

<b>BTS, NICE and SIGN</b>			
<b>Scope on asthma</b>			
<b>Document cover sheet</b>			
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3 **BRITISH THORACIC SOCIETY, NATIONAL INSTITUTE**  
4 **FOR HEALTH AND CARE EXCELLENCE, AND**  
5 **SCOTTISH INTERCOLLEGIATE GUIDELINES**  
6 **NETWORK**

7

## **Guideline scope**

8 **Asthma: diagnosis, monitoring and chronic**  
9 **asthma management**

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

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

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

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

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

22 **1 Why the update is needed**

23 The [NICE guideline on asthma](#) was published in 2017 and BTS/SIGN last  
24 updated their [asthma guideline](#) in 2019. The guidelines overlap in the clinical  
25 areas included, and healthcare practitioners in the UK have been using both  
26 sets of guidance.

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

7 This update to national asthma guidelines is timely for people with asthma and  
8 their healthcare teams. There have been various initiatives that aim to  
9 improve outcomes for people with asthma in the UK, but outcomes  
10 nevertheless remain poor. Mortality from asthma continues to increase in the  
11 UK, and it remains a leading cause of morbidity. According to the National  
12 Office of Statistics there were more than 1,400 asthma deaths in the UK in  
13 2018, an increase of 8% compared to 2017. For outcomes to improve, people  
14 with asthma need excellent, evidence-based care.

15 There are many uncertainties about the best way to diagnose, monitor and  
16 treat asthma. For example, there have been recent developments in our  
17 understanding of the value of physiological tests, and there are differing  
18 opinions about the most appropriate regimens for inhaled corticosteroids and  
19 what to do when levels of treatment need to be stepped up and down. The  
20 evidence in these areas of uncertainty will be reviewed and the relevant  
21 recommendations will be updated and published in the new joint guideline.

## 22 **2 Who the guideline is for**

23 This guideline is for:

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

29 It may also be relevant for:

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

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

## 7 **Equality considerations**

8 NICE has carried out [an equality impact assessment](#) [add hyperlink in final  
9 [version](#)] during scoping. The assessment:

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

12 The guideline will look at inequalities relating to socio-economic group,  
13 ethnicity and geographical location.

## 14 **3 What the updated guideline will cover**

### 15 **3.1 Who is the focus?**

#### 16 **Groups that will be covered**

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

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

### 22 **3.2 Settings**

#### 23 **Settings that will be covered**

- 24 • All settings where NHS funded care is provided.

### 1 **3.3 Activities, services or aspects of care**

#### 2 **Key areas that will be covered**

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

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

#### 11 **Proposed outline for the guideline**

<b>Published NICE guideline</b>	<b>Published BTS/SIGN guideline</b>	<b>What NICE/SIGN/BTS plan to do</b>
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 recommendations will be maintained as part of a new 'asthma clinical pathway'
	Management of difficult asthma	Not included in update but 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 This will be merged with the section on self-management
	Non-pharmacological management	Not included in update but 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	Organisation of care and delivery	No evidence review: editorially refresh and align recommendations

and children (Diagnostic hubs)		
	Provision of information on asthma	Not included in update but recommendations will be maintained as part of a new 'asthma clinical pathway'

1

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

8 New asthma clinical pathway - the new joint guideline will form part of a  
9 broader set of guidance and materials, produced by BTS, SIGN and NICE, on  
10 diagnosing and managing asthma throughout a person's lifetime – a new  
11 'asthma clinical pathway'.

## 12 **Areas that will not be covered in this update**

13 1 Non-pharmacological management of asthma.

14 2 Biologics (for example, omalizumab).

15 3 Bronchial thermoplasty.

16 4 Management of acute asthma.

17 5 Difficult or severe asthma.

18 6 Sputum cell counts.

19 7 Phenotyping (currently relevant only in severe asthma).

