommendations and how they might affect practice, see the <u>rationale and impact section on principles</u> of pharmacological treatment.

Full details of the evidence and the committee's discussion are in <u>evidence review P:</u> drug classes for initial asthma management.

#### **Inhalers**

- 1.6.5 Base the choice of inhaler(s) for asthma on:
  - an assessment of correct technique
  - the preference of the person receiving the treatment
  - the lowest environmental impact among suitable devices
  - the presence of an integral dose counter.

A spacer should usually be prescribed for use with a metered dose inhaler,

particularly in children. See the <u>patient decision aid on asthma inhalers and</u> climate change. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]

- 1.6.6 Give people with asthma information on their inhaler treatments. This should include the medicines they contain, how they work, when they should be taken and the correct technique to use for each device. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.6.7 Observe the person using their inhaler device (and spacer if used) to check they can use it properly:
  - at every asthma review, either routine or unscheduled
  - at every asthma-related consultation
  - when there is deterioration in asthma control
  - when the inhaler device is changed
  - when the person asks for it to be checked or changed.

If the person is assessed as being unable to use a device properly, find an alternative. [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]

- 1.6.8 If possible, prescribe the same type of device to deliver preventer and reliever treatments where more than one inhaler is needed. Consider providing an additional metered dose short-acting beta<sub>2</sub> agonist (SABA) inhaler plus spacer for emergency use for children under 12 years who may be unable to activate a dry powder inhaler during an acute asthma attack. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.6.9 Encourage people to take their used or expired inhalers to their pharmacy for disposal. [BTS/SIGN 2019]

# Digital inhalers

1.6.10 Digital inhalers are not recommended for routine use in people with asthma.

#### [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this 2024 recommendation and how it might affect practice, see the rationale and impact section on digital inhalers.

Full details of the evidence and the committee's discussion are in <u>evidence review R:</u> smart inhalers.

# 1.7 Pharmacological management in people aged 12 and over

See also <u>algorithm C for a summary of the pharmacological management of asthma in</u> people aged 12 years and over.

# Initial management of newly diagnosed asthma in people aged 12 and over

1.7.1 Offer a low-dose inhaled corticosteroid (ICS)/formoterol combination inhaler to be taken as needed for symptom relief (as-needed <u>AIR therapy</u>) to people aged 12 and over with newly diagnosed asthma. [BTS/NICE/SIGN 2024]

In November 2024, only certain budesonide/formoterol inhalers were licensed for as-needed AIR therapy in mild asthma. The use of any other ICS/formoterol inhalers would therefore be off-label. The current evidence supporting the use of budesonide/formoterol is based on the use of a dry powder inhaler. See <a href="NICE's information on prescribing medicines">NICE's information on prescribing medicines</a> or <a href="SIGN's information on prescribing licensed medicines out with their marketing authorisation">NICE's information on prescribing licensed medicines out with their marketing authorisation</a>.

1.7.2 If the person needing asthma treatment presents highly symptomatic (for example, regular nocturnal waking) or with a severe exacerbation, start treatment with low-dose MART (<u>maintenance and reliever therapy</u>) in addition to treating the acute symptoms as indicated (that is, a course of oral corticosteroids may be needed). Consider stepping down to as-needed AIR therapy using a low-dose ICS/formoterol inhaler at a later date if their asthma is controlled. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on medicines for the</u> initial management of newly diagnosed asthma in people aged 12 and over.

Full details of the evidence and the committee's discussion are in <u>evidence review P:</u> drug classes for initial asthma management.

# Medicine combination and sequencing in people aged 12 and over

For guidance on dose ranges of inhaled corticosteroids see <u>inhaled corticosteroid doses</u> for the BTS, NICE and SIGN asthma guideline.

- 1.7.3 Offer low-dose MART to people aged 12 and over with asthma that is not controlled on a low-dose ICS/formoterol combination inhaler used only as needed. [BTS/NICE/SIGN 2024]
- 1.7.4 Offer moderate-dose MART to people aged 12 and over with asthma that is not controlled on low-dose MART. [BTS/NICE/SIGN 2024]
- 1.7.5 For people aged 12 and over with asthma that is not controlled on moderate-dose MART despite good adherence:
  - Check the fractional exhaled nitric oxide (FeNO) level if available, and the blood <u>eosinophil count</u>. If either of these is raised, refer to a <u>specialist in</u> asthma care.
  - If neither FeNO or eosinophil count is raised, consider a trial of either a
     leukotriene receptor antagonist (LTRA) or a long-acting muscarinic receptor
     antagonist (LAMA) used in addition to moderate-dose MART. Give the
     medicine for a trial period of 8 to 12 weeks unless there are side effects. At
     the end of the trial:
    - if asthma is controlled, continue the treatment
    - if control has improved but is still inadequate, continue the treatment and start a trial of the other medicine (LTRA or LAMA)

• if control has not improved, stop the LTRA or LAMA and start a trial of the alternative medicine (LTRA or LAMA). [BTS/NICE/SIGN 2024]

November 2024: Follow the MHRA safety advice on the risk of neuropsychiatric reactions in people taking montelukast.

1.7.6 Refer people to a specialist in asthma care when asthma is not controlled despite treatment with moderate-dose MART, and trials of an LTRA and a LAMA. (See the Accelerated Access Collaborative consensus pathway on the management of uncontrolled asthma in adults.) [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on medicine</u> combination and sequencing in people aged 12 and over.

Full details of the evidence and the committee's discussion are in <u>evidence review Q</u>: drug combinations and sequencing for asthma management.

# Transferring people aged 12 and over from other treatment pathways

These recommendations are for people with <u>uncontrolled asthma</u> who are on the treatment pathway recommended by previous NICE and BTS/SIGN guidelines.

- 1.7.7 Change treatment for people with confirmed asthma who are currently using a short-acting beta<sub>2</sub> agonist (SABA) only to a low-dose ICS/formoterol combination inhaler used as needed (as-needed AIR therapy). [BTS/NICE/SIGN 2024]
- 1.7.8 Consider changing treatment to low-dose MART for people with asthma that is not controlled on:
  - regular low-dose ICS plus SABA as needed
  - regular low-dose ICS/LABA (<u>long-acting beta<sub>2</sub> agonist</u>) combination inhaler plus SABA as needed

- regular low-dose ICS and supplementary therapy (LTRA) plus SABA as needed.
- regular low-dose ICS/LABA combination inhaler and supplementary therapy (LTRA) plus SABA as needed. [BTS/NICE/SIGN 2024]
- 1.7.9 Consider changing treatment to moderate-dose MART for people with asthma that is not controlled on:
  - regular moderate-dose ICS plus SABA as needed
  - regular moderate-dose ICS/LABA combination inhaler plus SABA as needed
  - regular moderate-dose ICS and supplementary therapy (LTRA or LAMA, or both) plus SABA as needed
  - regular moderate-dose ICS/LABA combination inhaler and supplementary therapy (LTRA or LAMA, or both) plus SABA as needed. [BTS/NICE/SIGN 2024]
- 1.7.10 When changing from low- or moderate-dose ICS (or ICS/LABA combination inhaler) plus supplementary therapy to MART, consider whether to stop or continue the supplementary therapy based on the degree of benefit achieved when first introduced. [BTS/NICE/SIGN 2024]
- 1.7.11 Refer people with asthma that is not controlled on treatment containing a high dose of ICS to a specialist in asthma care. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on transferring people</u> aged 12 and over from other treatment pathways.

Full details of the evidence and the committee's discussion are in <u>evidence review P:</u> <u>drug classes for initial asthma management and evidence review Q: drug</u> combinations and sequencing for asthma management.

# 1.8 Pharmacological management in children aged 5

### to 11

For guidance on doses on inhaled corticosteroids see <u>inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline</u>.

See also algorithm D for a summary of the pharmacological management of asthma in children aged 5 to 11 years.

# Initial management in children aged 5 to 11

Offer a twice-daily paediatric low-dose inhaled corticosteroid (ICS), with a short-acting beta<sub>2</sub> agonist (SABA) as needed, as initial treatment for children aged 5 to 11 years with newly diagnosed asthma. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this recommendation and how it might affect practice, see the <u>rationale and impact section on medicines for initial management in children aged 5 to 11</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review P:</u> drug classes for initial asthma management.

