



## Guideline Summary NGC-10509

### Guideline Title

**International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma.**

### Bibliographic Source(s)

Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, Adcock IM, Bateman ED, Bel EH, Bleecker ER, Boulet LP, Brightling C, Chané P, Dahlen SE, Djukanovic R, Frey U, Gaga M, Gibson P, Hamid Q, Jajour NN, Mauad T, Sorkness RL, Teague WG. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014 Feb 1;43(2):343-73. [223 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

### Scope

#### Disease/Condition(s)

Severe asthma

#### Guideline Category

Diagnosis

Evaluation

Management

Treatment

#### Clinical Specialty

Allergy and Immunology

Family Practice

Internal Medicine

Pediatrics

Pulmonary Medicine

#### Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

#### Guideline Objective(s)

- To revise the definition of severe asthma, discuss the possible phenotypes and provide guidance about the management of patients with severe asthma
- To serve as the basis for development and implementation of locally-adapted guidelines

#### Target Population

Adults and children with severe asthma

#### Interventions and Practices Considered

## Assessment/Evaluation

1. Chest high-resolution computed tomography (HRCT)
2. Sputum eosinophil counts

## Management/Treatment

1. Anti-immunoglobulin E (IgE) (omalizumab)
2. Macrolide antibiotics (as indicated)
3. Antifungal agents (as indicated)
4. Bronchial thermoplasty

**Note:** The use of fraction of expired nitric oxide (FeNO) to guide therapy and methotrexate were considered but not recommended.

## Major Outcomes Considered

- Asthma control
- Adverse effects of treatments
- Clinical efficacy of treatments
- Exacerbation rates
- Long-term effects on lung function

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

#### Evidence Review

The Guideline Committee based the evidence summaries on existing up-to-date well done systematic reviews. Systematic reviews were supplemented, if necessary, with additional recent randomized controlled trials (RCTs). When there was no recent valid systematic review available, the Guideline Committee did not perform rigorous systematic reviews, but systematically searched MEDLINE and/or Cochrane Central Register of Controlled Trials (CENTRAL) for relevant studies from inception of the database through September 2012 (search strategies are provided in the online supplementary material appendix 2 [see the "Availability of Companion Documents" field]). The Guideline Committee also queried the authors of identified trials and committee members for any additional studies that had not been identified. The Guideline Committee did not search for observational studies to look for evidence about the important outcomes that were not reported in the RCTs. However, when there was no RCT available to provide evidence about any outcome of interest the authors did look for the best available evidence to support recommendations.

### Number of Source Documents

The original literature search identified 2192 studies, 68 of which were included in the development of the guideline.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Quality of evidence (confidence in the available estimates of treatment effects) is categorized according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) as: high, moderate, low or very low based on consideration of risk of bias, directness, consistency and precision of the estimates. Low and very low quality evidence indicates that the estimated effects of interventions are very uncertain and further research is very likely to have an important impact on resulting recommendations.

### Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

### Description of the Methods Used to Analyze the Evidence

#### Evidence Review

Evidence summaries (online supplementary material 1 [see the "Availability of Companion Documents" field]) for each question were prepared by the American Thoracic Society (ATS) methodologist following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach using GRADEpro software version 3.6. The summaries of evidence were reviewed by all committee members and corrections made when appropriate.

When possible and justified the Guideline Committee combined the results of identified studies using meta-analysis using the Cochrane Collaboration Review Manager 5.1.6. All reviewed original studies were evaluated to inform judgments about the available evidence. The Guideline Committee assessed the risk of bias at the outcome level using the Cochrane

Collaboration's risk of bias tool. Subsequently, the Guideline Committee assessed the quality of the body of evidence (i.e., confidence in the estimated effects) for each of the outcomes of interest following the GRADE approach based on the following criteria: risk of bias, precision, consistency and magnitude of the estimates of effects, directness of the evidence, risk of publications bias, presence of dose–effect relationship, and an assessment of the effect of residual, opposing confounding. Quality was categorized into 4 levels ranging from very low to high quality (see the "Rating Scheme for the Strength of the Evidence" field).