20

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

24 Severe asthma - asthma that needs treating with high-dose inhaled  
25 corticosteroids (see [inhaled corticosteroid doses in NICE's asthma  
26 guideline](#)) plus a second controller (or systemic corticosteroids, or both)  
27 to prevent it from becoming 'uncontrolled', or which remains

1 'uncontrolled' despite this therapy (European Respiratory Society and  
2 American Thoracic Society).

### 3 **Related NICE guidance**

#### 4 **Published**

- 5 • [COVID-19 rapid guideline: severe asthma](#) (2020) NICE guideline NG166
- 6 • [Intrapartum care for women with existing medical conditions or obstetric](#)  
7 [complications and their babies](#) (2019) NICE guideline NG121
- 8 • [Emergency and acute medical care in over 16s: service delivery and](#)  
9 [organisation](#) (2018) NICE guideline NG94
- 10 • [Bronchiolitis in children: diagnosis and management](#) (2015) NICE guideline  
11 NG9
- 12 • [Measuring fractional exhaled nitric oxide concentration in asthma: NIOX](#)  
13 [MINO, NIOX VERO and NObreath](#) (2014) NICE diagnostics guidance  
14 DG12
- 15 • [Omalizumab for treating severe persistent allergic asthma](#) (2013) NICE  
16 technology appraisal guidance TA278
- 17 • [Bronchial thermoplasty for severe asthma](#) (2018) NICE interventional  
18 procedure guidance IPG635
- 19 • [Inhaled corticosteroids for the treatment of chronic asthma in adults and in](#)  
20 [children aged 12 years and over](#) (2008) NICE technology appraisal  
21 guidance TA138
- 22 • [Inhaled corticosteroids for the treatment of chronic asthma in children](#)  
23 [under the age of 12 years](#) (2007) NICE technology appraisal guidance  
24 TA131
- 25 • [Inhaler devices for routine treatment of chronic asthma in older children](#)  
26 [\(aged 5-15 years\)](#) (2002) NICE technology appraisal guidance TA38
- 27 • [Guidance on the use of inhaler systems \(devices\) in children under the age](#)  
28 [of 5 years with chronic asthma](#) (2000) NICE technology appraisal guidance  
29 TA10

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

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

## 5 **NICE guidance about the experience of people using NHS services**

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

- 9 • [Medicines optimisation](#) (2015) NICE guideline NG5
- 10 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- 11 • [Service user experience in adult mental health](#) (2011) NICE guideline  
12 CG136
- 13 • [Medicines adherence](#) (2009) NICE guideline CG76

## 14 **3.4 Economic aspects**

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

## 21 **3.5 Key issues and draft questions**

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

### 24 1 Diagnosis

25 No evidence review will be undertaken on the diagnostic accuracy of signs  
26 and symptoms, history of atopic disorders, symptoms in response to exercise,  
27 clinical history of symptoms in people taking NSAIDs or beta blockers and  
28 case identification for occupational asthma. Evidence from the published  
29 guidelines will be reviewed and recommendations aligned.