### Medicine combination and sequencing in children aged 5 to 11

### **MART** pathway

1.8.2 Consider paediatric low-dose MART (<u>maintenance and reliever therapy</u>) for children with asthma that is not controlled on paediatric low-dose ICS plus SABA as needed, as long as they are assessed to have the ability to manage a MART regimen. [BTS/NICE/SIGN 2024]

In November 2024, no asthma inhalers were licensed for MART in children under 12, so this use would be off-label. The current evidence supporting the use of MART in children aged 5 to 11 is based on the use of a dry powder inhaler. See <a href="NICE's information on prescribing medicines">NICE's information on prescribing medicines</a> or <a href="SIGN's information on prescribing licensed medicines">SIGN's information on prescribing licensed medicines</a> outwith their marketing authorisation.

1.8.3 Consider increasing to paediatric moderate-dose MART if asthma is not controlled on paediatric low-dose MART. [BTS/NICE/SIGN 2024]

#### **Conventional pathway**

- 1.8.4 Consider adding a <u>leukotriene receptor antagonist</u> (LTRA) to twice daily paediatric low-dose ICS plus SABA as needed when a child has <u>uncontrolled asthma</u> and is assessed as unable to manage the MART regimen. Give the LTRA for a trial period of 8 to 12 weeks (unless there are side effects), then stop it if it is ineffective. [BTS/NICE/SIGN 2024]
  - November 2024: Follow the MHRA safety advice on the risk of neuropsychiatric reactions in people taking montelukast.
- 1.8.5 Offer a twice daily paediatric low-dose ICS/LABA (long-acting beta<sub>2</sub> agonist) combination inhaler plus SABA as needed to children assessed as unable to manage the MART regimen if their asthma is not controlled on paediatric low-dose ICS plus SABA as needed (with or without an LTRA depending on previous response). [BTS/NICE/SIGN 2024]
- 1.8.6 Offer a twice daily paediatric moderate-dose ICS/LABA inhaler plus SABA as needed to children with asthma that is not controlled on paediatric low-dose ICS/LABA plus SABA as needed (with or without an LTRA depending on previous response). [BTS/NICE/SIGN 2024]

#### All children aged 5 to 11

1.8.7 Refer children to a <u>specialist in asthma care</u> if their asthma is not controlled on paediatric moderate-dose MART or paediatric moderate-dose ICS/LABA maintenance treatment (with or without an LTRA, depending on previous response). [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on medicine</u> combination and sequencing in children aged 5 to 11.

Full details of the evidence and the committee's discussion are in <u>evidence review Q:</u> drug combinations and sequencing for asthma management.

# 1.9 Pharmacological management in children under 5

These recommendations are for children under 5 with newly suspected or confirmed asthma, or with asthma symptoms that are uncontrolled on their current treatment.

See also <u>algorithm E for a summary of the pharmacological management of asthma in</u> children under 5.

- 1.9.1 Consider an 8 to12 week trial of twice-daily paediatric low-dose inhaled corticosteroid (ICS) as maintenance therapy (with a short-acting beta<sub>2</sub> agonist [SABA] for reliever therapy) in children under 5 with suspected asthma and:
  - symptoms at presentation that indicate the need for maintenance therapy (for example, interval symptoms in children with another <u>atopic disorder</u>), or
  - severe acute episodes of difficulty breathing and wheeze (for example, requiring hospital admission, or needing 2 or more courses of oral corticosteroids). [BTS/NICE/SIGN 2024]
- 1.9.2 If symptoms do not resolve during the trial period, take the following sequential steps:
  - check inhaler technique and adherence
  - check whether there is an environmental source of their symptoms (for example mould in the home, cold housing, smokers or indoor air pollution)
  - review whether an alternative diagnosis is likely.

If none of these explain the failure to respond to treatment, refer the child to a specialist in asthma care. [BTS/NICE/SIGN 2024]

- 1.9.3 Consider stopping ICS and SABA treatment after 8 to 12 weeks if symptoms are resolved. Review the symptoms after a further 3 months. [BTS/NICE/SIGN 2024]
- 1.9.4 If symptoms resolve during the trial period, but then:
  - symptoms recur by the 3-month review, or
  - the child has an acute episode requiring systemic corticosteroids or hospitalisation, restart regular ICS (begin at a paediatric low dose and titrate up to a paediatric moderate dose if needed) with SABA as needed and consider a further trial without treatment after reviewing the child within 12 months. [BTS/NICE/SIGN 2024]
- 1.9.5 If suspected asthma is uncontrolled in children under 5 on a paediatric moderate dose of ICS as maintenance therapy (with SABA as needed), consider a <a href="Leukotriene receptor antagonist">Leukotriene receptor antagonist</a> (LTRA) in addition to the ICS. Give the LTRA for a trial period of 8 to 12 weeks (unless there are side effects), then stop it if it is ineffective. [BTS/NICE/SIGN 2024]

November 2024: Follow the MHRA safety advice on the risk of neuropsychiatric reactions in people taking montelukast.

1.9.6 If suspected asthma is uncontrolled in children under 5 on a paediatric moderate dose of ICS as maintenance therapy and a trial of an LTRA has been unsuccessful or not tolerated, stop the LTRA and refer the child to a specialist in asthma care for further investigation and management. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on pharmacological</u> management in children under 5.

Full details of the evidence and the committee's discussion are in <u>evidence review P:</u> drug classes for initial asthma management.

# 1.10 Decreasing maintenance therapy

- 1.10.1 At annual review discuss with the person with asthma (or their family or carer, if appropriate) the potential risks and benefits of decreasing their maintenance therapy when their asthma has been well controlled on their current maintenance therapy. [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.10.2 When decreasing maintenance therapy:
  - Stop or reduce dose of medicines in an order that takes into account the clinical effectiveness when introduced, side effects and the person's preference.
  - Allow at least 8 to 12 weeks before considering a further treatment reduction.
  - If considering step-down treatment for people aged 12 and over who are using low-dose maintenance inhaled corticosteroid (ICS) plus a short-acting beta<sub>2</sub> agonist (SABA) as needed or low-dose MART (<u>maintenance and reliever therapy</u>), step down to low-dose ICS/formoterol combination inhaler as needed (as-needed <u>AIR therapy</u>). [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.10.3 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 follow-up with a healthcare professional. [NICE 2017]
- 1.10.4 Review and update the person's asthma action plan when decreasing maintenance therapy. [NICE 2017]

# 1.11 Adherence

1.11.1 Check adherence, using prescription records, and inhaler technique at every asthma-related healthcare review. Use the principles outlined in the NICE guidelines on shared decision making (endorsed by SIGN for use in Scotland) and medicines adherence. [NICE 2017, BTS/SIGN 2019]

# 1.12 Asthma in pregnancy and breastfeeding

For recommendations on intrapartum care, see the <u>NICE guideline on intrapartum care for</u> women with existing medical conditions or obstetric complications and their babies.

### **Pregnancy**

- People with asthma should have an asthma review during early pregnancy and in the postpartum period. Emphasise the importance and safety of maintaining good control of asthma during pregnancy and of continuing asthma medicines to avoid problems for themselves and their baby. [BTS/SIGN 2019]
- 1.12.2 Advise anyone who is pregnant and who smokes about the dangers for themselves and their babies and give appropriate support to stop smoking. See the NICE guideline on tobacco for more information. [BTS/SIGN 2019]
- 1.12.3 Advise using the following medicines as normal during pregnancy:
  - short-acting and long-acting beta<sub>2</sub> agonists
  - inhaled corticosteroids
  - oral theophyllines. [BTS/SIGN 2019]
- Offer oral corticosteroids during pregnancy if needed to treat exacerbations of asthma. Advise that the benefits of treatment with oral corticosteroids outweigh the risks. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.12.5 If leukotriene receptor antagonists or long-acting muscarinic receptor antagonists are needed to achieve asthma control, they should not be stopped during pregnancy. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]

### **Breastfeeding**

Use medicines as normal when breastfeeding in line with <u>recommendations in the</u> BNF. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]

# 1.13 Asthma in adolescents

For guidance on transitioning to adult services, see the <u>NICE guideline on transition from children's to adults' services for young people using health or social care services and the Scottish Parliament Information Centre briefing on transitions of young people with service and care needs between child and adult services in Scotland.</u>

- Discuss future career choices with adolescents with asthma and highlight occupations that might increase susceptibility to work-related asthma symptoms.

