

**BRITISH THORACIC SOCIETY, NATIONAL INSTITUTE
FOR HEALTH AND CARE EXCELLENCE, AND
SCOTTISH INTERCOLLEGIATE GUIDELINES
NETWORK**

Guideline scope

Asthma: diagnosis, monitoring and chronic asthma management

NICE, the British Thoracic Society (BTS) and the Scottish Intercollegiate Guideline Network (SIGN) have agreed to develop a joint national guideline on asthma.

The guideline will update the NICE guideline on asthma: diagnosis, monitoring and chronic asthma management (NG80) and the relevant sections of the published BTS/SIGN guideline: British guideline on the management of asthma (SIGN 158).

BTS, NICE and SIGN worked together to develop this scope.

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

This guideline will also be used to update the [NICE quality standard](#) for asthma.

1 Why the update is needed

The [NICE guideline on asthma](#) was published in 2017 and BTS/SIGN last updated their [asthma guideline](#) 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 practitioners.

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 National Office of 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 differing opinions about the most appropriate regimens for inhaled corticosteroids and what to do when treatment needs to be stepped up or down. The evidence in these areas of uncertainty will be reviewed and the relevant recommendations will be updated and published in the new joint guideline.

2 Who the guideline is for

This guideline is for:

- healthcare professionals in primary, secondary and tertiary care
- healthcare professionals in community care (including pharmacists)
- local authorities
- commissioners and providers of asthma clinics
- people using services and their families and carers, and the public.

It may also be relevant for:

- private sector or voluntary organisations commissioned to provide services for the NHS or local authorities
- people working in related services.

This guideline will cover health and care in England and Scotland. Decisions on how this guideline will apply in other UK countries will be made by ministers in the [Welsh Government](#) and [NI Executive](#).

Equality considerations

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will take account of inequalities relating to socio-economic group, ethnicity and geographical location when developing new recommendations and editorially refreshing and aligning recommendations .

3 What the updated guideline will cover

3.1 Who is the focus?

Groups that will be covered

- Adults, young people and children who are being investigated for suspected asthma, or who have been diagnosed with asthma.

The age cut-off points will be adjusted for specific reviews according to the most appropriate age groupings so that different recommendations for the intervention in question can be made for different age groups.

3.2 Settings

Settings that will be covered

- All settings where NHS funded care is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered

The areas to be included in this guideline have been agreed by BTS, NICE and SIGN. The table below outlines the plans for each area of the existing NICE guideline and BTS/SIGN guideline.

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Proposed outline for the guideline

Published NICE guideline	Published BTS/SIGN guideline	What NICE/SIGN/BTS plan to do
Initial clinical assessment		Editorially refresh and align recommendations
Diagnosing asthma in young children		Editorially refresh and align recommendations
Objective tests for diagnosing asthma in adults, young people and children		Review evidence: update existing recommendations as needed
Diagnosis	Diagnosis	Review evidence: update existing recommendations as needed
Diagnostic summary		Review evidence: update existing recommendations as needed
Principles of pharmacological treatment		Editorially refresh and align recommendations
Pharmacological treatment pathway for adults (aged 17 and over)	Pharmacological management	Review evidence: update existing recommendations as needed
Pharmacological treatment pathway for children and young people aged 5 to 16	Pharmacological management	Review evidence: update existing recommendations as needed
Pharmacological treatment pathway for children under 5	Pharmacological management	Review evidence: update existing recommendations as needed

	Management of acute asthma	Not included in update but BTS/SIGN recommendations will be maintained as part of a new 'asthma clinical pathway'
	Management of difficult asthma	Not included in update but BTS/SIGN recommendations will be maintained as part of a new 'asthma clinical pathway'
	Asthma in adolescents	No evidence review: editorially refresh and align recommendations
Include recommendations on asthma from the NICE guideline on intrapartum care for women with existing medical conditions or obstetric complications and their babies (NG121)	Asthma in pregnancy	No evidence review: editorially refresh and align recommendations
	Inhaler devices including their impact on the environment	No evidence review: editorially refresh and align recommendations
Adherence		No evidence review: editorially refresh and align recommendations, except review evidence for smart inhalers and update existing recommendations as needed. This will be merged with the section on self-management
	Non-pharmacological management	Not included in update but BTS/SIGN recommendations will be maintained as part of a new 'asthma clinical pathway'
Self-management	Supported self-management	No evidence review: editorially refresh and align recommendations
Decreasing maintenance therapy		No evidence review: editorially refresh and align recommendations
Risk stratification		Review evidence: update existing recommendations as needed
Monitoring asthma control	Monitoring asthma	Review evidence: update existing recommendations as needed
	Occupational asthma	No evidence review: editorially refresh and align recommendations