## Methods Used to Formulate the Recommendations

Expert Consensus

### Description of Methods Used to Formulate the Recommendations

#### Committee Composition and Meetings

This guideline represents a collaborative effort between the American Thoracic Society (ATS) and European Respiratory Society (ERS). The Committee consisted of clinicians and researchers with recognized expertise in severe asthma (21 pulmonologists of whom 3 were pediatricians, 2 pathologists and 2 physiologists plus one scientist) and an ATS methodologist with expertise in the guideline development process and the application of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Nine face-to-face meetings were held between 2009 and 2012 coinciding with the ATS and ERS annual conferences during which the Committee discussed and decided about the scope of the document, the specific questions to be addressed and the existing research evidence. Multiple conference calls were also held and frequent email correspondence was used to discuss specific issues requiring the input from all committee members.

#### Formulating Specific Clinical Questions and Determining Outcomes of Interest

The Committee identified several questions related to the definition, phenotyping, diagnosis and treatment of severe asthma. The Committee drafted a list of 24 specific questions about the diagnosis and treatment of severe asthma and ranked them by priority. Eight specific questions were chosen to be explicitly answered with recommendations for clinical practice. The remaining questions are listed in the online supplementary material 2 and will be addressed in the updates of these guidelines.

The Committee selected outcomes of interest for each question following the approach suggested by the GRADE Working Group. All outcomes were identified a priori and the Committee explicitly rated their relative importance for decision making. Ranking outcomes by their relative importance can help to focus attention on those outcomes that are considered most important and help to resolve or clarify potential disagreements.

#### Development of Clinical Recommendations

During the meetings and conference calls, the Committee developed recommendations based on the evidence summaries. For each recommendation, the Committee considered and agreed on the following: the quality of the evidence, the balance of desirable and undesirable consequences of compared management options and the assumptions about the values and preferences associated with the decision. The Committee also explicitly took into account possible extent of resource use associated with alternative management options. Recommendations and their strength were decided by consensus and no recommendation required voting. The Committee agreed on the final wording of recommendations and remarks with further qualifications for each recommendation. The final document including recommendations was reviewed and approved by all members of the committee.

### Rating Scheme for the Strength of the Recommendations

#### Strength of Recommendations

Implications for	Strong Recommendation	Conditional Recommendation
<b>Patients</b>	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
<b>Clinicians</b>	Most individuals should receive the intervention. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
<b>Policy Makers</b>	The recommendation can be adopted as policy in most situations.	Policy making will require substantial debate and involvement of various stakeholders.

### Cost Analysis

The guideline developers reviewed published cost analyses.

### Method of Guideline Validation

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

A final draft document was reviewed by each member of the Committee, finalized, approved, and submitted to the American Thoracic Society (ATS) and European Respiratory Society (ERS) for peer review. The document was revised to incorporate the pertinent comments suggested by the external reviewers and the input provided by the ATS Documents Editor and the ERS Guidelines Director.

## Recommendations

### Major Recommendations

The strength of the recommendations (strong, conditional) and levels of evidence (high, moderate, low or very low) are defined at the end of the "Major Recommendations" field.

#### **Evaluation**

##### **Question 1**

Should chest high-resolution computed tomography (HRCT) scans be routinely ordered in patients with symptoms of severe asthma without known specific indications for performing this test (based on history, symptoms and/or results of other investigations)?

##### **Recommendation 1**

In children and adults with severe asthma without specific indications for chest HRCT based on history, symptoms and/or results of prior investigations the Guideline Committee suggests that a chest HRCT only be done when the presentation is atypical (**conditional recommendation, very low quality evidence**).

##### *Values and Preferences*

This recommendation places a relatively high value on identification of alternative diagnosis and comorbidities and a relatively low value on avoiding potential complications and cost of chest HRCT.

##### *Remarks*

An atypical presentation of severe asthma includes such factors as, for example, excessive mucus production, rapid decline in lung function, reduced carbon monoxide transfer factor coefficient and the absence of atopy in a child with difficult asthma.

#### **Currently Available Biomarkers to Guide Therapy**

##### **Question 2**

Should treatment guided by sputum eosinophil count, rather than treatment guided by clinical criteria alone, be used in patients with severe asthma?

##### **Recommendation 2**

In adults with severe asthma, the Guideline Committee suggests treatment guided by clinical criteria and sputum eosinophil counts performed in centres experienced in using this technique rather than by clinical criteria alone (**conditional recommendation, very low quality evidence**).