  [BTS/SIGN 2019]
- 1.13.2 Ask adolescents with asthma if they vape or smoke and encourage them to stop. If they smoke, give them advice and signpost them to local NHS stop smoking services. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.13.3 Ask about factors that may affect a person's use of their inhaler device in real life settings, such as school and social situations. [BTS/SIGN 2019]

# 1.14 Self-management

- 1.14.1 For adults, young people and children aged 5 and over with a diagnosis of asthma (and their families or carers, if appropriate):
  - Offer an asthma self-management programme, comprising a documented personalised action plan and education. In adults, they may be based on symptoms or peak expiratory flow (or both); symptom-based plans are usually preferred for children.
  - Explain that there are things that can trigger asthma symptoms and exacerbations, including indoor and outdoor pollution. Include in the personalised action plan approaches for minimising exposure to air pollution and any other personal triggers. For more guidance on how to minimise exposure and the effect of air pollution on health, see the recommendations on:
    - vulnerable groups in the <u>NICE guideline on air pollution: outdoor air</u> quality and health

- people with asthma, other respiratory conditions or cardiovascular conditions in the NICE guideline on indoor air quality at home, and
- smoking in the <u>NICE guideline on tobacco</u>. [NICE 2017, amended 2021; BTS/ SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.14.2 Review the content of the personalised action plan, and check that the person understands it, at the following:
  - hospital admission, including in virtual wards
  - acute consultations in primary care or emergency department
  - annual reviews. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.14.3 Consider an asthma self-management programme, comprising a written personalised action plan (including approaches to minimising exposure to indoor and outdoor air pollution) and education, for the families or carers of children under 5 with suspected or confirmed asthma. [NICE 2017, amended NICE 2021]
- 1.14.4 For adults (aged 17 and over) who are using an inhaled corticosteroid (ICS) in a single inhaler, offer an increased dose of ICS for 7 days, within a self-management programme, when asthma control deteriorates. Clearly outline in the person's asthma action plan how and when to do this, and what to do if symptoms do not improve.

When increasing ICS treatment:

- consider quadrupling the regular ICS dose
- do not exceed the maximum licensed daily dose. [NICE 2017]
- 1.14.5 Include advice in self-management programmes on contacting a healthcare professional for a review if asthma control deteriorates (see the recommendations on monitoring asthma control). [NICE 2020, amended BTS/NICE/SIGN 2024]
- 1.14.6 When implementing self-management interventions in primary care, take into account strategies to aid this, which could include:

- the use of proactive alerts to ensure routine reviews
- structured protocols for asthma reviews
- support from primary care and community pharmacists
- mailing or emailing of educational resources
- telephone calls to provide ongoing support and advice
- IT-based education and monitoring
- involvement of community workers to support clinical teams in deprived and/ or ethnic minority communities. [BTS/SIGN 2019]
- 1.14.7 Schools and health services should work together to provide in-school asthma self-management education programmes provided by appropriately trained personnel. [BTS/SIGN 2019]
- 1.14.8 Provide self-management education in line with the recommendations on education programmes in the <u>section on enabling patients to actively participate in their care in the NICE guideline on patient experience in adult NHS services</u>.

  [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]

For a short explanation of why the committee made the 2020 recommendation on self-management and how it might affect practice, see the <u>rationale and impact</u> section on self-management.

Full details of the evidence and the committee's discussion are in the <u>evidence review</u> from NG80: increasing ICS treatment within supported self-management for children and young people.

# 1.15 Risk-stratified care

1.15.1 Consider actively identifying people with asthma who are at risk of poor outcomes and tailor care to their needs. Risk factors should include:

- non-adherence to medicines
- over-use of short-acting beta<sub>2</sub> agonist (SABA) inhalers (more than 2 inhalers per year)
- needing 2 or more courses of oral corticosteroids per year
- 2 or more visits to an emergency department or any hospital admission for asthma. [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this recommendation and how it might affect practice, see the <u>rationale and impact section on risk-stratified care</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review O:</u> risk stratified care for people with asthma.

# 1.16 Organisation and delivery of care

- In primary care, people with asthma should be reviewed at least annually and after any exacerbation by a healthcare professional with appropriate training in asthma management. The review should incorporate a written personalised action plan. [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]
- 1.16.2 Consider telehealthcare as an option for supporting self-management. [BTS/SIGN 2019]
- 1.16.3 Consider computerised decision support systems for patient use to support selfmanagement. [BTS/SIGN 2019]

# Terms used in this guideline

This section defines terms that have been used in a particular way for this guideline. For other definitions see the <u>NICE glossary</u> and the <u>Think Local, Act Personal Care and Support Jargon Buster</u>.

### AIR therapy

Anti-inflammatory reliever (AIR) therapy is treatment with a reliever inhaler that contains a combination of an inhaled corticosteroid and formoterol. When this is used in response to symptoms without regular maintenance therapy it is called as-needed AIR therapy. In November 2024 the only product licensed for as-needed AIR therapy contained budesonide/formoterol.

#### Asthma control

Complete control of asthma is defined as no daytime symptoms, no night-time awakening due to asthma, no asthma attacks, no need for rescue medication, no limitations on activity including exercise, normal lung function (in practical terms forced expiratory volume in 1 second [ $\overline{\text{FEV}}_1$ ] and/or peak expiratory flow [PEF] more than 80% predicted or best), and minimal side effects from treatment.

# Atopic disorder

Atopic disorders are allergic conditions including allergic rhinitis (hay fever), atopic dermatitis (eczema), allergic asthma and other specific and non-specific allergic conditions such as food allergies.

# Bronchial challenge test

A test to measure airway responsiveness (bronchial responsiveness). It is performed by giving small increments of a bronchoconstrictor (most commonly methacholine) and measuring the FEV<sub>1</sub> after each dose until it falls by a predetermined amount (usually 20% from baseline).

# **Bronchial hyperresponsiveness**

A measure of how easily bronchospasm can be induced in the airways. It is measured using a bronchial challenge test.

# Bronchodilator reversibility

A measure of the ability to reverse obstruction in the airways using medicines that widen

the airways (bronchodilators).

# **Eosinophil** count

The number of eosinophils (a type of white blood cell) measured in a blood sample. Their levels are raised in asthma and other allergic diseases, and less commonly with malignant diseases, parasite infections, reactions to some medicines, and a small number of rare diseases.

#### FeNO test

A test that measures the amount of nitric oxide (NO) present on exhalation, usually expressed in parts per billion.

### FEV<sub>1</sub>

The amount of air that can be forcibly exhaled from the lungs in one second (forced expiratory volume in one second).

### Leukotriene receptor antagonist

A type of oral medicine that blocks cysteinyl leukotrienes, used in the treatment of asthma and seasonal allergies. Also known as leukotriene modifiers.

# Long-acting beta<sub>2</sub> agonist

A long-acting medicine that acts on beta-receptors in the airway to relax airway smooth muscle and relieve symptoms of asthma.

### Long-acting muscarinic receptor antagonist

A long-acting medicine that acts on muscarinic receptors in the airway to relax airway smooth muscle and relieve symptoms of asthma.

# Maintenance and reliever therapy (MART)

A form of combined ICS plus formoterol treatment in which a single inhaler containing ICS

and formoterol is used for daily maintenance therapy and the relief of symptoms as needed. The terms low-dose MART and moderate-dose MART refer to the dosage of the maintenance component of MART. People using MART do not normally need a SABA.