Objective tests for diagnosing asthma in adults, young people and children (Diagnostic hubs)	Organisation of care and delivery	No evidence review: editorially refresh and align recommendations
	Provision of information on asthma	Not included in update but BTS/SIGN recommendations will be maintained as part of a new 'asthma clinical pathway'

Editorially refresh and align recommendations - we will use this approach where both guidelines have similar recommendations that are not contradictory but are worded differently or have different levels of detail. They may be edited to make sure they meet current editorial standards and reflect the current policy and practice context. They will be included as a single set of recommendations in the NICE/BTS/SIGN guideline.

New asthma clinical pathway - The Asthma pathway will bring together recommendations from BTS/SIGN and NICE guidelines into a pathway of care covering diagnosis and management of chronic and severe asthma throughout an individual's lifetime. This will include content developed in the ongoing update on diagnosis, monitoring and chronic asthma management chronic asthma, alongside other content from the 3 organisations.

Areas that will not be covered in this update

- 1 Non-pharmacological management of asthma.
- 2 Biologics (for example, omalizumab).
- 3 Bronchial thermoplasty.
- 4 Management of acute asthma.
- 5 Difficult or severe asthma.
- 6 Sputum cell counts.
- 7 Phenotyping (currently relevant only in severe asthma).

Difficult asthma – where a previous diagnosis of asthma exists, and asthma-like symptoms and asthma attacks persist, despite high-dose asthma therapy.

Severe asthma – asthma that needs treating with high-dose inhaled corticosteroids (see [inhaled corticosteroid doses in NICE's asthma guideline](#)) plus a second controller (or systemic corticosteroids, or both) to prevent it from becoming 'uncontrolled', or which remains 'uncontrolled' despite this therapy (European Respiratory Society and American Thoracic Society).

Related NICE guidance

Published

- [Mepolizumab for treating severe eosinophilic asthma](#) (2021) NICE technology appraisal guidance TA671
- [COVID-19 rapid guideline: severe asthma](#) (2020) NICE guideline NG166
- [Intrapartum care for women with existing medical conditions or obstetric complications and their babies](#) (2019) NICE guideline NG121
- [Benralizumab for treating severe eosinophilic asthma](#) (2019) NICE technology appraisal guidance TA565
- [Emergency and acute medical care in over 16s: service delivery and organisation](#) (2018) NICE guideline NG94
- [Bronchial thermoplasty for severe asthma](#) (2018) NICE interventional procedure guidance IPG635
- [Reslizumab for treating severe eosinophilic asthma](#) (2017) NICE technology appraisal guidance TA479
- [Bronchiolitis in children: diagnosis and management](#) (2015) NICE guideline NG9
- [Measuring fractional exhaled nitric oxide concentration in asthma: NIOX MINO, NIOX VERO and NObreath](#) (2014) NICE diagnostics guidance DG12
- [Omalizumab for treating severe persistent allergic asthma](#) (2013) NICE technology appraisal guidance TA278
- [Inhaled corticosteroids for the treatment of chronic asthma in adults and in children aged 12 years and over](#) (2008) NICE technology appraisal guidance TA138

- [Inhaled corticosteroids for the treatment of chronic asthma in children under the age of 12 years](#) (2007) NICE technology appraisal guidance TA131
- [Inhaler devices for routine treatment of chronic asthma in older children \(aged 5-15 years\)](#) (2002) NICE technology appraisal guidance TA38
- [Guidance on the use of inhaler systems \(devices\) in children under the age of 5 years with chronic asthma](#) (2000) NICE technology appraisal guidance TA10

In development

- [Dupilumab for treating severe asthma](#). NICE technology appraisal guidance. Publication expected November 2021.
- [Tezepelumab for treating severe asthma](#). NICE technology appraisal guidance. Publication date to be confirmed.

