Complete Summary

GUIDELINE TITLE

Managing asthma long term in youths ≥12 years of age and Adults: Expert panel report 3: guidelines for the diagnosis and management of asthma.

BIBLIOGRAPHIC SOURCE(S)

Managing asthma long term in youths >=12 years of age and adults. In: National Asthma Education and Prevention Program (NAEPP). Expert panel report 3: guidelines for the diagnosis and management of asthma. Bethesda (MD): National Heart, Lung, and Blood Institute; 2007 Aug. p. 326-62. [103 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: National Asthma Education and Prevention Program Expert Panel Report: guidelines for the diagnosis and management of asthma update on selected topics-2002. J Allergy Clin Immunol 2002 Nov;110(5 pt 2):S141-219.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 21, 2007, Xolair (Omalizumab): New reports of serious and life-threatening allergic reactions (anaphylaxis) in patients after treatment with Xolair.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Asthma

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Emergency Medicine
Family Practice
Geriatrics
Internal Medicine
Pediatrics
Preventive Medicine
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Plans
Nurses
Physician Assistants
Physicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

- To present recommendations for the diagnosis and management of asthma that will help clinicians and patients make appropriate decisions about asthma care
- To develop clinical practice tools and educational materials for patients and the public
- To revise the National Asthma Education and Prevention Program Expert Panel Report-2 Stepwise Approach for Managing Asthma in order to incorporate findings from the review of the scientific evidence
- To present recommendations on the long-term management of asthma in youths $\geq$12 years of age and adults

TARGET POPULATION

Youths ≥12 years of age and adults with asthma

INTERVENTIONS AND PRACTICES CONSIDERED

1. Stepwise approach to pharmacologic therapy to control asthma
2. Pharmacologic options
    - Long-term control medications
        - Corticosteroids (inhaled or systemic)
        - Cromolyn sodium and nedocromil
        - Immunomodulators
        - Leukotriene receptor antagonists
        - Long-acting beta$_2$-agonist(s)
        - Methylxanthines
    - Quick-relief medications
        - Anticholinergics
        - Short-acting beta$_2$-agonist(s)
        - Systemic corticosteroids
3. Monitoring and follow-up
4. Patient education
5. Written asthma action plan
6. Referral to specialist

MAJOR OUTCOMES CONSIDERED

- Lung function measurements
    - Forced expiratory volume in one second (FEV_1)
    - Peak expiratory flow (PEF)
- Symptom control as indicated by:
    - Symptom scores
    - Symptom frequency
    - Use of acute bronchodilator medication
    - Exacerbations
    - Use of oral corticosteroids

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In October 2004, the Expert Panel assembled for its first meeting. Using the Expert Panel Report (EPR)—2 1997 and EPR—Update 2002 as the framework, the Expert Panel organized the literature searches and subsequent report around the four essential components of asthma care, namely: (1) assessment and monitoring, (2) patient education, (3) control of factors contributing to asthma

severity, and (4) pharmacologic treatment. Subtopics were developed for each of these four broad categories.

Inclusion/Exclusion Criteria

The literature review was conducted in three cycles over an 18-month period (September 2004 to March 2006). Search strategies for the literature review initially were designed to cast a wide net but later were refined by using publication type limits and additional terms to produce results that more closely matched the framework of topics and subtopics selected by the Expert Panel. The searches included human studies with abstracts that were published in English in peer-reviewed medical journals in the MEDLINE database. Two timeframes were used for the searches, dependent on topic: January 1, 2001, through March 15, 2006, for pharmacotherapy (medications), peak flow monitoring, and written action plans, because these topics were recently reviewed in the EPR—Update 2002; and January 1, 1997, through March 15, 2006, for all other topics, because these topics were last reviewed in the EPR—2 1997.

Search Strategies

Panel members identified, with input from a librarian, key text words for each of the four components of care. A separate search strategy was developed for each of the four components and various key subtopics when deemed appropriate. The key text words and Medical Subject Headings (MeSH) terms that were used to develop each search string are found in an appendix posted on the National Heart, Lung, and Blood Institute (NHLBI) Web site.