# Peak expiratory flow (PEF) variability

PEF is a measure of the maximum speed of expiration, generally expressed in litres per minute. PEF variability is a measure of the extent to which this varies over time and can be expressed numerically as amplitude percentage mean. This is calculated by subtracting the lowest value measured each day from the highest value on the same day, and averaging this over the number of days on which PEF is measured

# Skin prick testing

A test that measures the allergic response of an individual to certain specific allergens when a very small amount of the specific allergen is introduced into the skin (usually the inner forearm).

### Specialist in asthma care

A healthcare professional with higher training in respiratory medicine and proficiency in the management of asthma. In the context of this guideline, this requires both the relevant expertise and access to the resources that enable delivery of the diagnostic and management pathways described in the recommendations.

### Uncontrolled asthma

A term used when asthma is having an impact on a person's lifestyle, or is restricting their normal activities, because of symptoms such as coughing, wheezing, shortness of breath and chest tightness. Uncontrolled asthma can include one or both of:

- any asthma exacerbation needing treatment with oral corticosteroids
- frequent regular symptoms such as:
  - needing a reliever inhaler 3 or more days per week, or
  - having 1 or more nights per week when asthma causes night-time waking.

Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) (NG245) These can be quantified by questionnaires such as the Asthma Control Questionnaire or Asthma Control test.

### Recommendations for research

The guideline committee has made the following recommendations for research.

### Key recommendations for research

### 1 Medicines for initial management

What is the clinical and cost-effectiveness of regular 'fixed-dose' inhaled corticosteroid (ICS) regimens (using SABA [short-acting beta<sub>2</sub> agonist] as a reliever) compared with 'asneeded' strategies (for example ICS/formoterol) as the initial standard treatment for asthma in children aged 5 to 11 years? [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale and impact section on medicines for initial management in</u> children aged 5 to 11.

Full details of the evidence and the committee's discussion are in <u>evidence review P</u>: drug classes for initial asthma management.

### 2 Medicine combination and sequencing

What is the best step-up treatment for people whose asthma is not controlled on a combination inhaler of ICS plus formoterol used as needed? [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale and impact section on medicine combination and sequencing in people aged 12 and over.</u>

Full details of the evidence and the committee's discussion are in <u>evidence review Q:</u> <u>drug combinations and sequencing for asthma management.</u>

### 3 Diagnostic pathways

What is the cost-effectiveness and feasibility of the proposed BTS/NICE/SIGN diagnostic pathways for asthma in children and young people aged 5 and over and in adults aged 17 and over? [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale and impact section on objective tests for diagnosing</u> asthma in adults, young people and children aged 5 to 16 with a history suggestive of asthma.

Full details of the evidence and the committee's discussion are in:

- evidence review A: diagnostic test accuracy of spirometry in people suspected of asthma
- evidence review B: diagnostic test accuracy for bronchodilator reversibility in people suspected of asthma
- evidence review C: diagnostic test accuracy of peak expiratory flow variability for the diagnosis of asthma
- evidence review D: accuracy of skin prick test in children for the diagnosis of asthma
- evidence review E: diagnostic test accuracy of IgE in children
- evidence review F: diagnostic accuracy of fractional exhaled nitric oxide (FeNO) measures
- evidence review G: diagnostic accuracy of eosinophil blood count measures in the diagnosis of asthma
- <u>evidence review H: bronchial challenge with histamine and methacholine for the</u> diagnosis of asthma
- evidence review I: bronchial challenge test with mannitol
- <u>evidence review J: bronchial challenge testing in response to exercise for the</u> diagnosis of asthma
- evidence review K: diagnostic accuracy of combination of tests.

#### 4 Inhalers

Can digital inhaler monitors cost-effectively improve adherence to preventer inhalers for people with asthma? Does this improve asthma control and who would benefit most from this intervention? [BTS/NICE/SIGN 2024]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale and impact section on digital inhalers</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review R:</u> smart inhalers.

### 5 Monitoring inhaler technique

What is the current frequency and the current method being used to check the inhaler technique of people with asthma? What is the optimal frequency and the best method of checking inhaler technique to improve clinical outcomes for people with asthma? [NICE 2017]

### 6 Monitoring asthma control using telehealthcare

What is the long-term (more than 12 months) clinical and cost-effectiveness of using telehealthcare as a means to monitor asthma control in adults, young people and children? Methods of telehealthcare can include telephone interview (with healthcare professional involvement) and internet or smartphone-based monitoring support (no healthcare professional involvement). [NICE 2017]

### 7 Decreasing pharmacological treatment

In adults, young people and children with well-controlled asthma, what are the objective measurements and prognostic factors that indicate that a decrease in regular maintenance treatment is appropriate? [NICE 2017]

### 8 Improving adherence to asthma medication

What are the most clinically and cost-effective strategies to improve medicines adherence

in adults, young people and children with asthma who are non-adherent to prescribed medicines? [NICE 2017]

### Other recommendations for research

### Increasing the dose of ICS within a personalised selfmanagement programme for children and young people

For children and young people with asthma that is managed in primary care, is there an advantage to increasing the ICS dose when asthma control has deteriorated compared with using the usual dose in a self-management programme? [NICE 2020]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale</u> and <u>impact section on self-management</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review</u> from NG80: increasing ICS treatment within supported self-management for children and young people.

## Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice.

As this guideline applies to England and Scotland, the perspective was for both England and Scotland.

# Objective tests for diagnosing asthma in adults, young people and children aged 5 to 16 with a history suggestive of asthma

Recommendations 1.2.1 to 1.2.9

### Why the committee made the recommendations

Although evidence on symptoms and signs of asthma was not reviewed for this guideline update, the committee emphasised the importance of taking a good clinical history in all their discussions of diagnosis. Evidence on objective tests was only included if it was carried out in people in whom asthma was suspected on clinical grounds. Therefore, the recommendations for diagnostic testing should only be applied when the history and examination findings support a diagnosis of asthma. The committee also noted that, depending on the mode of presentation, other diagnoses might be considered, but they confined their recommendations to confirmation or exclusion of asthma.

The committee reviewed evidence on tests of variation in airflow obstruction and markers of allergy separately for adults and children. They took into account the sensitivity and specificity of the various tests but did not base their recommendations on these measures alone. They noted that no test showed high enough values of both sensitivity and specificity to be diagnostic in all cases. However, some of them showed high specificity and were potentially useful as rule-in tests with a suitably high cut-off value. It was agreed that a combination of tests would be needed for most people.

When considering combinations of tests, the extent to which the available tests correlate with one another is important because there is less benefit in performing a test that gives

similar information to a preceding one. Practical aspects were taken into account using the committee's knowledge and experience. These included the availability of the tests, which varies considerably (in particular, bronchial challenge testing is not available in primary care and not readily available in secondary care), the ability of people to perform the tests, and the acceptability of the tests to the person, which is particularly relevant in younger children.

The committee also considered the cost of the available tests. However, no health economic study on the most cost-effective sequence or combination of tests was identified. Therefore, a health economic model was developed to help address this.

The committee discussed what cut-off values should be recommended for the tests. For some of the tests it was agreed that it was inappropriate to state a numerical value for an abnormal result. For example, normal ranges for blood tests may vary slightly between laboratories. Therefore, for eosinophil counts and IgE levels, a raised measurement (suggesting asthma) should be regarded as one above the upper end of the local reference range. There are also several standardised methods of performing bronchial challenge tests, and the definition of bronchial hyperresponsiveness will be dependent on the method used.

Spirometry should always be performed using an international standard protocol but the method of expressing reversibility after bronchodilator varies. Ideally this would be based on change in z-scores, but these are not measured by all spirometry equipment. Change in absolute values of FEV<sub>1</sub> is arguably best given as the percentage change compared with the person's predicted FEV<sub>1</sub>, and using this parameter a change of 10% or more is abnormal. Using the more traditional means of expressing the change as a percentage of the baseline FEV<sub>1</sub>, increased reversibility would be 12% or more in adults and children. In adults, the change should also be 200 ml or more. The committee agreed to include both ways of measuring reversibility in its recommendations.