- 1 1.1 In people under investigation for asthma, what is the diagnostic test  
2 accuracy and cost-effectiveness of spirometry and flow volume loop  
3 measures?
- 4 1.2 In people under investigation for asthma, what is the diagnostic test  
5 accuracy and cost effectiveness of bronchodilator response (using peak  
6 expiratory flow or forced expiratory volume in 1 second [FEV1])?
- 7 1.3 In people under investigation for asthma, what is the diagnostic test  
8 accuracy and cost effectiveness of peak expiratory flow variability?
- 9 1.4 In people under investigation for asthma, what is the diagnostic test  
10 accuracy and cost effectiveness of skin prick tests in children?
- 11 1.5 In people under investigation for asthma, what is the diagnostic test  
12 accuracy and cost effectiveness of total and specific serum IgE  
13 measures in children?
- 14 1.6 In people under investigation for asthma, what is the diagnostic test  
15 accuracy and cost effectiveness of FeNO measures?
- 16 1.7 In people under investigation for asthma, what is the diagnostic test  
17 accuracy and cost effectiveness of eosinophil blood count measures?
- 18 1.8 In people under investigation for asthma, what is the diagnostic test  
19 accuracy and cost effectiveness of bronchial challenge testing (direct)  
20 with histamine and methacholine?
- 21 1.9 In people under investigation for asthma, what is the diagnostic test  
22 accuracy and cost effectiveness of bronchial challenge testing (indirect)  
23 with mannitol and exercise?
- 24 2 Monitoring, ongoing assessment and risk stratification
- 25 2.1 In people with asthma, what is the clinical and cost effectiveness of  
26 using symptom diaries or validated questionnaires that measure  
27 symptom control (for example, Asthma Control Test, Asthma Control  
28 Questionnaire, Child Asthma Control Test, Royal College of Physicians 3  
29 questions) or health-related quality of life (for example, Asthma Quality  
30 of Life Questionnaire, Paediatric Asthma Quality of Life Questionnaire) to  
31 monitor asthma?
- 32 2.2 In people with asthma, what is the clinical and cost effectiveness of  
33 using measures of pulmonary function (for example, spirometry or peak  
34 expiratory flow) to monitor asthma?

1 2.3 In people with asthma, what is the clinical and cost effectiveness of  
2 using FeNO measures to monitor asthma?

3 2.4 In people with asthma (age less than 5 years, 5 to 12 years, and  
4 more than 12 years), which individual characteristic or combination of  
5 characteristics effectively predicts future loss of control or future risk of  
6 attacks?

7 No evidence review will be undertaken on telemonitoring and adherence.

8 Evidence from the published guidelines will be reviewed and  
9 recommendations aligned.

### 10 3 Pharmacological management of chronic asthma

#### 11 **People with asthma who are treatment-naive**

12 3.1 What is the most clinically and cost-effective drug class or  
13 combination of drug classes (short-acting beta agonist [SABA] prn,  
14 SABA prn plus regular inhaled corticosteroid [ICS], or ICS / long-acting  
15 beta-agonist [LABA] inhaler prn) for the management of asthma in  
16 people who are treatment-naive?

17 3.2 What is the most clinically and cost-effective sequence in which to  
18 introduce additional drugs or combination of drugs for the management  
19 of asthma when initial management fails to provide adequate control:  
20 ICS low or high dose; ICS plus LABA (ICS plus LABA with SABA prn);  
21 ICS plus LABA used as maintenance and reliever therapy (Single  
22 Maintenance and Reliever Therapy [SMART] or Maintenance and  
23 Reliever Therapy [MART]); leukotriene receptor antagonists;  
24 theophylline or aminophylline; long-acting muscarinic receptor  
25 antagonists?

#### 26 **3.6 Main outcomes**

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

- 29 • Diagnosis
  - 30 – Accuracy of diagnostic tests
- 31 • Management

- 1 – Lung function and inflammation
- 2 – Symptoms
- 3 – Health-related quality of life
- 4 • Exacerbations or attacks
- 5 – Frequency of asthma attacks
- 6 • Need for rescue medication (oral corticosteroids and SABA)
- 7 • Unscheduled use of healthcare services
- 8 • Time off school or work
- 9 • Mortality

## 10 **4 NICE quality standards and NICE Pathways**

### 11 **4.1 NICE quality standards**

#### 12 **NICE quality standards that may need to be revised or updated** 13 **when this guideline is published**

- 14 • [Asthma](#) (2013) NICE quality standard QS25

### 15 **4.2 NICE Pathways**

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

## 19 **Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 2 September to 30 September 2021.

The guideline is expected to be published in November 2023.

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

[After consultation, delete the first paragraph above and replace it with 'This is the final scope, which takes into account comments from registered stakeholders during consultation'.]

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