In children with severe asthma, the Guideline Committee suggests treatment guided by clinical criteria alone rather than by clinical criteria and sputum eosinophil counts (**conditional recommendation, very low quality evidence**).

##### *Values and Preferences*

The recommendation to use sputum eosinophil counts to guide therapy in adults places a higher value on possible clinical benefits from adjusting the treatment in selected patients and on avoidance of inappropriate escalation of treatment and a lower value on increased use of resources.

The recommendation not to use sputum eosinophil counts to guide therapy in children places higher value on avoiding an intervention that is not standardised and not widely available and lower value on the uncertain and possibly limited clinical benefit.

##### *Remarks*

Because at the present time, measurement of sputum eosinophils has not yet been sufficiently standardised and is not widely available the Guideline Committee suggests such an approach be used only in specialised centres experienced in this technique. Patients who are likely to benefit from this approach are those who can produce sputum, demonstrate persistent or at least intermittent eosinophilia and have severe asthma with frequent exacerbations. Clinicians should recognise that different choices will be appropriate for different patients.

##### **Question 3**

Should treatment guided by fraction of expired nitric oxide (FeNO) in addition to clinical criteria, rather than treatment guided by clinical criteria alone, be used in patients with severe asthma?

##### **Recommendation 3**

The Guideline Committee suggests that clinicians do not use FeNO to guide therapy in adults or children with severe asthma (**conditional recommendation, very low quality evidence**).

##### *Values and Preferences*

This recommendation places a higher value on avoiding additional resource expenditure and a lower value on uncertain benefit from monitoring FeNO.

#### **Therapeutic Approaches**

##### **Question 4**

Should a monoclonal anti-immunoglobulin E (IgE) antibody be used in patients with severe allergic asthma?

##### **Recommendation 4**

In patients with severe allergic asthma the Guideline Committee suggests a therapeutic trial of omalizumab both in adults (**conditional recommendation, low quality evidence**) and in children (**conditional recommendation, very low quality evidence**).

##### *Values and Preferences*

This recommendation places higher value on the clinical benefits from omalizumab in some patients with severe allergic asthma and lower value on increased resource use.



asthma and lower value on increased resource use.

#### Remarks

Adults and children (aged  $\geq 6$  years) with severe asthma who are considered for a trial of omalizumab, should have confirmed IgE-dependent allergic asthma uncontrolled despite optimal pharmacological and non-pharmacological management and appropriate allergen avoidance, if their total serum IgE level is 30–700 IU·mL<sup>-1</sup> (in three studies the range was wider at 30–1300 IU·mL<sup>-1</sup>). Treatment response should be globally assessed by the treating physician taking into consideration any improvement in asthma control, reduction in exacerbations and unscheduled healthcare utilisation, and improvement in quality of life. If a patient does not respond within 4 months of initiating treatment, it is unlikely that further administration of omalizumab will be beneficial.

#### Question 5

Should methotrexate be used in the treatment of severe asthma?

#### Recommendation 5

The Guideline Committee suggests that clinicians do not use methotrexate in adults or children with severe asthma (**conditional recommendation, low quality evidence**).

#### Values and Preferences

This recommendation places a relatively higher value on avoiding adverse effects of methotrexate and a relatively lower value on possible benefits from reducing the dose of systemic corticosteroids.

#### Remarks

Evidence from randomised trials is only available for adults. Because of the probable adverse effects of methotrexate and need for monitoring therapy the Guideline Committee suggests that any use of methotrexate is limited to specialised centres and only in patients who require daily oral corticosteroids (OCS). If a decision to use methotrexate is made, a chest radiograph, complete blood count with differential and platelets, liver function tests, serum creatinine and transfer factor of the lung for carbon monoxide (DLCO), are recommended prior to and after commencing therapy.

#### Question 6

Should macrolide antibiotics be used in patients with severe asthma?

#### Recommendation 6

The Guideline Committee suggests that clinicians do not use macrolide antibiotics in adults and children with severe asthma for the treatment of asthma (**conditional recommendation, very low quality evidence**).

#### Values and Preferences

This recommendation places a relatively higher value on prevention of development of resistance to macrolide antibiotics, and relatively lower value on uncertain clinical benefits.