An optimal cut-off value is also difficult to give for FeNO (fractional exhaled nitric oxide). There is good evidence that FeNO levels increase with age and with height, and ideally normal ranges would be available which correct for these factors. However, there are currently no standard charts and FeNO equipment does not give an age/height corrected output. Although not ideal, the committee agreed that they need to suggest a simple cut-off value. And because FeNO is the first, and possibly the only, test in the recommended sequences in both adults and children they agreed that the value should be reasonably high so that it would be specific, acknowledging that this sacrifices a degree of sensitivity.

Cut-offs of 50 ppb in adults and 35 ppb in children were agreed.

No evidence was available for diagnostic tests in children under 5. The age at which a child can co-operate with tests will vary, but the committee agreed that it is usually necessary to manage these children pragmatically based on symptoms and signs only.

#### **Adults**

Several tests showed good specificity for asthma, with values over 80% for blood eosinophils, FeNO (cut-off values 40-50 ppb), peak expiratory flow (PEF) variability, bronchial challenge tests, and spirometry with bronchodilator reversibility. However, sensitivity was poor for most of these, and only FeNO and bronchial challenge tests showed values over 70%. Although bronchial challenge is the most accurate test, overall, it is more costly than others and is less readily available.

Using the health economic model, the most cost-effective diagnostic strategy was found to be a gradual rule-in approach. It facilitates a positive diagnosis of asthma in a broad population using relatively inexpensive tests and confines the more expensive bronchial challenge tests to the end of the sequence.

The committee agreed that a cheap and highly specific test to rule in asthma should start the sequence. This should be either an eosinophil count or a FeNO measurement, but both need care in interpretation. For example, a raised eosinophil count can occur for other reasons including other allergic diseases, and FeNO is also affected by allergic diseases, although only those that affect the airways. Both measurements are altered in smokers. However, if used correctly in the presence of a history suggesting asthma, they are good rule-in tests.

The second test in the sequence should be to measure spirometry with reversibility. This is a more specific test than it is sensitive, but it represents a test of airway function to complement a first test which reflects atopy and so both components of asthma will have been assessed.

The committee were aware that there can be delays in accessing spirometry and FeNO testing, and it is hoped that access will improve. However, if these tests are not available or there is a significant delay in obtaining them, the committee agreed it would be reasonable to use PEF variability as a substitute rule-in test.

If asthma is not diagnosed at this stage, the only additional investigation that offers sensitivity without losing significant specificity is a bronchial challenge test. The committee are aware that these tests are not easily available in many areas but reasoned that making a positive recommendation should encourage services to improve access. They also noted that methacholine challenge is more sensitive than mannitol but did not want to further limit the recommendation.

#### Children aged 5 to 16

The committee noted that diagnostic testing is harder in children as they may find some tests difficult to perform and be unwilling to have blood tests.

A separate health economic model was developed for children using children-specific diagnostic accuracy data and inputs. In children, testing for sensitisation to house dust mite via skin prick test or finding an elevated IgE both showed high sensitivity. Therefore, the diagnostic strategy was a rule-in-rule-out approach. This proved to be the most cost-effective in children as it considerably reduced the proportion of children reaching the last stage and needing an expensive bronchial challenge test.

The committee agreed that a cheap and highly specific test was needed first to rule in asthma. FeNO is a more acceptable first test in children than an eosinophil count because it avoids the need to take blood, and because a level of 35 ppb or more is reasonably specific for asthma in the presence of a suggestive history.

The model suggested that a sensitive test should come next to rule out asthma. However, the committee noted that some children would not be able to have a FeNO test because the equipment is not available in all primary care settings, or because a minority may not be able to perform the necessary expiratory manouevre. They were also concerned that an increasing proportion of children with asthma are non-atopic and therefore unlikely to have a raised FeNO level. However, these children may show bronchodilator reversibility (BDR). It was therefore agreed that it would be appropriate to use spirometry with BDR as a second test for those without an elevated FeNO, or as the first test in those in whom FeNO could not be measured. Although this does not follow our optimal model exactly, including BDR at this stage is still cost-effective.

In children with a suggestive history of asthma, both skin prick testing for sensitisation to house dust mite and measurement of total IgE are sensitive tests, and the committee agreed that one or the other should be done next. If the test is negative, asthma is highly

unlikely and can be ruled out without resorting to bronchial challenge testing. Although taking blood for IgE is invasive, it does have the advantage that an eosinophil count could also be obtained, and if this is above  $0.5 \times 10^9$  per litre, it would support a diagnosis of asthma.

The committee were aware that there can be delays in obtaining spirometry, FeNO measurements or skin prick testing, and that it may not be possible to get blood samples from some children. It is hoped that access to these tests will improve. But if the tests are not available or there is a significant delay in obtaining them, the committee agreed it would be reasonable to use PEF variability as a substitute rule-in test.

The best single test is a bronchial challenge test, but these are also not readily available and cannot be done in primary care. If there is still diagnostic doubt after performing other tests, the committee agreed that a referral to an asthma specialist should be made for a second opinion, including consideration of a challenge test.

#### Further research

Although there is evidence underpinning each of the tests included in the recommended diagnostic sequences for adults and for children aged 5 to 16 years, the committee acknowledged that the sequences themselves have not been tested. The clinical and cost-effectiveness of the recommended diagnostic process should be formally evaluated.

#### Children under 5

The main issue in this age group is differentiating asthma from symptoms caused by recurrent viral infections. The committee were aware of evidence outside the review of diagnostic tests showing that asthma is more likely than recurrent viral wheeze when the episodes are frequent or severe, when they occur in the absence of other signs of viral illness and when the child shows other evidence of atopy. On this basis, they agreed that young children with recurrent wheeze and features suggesting asthma should be treated empirically with a low dose of inhaled corticosteroid (ICS) for a period of 8 to 12 weeks. If this is ineffective in reducing wheezing episodes, assuming that the ICS has been given satisfactorily, a referral to a specialist to consider other diagnoses is appropriate. If the ICS is associated with improvement, this is not proof of asthma as viral wheezing can remit and relapse spontaneously, so the committee agreed that the ICS should be stopped. If symptoms then reappear within a few weeks, asthma is the more likely diagnosis and the ICS should be re-started.

In view of the difficulty in diagnosing asthma in this age group the committee also agreed that any child who had been admitted to hospital, or been taken to the emergency department twice or more, because of wheezing or breathlessness should be referred to a specialist respiratory paediatrician for advice on diagnosis and management.

### How the recommendations might affect practice

The diagnostic tests recommended for both children and adults are not routinely carried out in current practice, with the exception of spirometry and reversibility testing, which is performed in some adults with suspected asthma. FeNO equipment is not available in some areas, but an eosinophil count and IgE level is easily obtainable everywhere. Bronchial challenge tests are not done in primary care and infrequently used in secondary care. The recommendations will increase the demand for challenge tests and initially there will be a capacity problem. Incorporating the recommended diagnostic sequences into clinical practice would therefore require significant investment. However, using the tests increases the accuracy of asthma diagnosis and will be cost-effective over time.

The recommendations for children under 5 are based on a pragmatic trial of treatment, as is current practice.

Return to recommendations

### Monitoring asthma control

Recommendations 1.5.1 to 1.5.4

### Why the committee made the recommendations

The committee agreed that there is some information that should always be obtained at a routine monitoring review, for example whether any courses of oral corticosteroid have been needed since the last review.

### Symptom questionnaires and diaries

The committee looked at evidence on the effects of monitoring asthma control using symptom questionnaires given at intervals ranging from weekly to twice in 3 months. Although there were a small number of beneficial outcomes in individual studies, overall,

there was no clinically useful effect of the monitoring in either adults or children. The committee noted that the interventions were complex, as they assessed the effects not just of the symptom monitoring but also the therapeutic adjustments made in response to the questionnaire result. Nonetheless, they concluded that they should not recommend questionnaires used at these relatively frequent intervals.

The committee were aware of evidence (that was not part of this review) showing that the results of asthma control questionnaires predict the risk of future asthma attacks. They therefore used their experience to recommend that questionnaires should be used as part of any asthma-related review. For most people this will be their annual review.

### **Pulmonary function**

The committee looked for evidence on the use of spirometry and PEF monitoring as measures of asthma control but did not find any data on spirometry used in this context.