BTS/NICE/SIGN guidance that will be updated by this guideline

- [Asthma: diagnosis, monitoring and chronic asthma management](#) (2017) NICE guideline NG80
- [British guideline on the management of asthma](#) (2019) SIGN 158

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to asthma:

- [Shared decision making](#) (2021) NICE guideline NG197
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

3.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and social care perspective, as appropriate

3.5 Key issues and draft questions

While writing this scope, we have identified the following key issues and draft questions related to them:

1 Diagnosis

No evidence review will be undertaken on the diagnostic accuracy of signs and symptoms, history of atopic disorders, symptoms in response to exercise, clinical history of symptoms in people taking NSAIDs or beta blockers and case identification for occupational asthma. Evidence from the published guidelines will be reviewed and recommendations aligned. This will include advice on referral in cases of diagnostic difficulty.

1.1 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of spirometry and flow volume loop measures?

1.2 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of bronchodilator response (using peak expiratory flow or forced expiratory volume in 1 second [FEV1])?

1.3 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of peak expiratory flow variability?

1.4 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of skin prick tests in children?

1.5 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of total and specific serum IgE measures in children?

- 1.6 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of FeNO measures?
- 1.7 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of eosinophil blood count measures?
- 1.8 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of bronchial challenge testing (direct) with histamine and methacholine?
- 1.9 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of bronchial challenge testing (indirect) with mannitol and exercise?
- 1.10 In people under investigation for asthma, what is the diagnostic test accuracy and cost effectiveness of combinations of tests (as specified in 1.1-1.9)?
- 2 Monitoring, ongoing assessment and risk stratification
- 2.1 In people with asthma, what is the clinical and cost effectiveness of using symptom diaries or validated questionnaires that measure symptom control (for example, Asthma Control Test, Asthma Control Questionnaire, Child Asthma Control Test, Royal College of Physicians 3 questions) or health-related quality of life (for example, Asthma Quality of Life Questionnaire, Paediatric Asthma Quality of Life Questionnaire) to monitor asthma?
- 2.2 In people with asthma, what is the clinical and cost effectiveness of using measures of pulmonary function (for example, spirometry or peak expiratory flow) to monitor asthma?
- 2.3 In people with asthma, what is the clinical and cost effectiveness of using FeNO measures to monitor asthma?
- 2.4 In people with asthma (age less than 5 years, 5 to 12 years, and more than 12 years), which individual characteristic or combination of characteristics effectively predicts future loss of control or future risk of attacks?

No evidence review will be undertaken on telemonitoring and adherence. Evidence from the published guidelines will be reviewed and recommendations aligned.

3 Pharmacological management of chronic asthma

3.1 What is the most clinically and cost-effective drug class or combination of drug classes (short-acting beta agonist [SABA] prn, SABA prn plus regular inhaled corticosteroid [ICS], or ICS / long-acting beta-agonist [LABA] inhaler prn) for the management of asthma in people who are treatment-naive?

3.2 What is the most clinically and cost-effective sequence in which to introduce additional drugs or combination of drugs for the management of asthma when initial management fails to provide adequate control: ICS low or high dose; ICS plus LABA (ICS plus LABA with SABA prn); ICS plus LABA used as maintenance and reliever therapy (Single Maintenance and Reliever Therapy [SMART] or Maintenance and Reliever Therapy [MART]); leukotriene receptor antagonists; theophylline or aminophylline; long-acting muscarinic receptor antagonists?

No evidence review will be undertaken on the treatment of asthma not responding to the agents listed above (difficult or severe asthma), but existing guidance on referral for specialist care will be reviewed.

4 Adherence

4.1 What is the most clinically and cost effective smart inhaler for the management of asthma?

3.6 Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

- Diagnosis
 - Accuracy of diagnostic tests
- Management
 - Lung function and inflammation
 - Symptoms
 - Health-related quality of life

- Exacerbations or attacks
 - Frequency of asthma attacks
- Need for rescue medication (oral corticosteroids and SABA)
- Unscheduled use of healthcare services
- Time off school or work
- Mortality

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- [Air pollution: outdoor air quality and health](#) (2019) NICE quality standard QS181
- [Asthma](#) (2013) NICE quality standard QS25

4.2 NICE Pathways

When this guideline is published, we will update the existing [NICE Pathway on asthma](#). NICE Pathways bring together everything NICE has said on a topic in an interactive flowchart.

Further information

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in November 2023.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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