#### Remarks

This recommendation applies only to the treatment of asthma; it does not apply to the use of macrolide antibiotics for other indications, e.g., treatment of bronchitis, sinusitis or other bacterial infections as indicated.

#### Question 7

Should antifungal agents be used in patients with severe asthma?

#### Recommendation 7

The Guideline Committee suggests antifungal agents in adults with severe asthma and recurrent exacerbations of allergic bronchopulmonary aspergillosis (ABPA) (**conditional recommendation, very low quality evidence**).

The Guideline Committee suggests that clinicians do not use antifungal agents for the treatment of asthma in adults and children with severe asthma without ABPA irrespective of sensitisation to fungi (i.e., positive skin prick test or fungus-specific IgE in serum) (**conditional recommendation, very low quality evidence**).

#### Values and Preferences

The recommendation to use antifungal agents in patients with severe asthma and ABPA places a higher value on possible reduction of the risk of exacerbations and improved symptoms, and a lower value on avoiding possible adverse effects, drug interactions and increased use of resources.

The recommendation not to use antifungal agents in patients with severe asthma without confirmed ABPA (irrespective of sensitisation) places a higher value on avoiding possible adverse effects, interactions of antifungal agents with other medications and increased use of resources, and a lower value on uncertain possible benefits.

#### Remarks

The recommendation not to use antifungal agents in patients with severe asthma without confirmed ABPA applies only to the treatment of asthma; it does not apply to the use of antifungal agents for other indications, e.g., treatment of invasive fungal infections. In children, the evidence is limited to isolated case reports. Children should be treated with antifungals only after the most detailed evaluation in a specialist severe asthma referral centre. As antifungal therapies are associated with significant and sometimes severe side-effects, including hepatotoxicity, clinicians should be familiar with these drugs and follow relevant precautions in monitoring for these, observing the limits to the duration of treatment recommended for each.

#### Question 8

Should bronchial thermoplasty be used in patients with severe asthma?

#### Recommendation 8

The Guideline Committee recommends that bronchial thermoplasty is performed in adults with severe asthma only in the context of an Institutional Review Board-approved independent systematic registry or a clinical study (**strong recommendation, very low quality evidence**).

#### Values and Preferences

This recommendation places a higher value on avoiding adverse effects and on increased use of resources, and on a lack of understanding of which patients may benefit, and a lower value on the uncertain improvement in symptoms and quality of life.

**Remarks**

This is a strong recommendation, because of the very low confidence in the currently available estimates of effects of bronchial thermoplasty in patients with severe asthma. Both potential benefits and harms may be large and the long-term consequences of this new approach to asthma therapy utilising an invasive physical intervention are unknown. Specifically designed studies are needed to define its effects on relevant objective primary outcomes such as exacerbation rates, and on long-term effects on lung function. Studies are also needed to better understand the phenotypes of responding patients, its effects in patients with severe obstructive asthma (forced expiratory volume in 1 second [FEV<sub>1</sub>] <60% of predicted value) or in whom systemic corticosteroids are used, and its long-term benefits and safety. Further research is likely to have an important impact on this recommendation.

**Definitions:**

**Quality of Evidence**

Quality of evidence (confidence in the available estimates of treatment effects) is categorized according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) as: high, moderate, low or very low based on consideration of risk of bias, directness, consistency and precision of the estimates. Low and very low quality evidence indicates that the estimated effects of interventions are very uncertain and further research is very likely to have an important impact on resulting recommendations.

**Strength of Recommendations**

Implications for	Strong Recommendation	Conditional Recommendation
<b>Patients</b>	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
<b>Clinicians</b>	Most individuals should receive the intervention. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
<b>Policy Makers</b>	The recommendation can be adopted as policy in most situations.	Policy making will require substantial debate and involvement of various stakeholders.

**Clinical Algorithm(s)**

None provided

**Evidence Supporting the Recommendations**

**Type of Evidence Supporting the Recommendations**

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

**Benefits/Harms of Implementing the Guideline Recommendations**

**Potential Benefits**

- Appropriate management of patients with severe asthma
- Both potential benefits and harms may be large and the long-term consequences of this new approach to asthma therapy utilising an invasive physical intervention are unknown.
- See the "Values and Preferences" sections in the original guideline document for more information on benefits vs harms.