There was evidence on PEF monitoring in both adults and children. The monitoring was typically linked to treatment changes triggered by designated thresholds of PEF and compared with the effects of treatment changes triggered by symptoms. In adults, regular PEF measurement was associated with worse quality-of-life parameters. The committee thought that this might be explained by regular monitoring inducing anxiety in some people if PEF is not consistently high, and by the inconvenience of making regular measurements.

In both adults and children, PEF monitoring was associated with an increase in asthma attacks, which appears to be a further disadvantage of regular monitoring. The committee found this hard to explain as monitoring itself seems unlikely to make asthma worse. It is possible that PEF measurements may have led to quicker identification and appropriate early treatment of some attacks. However, if this is the case, one might expect to see a reduction in the need for hospitalisation, or time off work or school, and these potential benefits were not seen.

The committee agreed that a minority of people with asthma benefit from regular measurement of PEF, for example those who are poor at perceiving changes in their airways and are therefore at risk of delaying treatment of asthma attacks. They also took into account evidence in adults that was not part of the formal review showing that action plans that incorporate PEF measurement can be beneficial. So, they recommended against the use of routine PEF monitoring, with the caveat that it might have value in some

circumstances.

#### **FeNO**

The evidence showed that, in both adults and children, regular FeNO monitoring led to a reduction in the number of asthma exacerbations. In children there was also a significant improvement in lung function. In adults, the reduction in exacerbations was achieved alongside an overall reduction in the dosage of maintenance ICS therapy. This was not the case in children, but the studies in this age group were more likely to be conducted in secondary or tertiary care, so it is likely that they had a higher maintenance therapy requirement.

The committee concluded that FeNO monitoring was cost-effective in adults but may not be in children. It was not possible on the current evidence to say what the optimum frequency of monitoring should be, but the committee agreed that an appropriate opportunity would be to make a routine measurement at the person's regular review (which will be an annual review for most people).

The FeNO level is a proxy measure of airway inflammation. It can therefore be very useful in determining how to adjust treatment, or as an indicator of treatment adherence, when a person with asthma has poor symptom control. Conversely, when symptom control is excellent and the possibility of reducing maintenance therapy arises, a normal FeNO level provides helpful reassurance. The committee therefore agreed that a FeNO measurement should be considered whenever a change in maintenance therapy might be appropriate.

### How the recommendations might affect practice

Asthma control questionnaires are already recommended as part of an annual review. Therefore, no change to practice is anticipated. The recommendations on pulmonary function are expected to reduce the use of PEF monitoring.

Measurement of FeNO is increasingly used in secondary care asthma clinics, but in primary care only a minority of GP practices have on-site access to the test. Regular FeNO monitoring represents a significant change in practice because most people with asthma are managed in primary care. This change will also carry a cost. The committee noted that FeNO measurement is also useful in diagnosing asthma (see <a href="section 1.2">section 1.2</a> on objective tests for diagnosing asthma), and increased access to the test will therefore be of dual benefit.

Return to recommendations

### Principles of pharmacological treatment

Recommendations 1.6.2 and 1.6.3

### Why the committee made the recommendations

The evidence review showed that clinical outcomes were poorest in all age groups with asthma when using SABA (short-acting beta<sub>2</sub> agonist) alone. The committee also took into account other evidence from several sources, including national reviews of asthma deaths in both adults and children, which highlighted the dangers of using SABA without ICS in people with asthma. They therefore recommended that SABA alone should not be used in people with a diagnosis of asthma.

The previous NICE and BTS/SIGN guidelines had recommended a number of actions which should be taken before increasing treatment, and the committee agreed by consensus that a FeNO check should also be done as long as the equipment is available to do this.

### How the recommendations might affect practice

The prescription of SABA alone has been commonplace, although this is becoming less so because of the publicity around asthma deaths. The recommendation will reduce its use further. The replacement therapies in adults and children are more expensive, but they should produce clinical benefits and cost savings through a reduction in exacerbations.

Return to recommendations

### Digital inhalers

Recommendation 1.6.10

### Why the committee made the recommendation

The committee looked at evidence comparing the use of digital smart inhalers with usual care and with digital inhalers with the feedback utility switched off. The trials included both children and adults with asthma, and a variety of types of inhaler. The evidence

showed improvement in adherence to treatment with digital inhalers, but this did not result in significant improvement in measures of asthma control. In addition, there was an unexplained increase in hospital admissions among people using digital inhalers when compared with usual care. The participants in the contributing trials varied considerably in terms of baseline adherence and asthma control, and benefit was generally more likely in the studies of people with poorer baseline values.

Digital inhalers are more expensive than conventional devices, partly because of the device itself and partly because of the set-up and monitoring requirements. The committee concluded that digital inhalers are not a cost-effective option for routine use in asthma. However, they are potentially valuable in selected people with asthma, for example those in whom the need for biologic therapy is being considered and there is a need to confirm good adherence. Further research is needed to identify more precisely the people and the circumstances in which they might be used.

### How the recommendation might affect practice

Digital inhalers are not recommended for routine use in the NHS, and this is in line with current practice.

Return to recommendations

# Medicines for the initial management of newly diagnosed asthma in people aged 12 and over

Recommendations 1.7.1 and 1.7.2

### Why the committee made the recommendations

The committee looked at evidence comparing 3 treatment options in people aged 12 and over with a new diagnosis of asthma. These were SABA as needed with no ICS; regular low-dose ICS plus SABA as needed; and a combination inhaler of an ICS (budesonide) plus formoterol, a fast onset long-acting beta<sub>2</sub> agonist (LABA), used as needed (as-needed AIR).

The most important difference between the groups was a reduction in severe exacerbations of asthma in the group using as-needed AIR therapy, and this applied to the

comparisons with both of the other treatment options. There were also fewer exacerbations with ICS plus SABA than with SABA alone. Apart from the difference in exacerbations, there were only small differences between outcomes when comparing ICS plus SABA as needed with as-needed AIR, and the committee did not assess these as clinically important. However, the evidence showed that use of ICS (either as-needed AIR or regular low-dose ICS plus SABA as needed) produced consistently better outcomes than SABA alone.

Health economic data showed that treatment with as-needed AIR was cheaper than regular ICS plus SABA as needed. The committee therefore concluded that combination inhalers used as needed should be the preferred treatment in newly diagnosed asthma in adults. However, there were concerns about the minority of people with asthma in whom the diagnosis is first made because of an acute attack. In these particularly symptomatic people, the committee agreed on safety grounds that initial treatment should be given regularly and recommended starting the low-dose MART (maintenance and reliever therapy) regimen.

### How the recommendations might affect practice

Most people aged 12 and over with newly diagnosed asthma are currently treated with either a SABA alone or with regular ICS plus SABA as needed. The new recommendations represent a significant change in practice. The use of combination inhalers is more expensive than SABA alone, but cheaper than regular ICS plus SABA as needed. Therefore, the cost impact will vary depending on the predominant form of treatment in each general practice. However, there should be future savings from a reduction in severe asthma exacerbations compared with either of the current treatment options.

Return to recommendations

# Medicine combination and sequencing in people aged 12 and over

Recommendations 1.7.3 to 1.7.6

### Why the committee made the recommendations

No studies were found in which treatment was added to as-needed AIR, the recommended

first treatment step in people aged 12 and over. This was unsurprising as the advantages of this as initial therapy have only recently been recognised. The committee therefore had to consider studies of people with asthma uncontrolled on other starting treatments, either a SABA when used as needed as sole therapy or when used in addition to regular lowdose ICS. They reasoned that these people would be sufficiently similar to people who are not controlled with as-needed AIR to allow recommendations to be made, but agreed that further research comparing different add-on therapies to ICS/formoterol as needed would be useful.

The evidence showed that regular low-dose ICS/LABA plus SABA as needed was superior to regular low-dose ICS plus SABA as needed. It produced greater improvements in lung function, and a reduction in the number of exacerbations and the amount of reliever therapy needed. Low-dose MART was also better than regular low-dose ICS plus SABA as needed in reducing asthma exacerbations, and people on this treatment needed less reliever therapy.

When low-dose ICS/LABA plus SABA as needed was compared with low-dose MART, the people using MART were found to have fewer exacerbations and hospital admissions. The committee noted that it would be simpler for people who are already using an ICS/ formoterol inhaler to start the MART regimen than to convert to new inhalers. The committee also considered the economic analysis done for this update and agreed that the MART regimen would be a cost-effective use of resources compared with low-dose ICS/LABA plus SABA as needed.

If treatment with MART using a low-dose maintenance regimen does not provide adequate asthma control, the committee agreed that increasing the maintenance element of MART to moderate dose is the appropriate next step. Evidence supporting this was available from studies comparing moderate dose MART with both regular moderate dose ICS/LABA with SABA as reliever and with regular moderate dose ICS with SABA as reliever. MART was superior in both comparisons, most notably in reducing severe asthma exacerbations.

If treatment with MART using a moderate-dose maintenance regimen does not provide adequate asthma control, the evidence on how best to increase treatment is less clear cut. People whose asthma is uncontrolled at this stage will be using additional doses of ICS/ formoterol for symptom relief and will effectively be on high-dose ICS. The committee agreed that ideally both FeNO and the eosinophil level should be checked, as well as carefully assessing whether the person is adhering to their prescribed treatment. If FeNO or eosinophil count is raised despite good adherence to this level of ICS, the risk of

adverse outcomes is relatively high and a referral to an asthma specialist for further assessment and management is appropriate.

If control is inadequate but neither FeNO nor eosinophil count is raised, the committee considered the possible options to be the addition of either a leukotriene receptor antagonist (LTRA) or a long-acting muscarinic receptor antagonist (LAMA). Evidence was available looking at the addition of either an LTRA or a LAMA to baseline treatment with moderate-dose ICS or moderate-dose ICS/LABA, but the 2 options were only compared directly in 2 small studies. Although the comparison showed a reduction in exacerbations with a LAMA compared with an LTRA, the committee did not have much confidence in the result because of the small study population. They noted that it would be simpler to add an LTRA than a LAMA because the latter would involve needing to teach the person with asthma how to use an additional inhaler device, and the need for 2 inhalers is also less environmentally desirable. An LTRA is also cheaper, but there is a risk of significant side effects, particularly neuropsychiatric disturbances. It was agreed that there was no convincing reason to recommend one option over the other and that the person with asthma should decide which should be tried first after a discussion of the potential benefits and harms.

If these medicines have been tried and the person's asthma continues to be inadequately controlled, further treatment is available using a variety of biologic agents. Use of these falls outside the scope of this guideline and requires specialist assessment. The committee therefore recommended that a referral should be made at this stage.

### How the recommendations might affect practice

The recommendations for increasing treatment are different from current standard practice, but they apply to people with a new diagnosis of asthma. People with an existing diagnosis of asthma who are stable on their current therapy do not have to switch treatment. People on current pathways who need an increase in treatment will be switched to MART, but this is one of the current options. There should therefore not be significant disruption to asthma care. The new treatment steps are cost-effective for the NHS and in particular will reduce the number of exacerbations requiring treatment and the number of hospital admissions for asthma.

Return to recommendations

# Transferring people aged 12 and over from other treatment pathways

Recommendations 1.7.7 to 1.7.11

### Why the committee made the recommendations

The treatment pathway recommended in this guideline update for people aged 12 and over relies on using MART with increasing dose of regular ICS/formoterol, depending on response to treatment. This is a different strategy from that recommended by previous guidelines (NICE and BTS/SIGN) and many people will be on treatment that is not part of this new pathway. The committee recognised that this will cause a problem for these people when their asthma is not controlled. They therefore discussed and agreed how treatment should be changed in these circumstances. They noted that the general advice about checking inhaler technique, adherence, etc. (see recommendation 1.6.1 in the section on principles of pharmacological treatment) before escalating treatment still applies here. The recommendations are not based on a specific evidence search, but the committee noted that people in the MART studies reviewed for recommendations 1.7.3 to 1.7.6 (see the section on medicine combination and sequencing in people aged 12 and over) were taking some form of non-MART therapy before study entry and that the improvement shown in comparison to both baseline and to the control treatments support the switch to MART.

### How the recommendations might affect practice

The recommendations will result in more people being switched to MART than to other treatment options, but MART is used at present, and the change should not be disruptive.

Return to recommendations

# Medicines for initial management in children aged 5 to 11

Recommendation 1.8.1

### Why the committee made the recommendation

Evidence for children aged 5 to 11 showed that regular paediatric low-dose ICS plus SABA as needed was superior to SABA alone, particularly in reducing exacerbations. Using regular ICS did not cause more side effects and was not associated with greater adrenal suppression. There was no evidence for ICS/formoterol combination inhalers used as needed in this age group. The committee therefore recommended regular paediatric low-dose ICS as the preferred treatment option for children aged 5 to 11. However, in view of the evidence supporting the use of ICS/LABA as needed combination inhalers in adults, they made a research recommendation to test the benefits of this combination in children.

### How the recommendation might affect practice

The recommendation for treatment of newly diagnosed asthma in children is in line with current practice.

Return to recommendations

# Medicine combination and sequencing in children aged 5 to 11

Recommendations 1.8.2 to 1.8.7

### Why the committee made the recommendations

The committee recommended regular low-dose ICS plus SABA as needed as initial treatment for children diagnosed with asthma. Several studies were available which directly addressed the question of optimal add-on therapy for children whose asthma is not controlled on this treatment. This evidence for MART was from a single study which showed that MART was superior to both regular moderate-dose ICS plus SABA as needed and to regular low-dose ICS/LABA plus SABA as needed. It reduced the number of exacerbations, reduced the need for reliever inhaler and caused fewer adverse events. The economic analysis done for this guideline update also supported the clinical evidence and the committee's discussion, with the MART regimen associated with fewer costs and more quality-adjusted life years (QALYs) than both ICS/LABA plus SABA as needed and ICS plus SABA as needed.

The results for the comparison of regular low-to-moderate dose ICS plus SABA as needed with regular low-dose ICS/LABA plus SABA as needed were equivocal, with fewer exacerbations on regular treatment with low-to-moderate dose ICS but more hospital admissions.

The committee agreed that paediatric low-dose MART is the best treatment for a child whose asthma is uncontrolled on regular paediatric low-dose ICS. They noted that MART is currently not licensed in the UK below the age of 12, although the key study recruited children younger than this, with a minimum age of 4. In addition, there were concerns that some children might struggle to use a dry-powder inhaler when particularly breathless. The committee therefore agreed to recommend MART as the preferred treatment providing the child is able to manage the MART regimen and the healthcare professional is willing to prescribe it.

For children whose asthma is uncontrolled on regular paediatric low-dose ICS and who are unable to manage the MART regimen, the choice of treatment would be between adding an LTRA, adding a LABA, or increasing the maintenance ICS dose. The evidence did not show one option to be clearly superior in terms of benefits or adverse events, although the committee noted that prescribers should warn people of possible neuropsychiatric problems with montelukast. (See the MHRA drug safety update on the risk of neuropsychiatric reactions in people taking montelukast.) The committee agreed that adding an LTRA to the regular ICS treatment should be tried first as this limits the child's exposure to ICS and is less expensive than using ICS/LABA inhalers. They used their knowledge and expertise to recommend further steps if asthma control is not achieved.

The committee also agreed that if asthma control was not achieved on a regular moderate dose of ICS (either as paediatric moderate-dose MART or regular paediatric moderate-dose ICS/LABA plus SABA as needed), an opinion should be sought from a specialist in asthma care before escalating to a paediatric high-dose ICS regimen.

### How the recommendations might affect practice

The recommendation for MART as the preferred step-up treatment is new, but this is not intended for children who are stable on current therapy, and introducing it should not be disruptive. It will bring advantages in terms of reducing asthma attacks. In addition, MART will not be suitable for some children, and the recommendations for treatment in this group are in line with current practice. Overall, the changes are modest and will be cost-effective for the NHS.