**Potential Harms**

- The downside of chest high-resolution computed tomography (HRCT) include the risks associated with an exposure to radiation burden and psychological stress, and increased resource expenditure. Patients with falsely positive results of chest HRCT may suffer additional harm from subsequent unnecessary diagnostic and therapeutic procedures.
- In 3 studies, bronchial thermoplasty increased the risk of hospitalization (relative risk [RR]: 2.3, 95% confidence interval [CI]: 1.3–3.9). All 3 studies reported only "respiratory adverse effects"; no study reported overall adverse effects or overall serious adverse effects. Bronchial thermoplasty increased the risk of respiratory adverse effects in the initial treatment phase (RR: 1.13, 95% CI: 0.99–1.28 [number of patients with at least 1 adverse event]; rate ratio: 3.3, 95% CI: 2.4–4.5 [number of adverse events]), irrespective of their severity.
- Antifungal therapies are associated with significant and sometimes severe side-effects, including hepatotoxicity, clinicians should be familiar with these drugs and follow relevant precautions in monitoring for these, observing the limits to the duration of treatment recommended for each.
- Both potential benefits and harms may be large and the long-term consequences of this new approach to asthma therapy utilising an invasive physical intervention are unknown.
- See the "Values and Preferences" sections in the original guideline document for more information on benefits vs harms.

## Qualifying Statements

### Qualifying Statements

The European Respiratory Society (ERS)/American Thoracic Society (ATS) guidelines about the management of severe asthma are not intended to impose a standard of care. They provide the basis for rational decisions in the management of severe asthma. Clinicians, patients, third-party payers, institutional review committees, other stakeholders, or the courts should never view these recommendations as dictates. No guidelines and recommendations can take into account all of the often-compelling unique individual clinical circumstances. Therefore, no one charged with evaluating clinicians' actions should attempt to apply the recommendations from these guidelines by rote or in a blanket fashion. Statements about the underlying values and preferences as well as qualifying remarks accompanying each recommendation are integral parts and serve to facilitate more accurate interpretation. They should never be omitted when quoting or translating recommendations from these guidelines.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness


### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, Adcock IM, Bateman ED, Bel EH, Bleecker ER, Boulet LP, Brightling C, Chaney P, Dahlen SE, Djukanovic R, Frey U, Gaga M, Gibson P, Hamid Q, Jajour NN, Mauad T, Sorkness RL, Teague WG. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014 Feb 1;43(2):343-73. [223 references] [PubMed](#) 

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2014 Feb 1

### Guideline Developer(s)

American Thoracic Society - Medical Specialty Society

European Respiratory Society - Professional Association

### Source(s) of Funding

The American Thoracic Society (ATS) and European Respiratory Society (ERS) provided meeting facilities during their annual conferences and financial support for conference calls. The views and interests of the ATS and ERS as well as of any commercial entity that provided external funding for both professional societies had no influence on the final recommendations.

### Guideline Committee

European Respiratory Society (ERS)/American Thoracic Society (ATS) Task Force on Severe Asthma

### Composition of Group That Authored the Guideline

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### Financial Disclosures/Conflicts of Interest

Committee members disclosed all potential conflicts of interest according to the American Thoracic Society (ATS) and European Respiratory Society (ERS) policies. The Guideline Committee chairs (K.F.C and S.E.W.) reviewed and resolved all potential conflicts of interest of committee members. All potential conflicts of interest (including those of the chairs) were discussed with the chair of the Ethics and Conflict of Interest Committee of the ATS. During all deliberations, members with perceived conflicts of interest abstained from decisions about specific recommendations related to the potential conflict of interest. The ATS methodologist (J.L.B.) did not participate in the vote on any of the recommendations.

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

### Guideline Availability

Electronic copies: Available from the [European Respiratory Journal Web site](#).

### Availability of Companion Documents

The full text of the guideline and supplemental appendices 1, 2, and 3 are available from the [European Respiratory Journal Web site](#).

### Patient Resources

The following is available:

- Severe asthma. Understanding the professional guidelines. Patient version. 2014. 8 p. Electronic copies: Available from the [European Respiratory Society Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

### NGC Status

This NGC summary was completed by ECRI Institute on October 9, 2014. The information was verified by the guideline developer on November 25, 2014.

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