Return to recommendations

### Pharmacological management in children under 5

Recommendations 1.9.1 to 1.9.6

### Why the committee made the recommendations

Evidence was available for 5 treatment options: SABA alone used as needed; regular ICS plus SABA as needed; SABA/ICS combination inhaler used as needed; regular SABA/ICS combination inhaler; and regular montelukast. The evidence did not encompass all possible comparisons of the 5 options, but overall, those that included the use of an ICS clearly showed greater benefits than those without an ICS, and regular ICS (either ICS alone or ICS/SABA) was superior to intermittent ICS/SABA. The most important benefits of regular ICS were seen in reducing exacerbations or hospital admissions. There was no advantage to using regular ICS/SABA instead of regular ICS alone.

In making recommendations for this age group, the committee took into account the difficulty of making a firm diagnosis of asthma. Episodes of cough and wheezing can occur with recurrent viral infections and be difficult to distinguish from asthma, and there are concerns about treating young children with long-term ICS when they may not need them.

The committee were aware of evidence outside the review of diagnostic tests showing that asthma is more likely than recurrent viral wheeze when the episodes are frequent or severe, when they occur in the absence of other signs of viral illness and when the child shows other evidence of atopy. They made recommendations on the staged introduction of ICS as part of the diagnostic process in infants. They agreed that young children with recurrent wheeze and features suggesting asthma should be treated empirically with a low dose of ICS for 8 to 12 weeks, and then this can be stopped. If symptoms soon re-appear after stopping ICS, this suggests that the ICS was beneficial rather than the improvement being due to the natural remission of a viral episode. Once the presence of asthma is established with reasonable certainty the committee agreed that regular paediatric low-dose ICS should be restarted, with subsequent steps added if needed.

As diagnosis in this age group is so difficult, the committee agreed that thresholds for referral to an asthma specialist should be low.

### How the recommendations might affect practice

The recommendations for treatment of newly diagnosed asthma in children are in line with current NICE recommendations.

Return to recommendations

### Self-management

Recommendation 1.14.5

### Why the committee made the recommendation

The evidence for children and young people found that increasing the dose of ICS when asthma control deteriorates did not result in any benefits or harms compared with the usual dose in terms of reducing subsequent asthma exacerbations. It was limited to only 1 study with a small number of participants who had a personalised action plan. The committee also looked at studies in adults, but they agreed that the evidence was not applicable because of the high average age of participants.

The committee discussed the importance of a personalised action plan to guide children and young people if their asthma worsens and to reassure them that they are in control of their treatment. Children and young people who find that increasing their dose of ICS is helpful when their asthma control worsens should be able to continue to do this as an agreed strategy in their action plan. However, based on their experience, the committee members agreed that it is important to review the child or young person's self-management plan if their asthma control is deteriorating. Reviews involve checking current medicines and inhaler technique, discussing any factors that may be triggering symptoms, discussing adherence and education needs, and reviewing their action plan. They should be carried out as needed, in addition to annual review.

The committee discussed the importance of an individualised approach for children and young people, because they have varied and changing support needs at different ages. Studies have shown that most child asthma deaths involve children who have frequent but mild symptoms that are not responding to management in their personalised action plan. This recommendation should help to ensure that these children and young people receive the support that they need if they start to have problems with their asthma control.

The committee agreed that further research is needed to give clearer guidance on increasing the dose of ICS in children and young people within a self-management programme. They <u>made a research recommendation on increasing the dose of ICS within a personalised self-management programme for children and young people to promote further research and inform future practice.</u>

### How the recommendation might affect practice

The recommendation will lead to an increase in the review of self-management programmes for children and young people and reduce the variation in current practice for this. The increase in resources needed for this is likely to be offset by a reduction in the cost of treating asthma exacerbations.

Return to recommendations

### Risk-stratified care

Recommendation 1.15.1

### Why the committee made the recommendation

The studies featured differing ways of attempting to improve asthma care for people judged to be at high risk of adverse outcomes. Therefore, firm conclusions on the overall benefits were hard to reach. In addition, the factors used to identify the high-risk population were not identical across the different studies. The committee therefore were unable to define precisely how to identify people at risk, although they agreed that poor prescription pick-up rates, overuse of SABA inhalers and previous exacerbations needing unscheduled medical care are very likely to be relevant.

Most of the studies showed some reduction in A&E attendance or hospitalisation after risk stratification. The committee particularly noted 2 UK studies in which at-risk patients were identified by alerts on GP computer systems. These indicated that risk-stratified care helped healthcare professionals to better identify people who needed a course of oral corticosteroids. This then successfully reduced the number of hospitalisations and the need for out-of-hours contacts and A&E attendance for asthma exacerbations. An associated health economic review showed that risk stratification is likely to be cost-effective.

Based on this evidence and their clinical experience, the committee agreed there should be a benefit in identifying people 'at risk' of poor asthma outcomes and recommended that primary care services should consider introducing a risk-stratification system which then allows care to be adjusted according to the greater needs of some people.

### How the recommendation might affect practice

Many general practices have some form of alert system in operation already, but others do not. For those, the recommendation will result in a change in practice. The committee were uncertain how many different systems are in current use, but in the absence of comparative data, they could not recommend that some practices would need to change from their current system.

Return to recommendations

### Context

The NICE guideline on asthma was published in 2017 and BTS/SIGN last updated their <u>asthma guideline</u> in 2019. The guidelines overlap in the clinical areas included, and healthcare practitioners in the UK have been using both sets of guidance.

However, these guidelines differ in their approach to diagnosis. Concern has been raised about the recommendations to use fractional exhaled nitric oxide (FeNO) measurement and spirometry more widely, contained in NICE guidance. Likewise, there are significant differences in several aspects of the treatment approach in each. BTS, NICE and SIGN agreed that updating and unifying current guidance would be helpful for healthcare professionals.

This update to national asthma guidelines is timely for people with asthma and their healthcare teams. There have been various initiatives that aim to improve outcomes for people with asthma in the UK, but outcomes nevertheless remain poor. Mortality from asthma continues to increase in the UK, and it remains a leading cause of morbidity. According to the Office for National Statistics, there were more than 1,400 asthma deaths in the UK in 2018, an increase of 8% compared with 2017. For outcomes to improve, people with asthma need excellent, evidence-based care.

There are many uncertainties about the best way to diagnose, monitor and treat asthma. For example, there have been recent developments in our understanding of the value of physiological tests. Also, there are new options for the use of inhaled corticosteroids and what to do when treatment needs to be stepped up or down. The evidence in these areas of uncertainty has been reviewed and the relevant recommendations updated.

# Finding more information and committee details

To find BTS, NICE or SIGN guidance on related topics, including guidance in development, see the BTS guidelines, the NICE topic page on asthma and the SIGN guidelines.

For full details of the evidence and the guideline committee's discussions, see the <u>evidence reviews</u>. You can also find information about <u>how the guideline was developed</u>, including <u>details of the committee</u>.

We have produced <u>tools</u> and <u>resources</u> to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see <u>resources</u> to help you put NICE guidance into practice.

## **Update information**

**November 2024:** We have reviewed the evidence and made new recommendations on diagnosis, treatment and monitoring for people with asthma. These recommendations are marked [BTS/NICE/SIGN 2024].

We have also made some changes without an evidence review. These are marked [NICE 2020, amended BTS/NICE/SIGN 2024], [BTS/SIGN 2019, amended BTS/NICE/SIGN 2024], [NICE 2017, amended BTS/NICE/SIGN 2024] or [NICE 2017, BTS/SIGN 2019, amended BTS/NICE/SIGN 2024]. We have updated the wording in line with current best practice.

We have also made some minor changes – for example for clarity or where recommendations have been amalgamated. These recommendations are marked [NICE 2017], [NICE 2017, amended NICE 2021] or [BTS/SIGN 2019].

**March 2021:** In recommendations 1.14.1 and 1.14.3, NICE clarified that approaches to minimising indoor air pollution and reducing exposure to outdoor air pollution should be included in a personalised action plan because pollution can trigger and exacerbate asthma.

**February 2020:** NICE reviewed the evidence on increasing the dose of inhaled corticosteroids within a self-management programme in children and young people with asthma and removed a recommendation. A new recommendation on self-management in children and young people was made. This recommendation is marked **[2020, amended BTS/NICE/SIGN 2024]**.

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