Literature Review Process

The systematic review covered a wide range of topics. Although the overarching framework for the review was based on the four essential components of asthma care, multiple subtopics were associated with each component. To organize a review of such an expanse, the Panel was divided into 10 committees, with about 4 to 7 reviewers in each (all reviewers were assigned to 2 or more committees). Within each committee, teams of two ("topic teams") were assigned as leads to cover specific topics. A system of independent review and vote by each of the two team reviewers was used at each step of the literature review process to identify studies to include in the guidelines update. The initial step in the literature review process was to screen titles from the searches for relevancy in updating content of the guidelines, followed by reviews of abstracts of the relevant titles to identify those studies meriting full-text review based on relevance to the guidelines and study quality.

The combined number of titles screened from cycles 1, 2, and 3 was 15,444. The number of abstracts and articles reviewed for all three cycles was 4,747. Of these, 2,863 were voted to the abstract Keep list following the abstract-review step. A database of these abstracts is posted on the NHLBI Web site. Of these abstracts, 2,122 were advanced for full-text review, which resulted in 1,654 articles serving as a bibliography of references used to update the guidelines, available on the NHLBI Web site. Articles were selected from this bibliography for evidence tables and/or citation in the text. In addition, articles reporting new and particularly relevant findings and published after March 2006 were identified by Panel

members during the writing period (March 2006–December 2006) and by comments received from the public review in February 2007.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

The system* used to describe the level of evidence is as follows:

Evidence Category A: Randomized controlled trials (RCTs), rich body of data.
Evidence is from end points of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants.

Evidence Category B: RCTs, limited body of data.
Evidence is from end points of intervention studies that include only a limited number of patients, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, category B pertains when few randomized trials exist; they are small in size, they were undertaken in a population that differs from the target population of the recommendation, or the results are somewhat inconsistent.

Evidence Category C: Nonrandomized trials and observational studies.
Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.

Evidence Category D: Panel consensus judgment.
This category is used only in cases where the provision of some guidance was deemed valuable, but the clinical literature addressing the subject was insufficient to justify placement in one of the other categories. The Panel consensus is based on clinical experience or knowledge that does not meet the criteria for categories A through C.

*Source: Jadad AR, Moher M, Browman GP, Booker L, Sigouin C, Fuentes M, Stevens R. Systematic reviews and meta-analyses on treatment of asthma: critical evaluation. *BMJ* 2000;320(7234):537-40.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Preparation of Evidence Tables

Evidence tables were prepared for selected topics. It was not feasible to generate evidence tables for every topic in the guidelines. Furthermore, many topics did not have a sufficient body of evidence or a sufficient number of high-quality studies to warrant the preparation of a table. The Panel decided to prepare evidence tables on those topics for which an evidence table would be particularly useful to assess the weight of the evidence—e.g., topics with numerous articles, conflicting evidence, or which addressed questions raised frequently by clinicians. Summary findings on topics without evidence tables, however, also are included in the updated guidelines text. Evidence tables were prepared with the assistance of a methodologist who served as a consultant to the Expert Panel. Within their respective committees, Expert Panel members selected the topics and articles for evidence tables. The evidence tables included all articles that received a "yes" vote from both the primary and secondary reviewer during the systematic literature review process. The methodologist abstracted the articles to the tables, using a template developed by the Expert Panel. The Expert Panel subsequently reviewed and approved the final evidence tables. A total of 20 tables, comprising 316 articles are included in the current update. Evidence tables are posted on the National Heart, Lung, and Blood Institute (NHLBI) Web site.

Ranking the Evidence

The Expert Panel agreed to specify the level of evidence used to justify the recommendations being made. Panel members only included ranking of evidence for recommendations they made based on the scientific literature in the current evidence review. They did not assign evidence rankings to recommendations pulled through from the Expert Panel Report (EPR)—2 1997 on topics that are still important to the diagnosis and management of asthma but for which there was little new published literature. These "pull through" recommendations are designated by EPR—2 1997 in parentheses following the first mention of the recommendation. For recommendations that have been either revised or further substantiated on the basis of the evidence review conducted for the EPR—3: Full Report 2007, the level of evidence is indicated in the text in parentheses following first mention of the recommendation. Refer to the "Rating Scheme for the Strength of the Evidence" for the system used to describe the level of evidence.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The steps used to develop this report include: (1) completing a comprehensive search of the literature; (2) conducting an in-depth review of relevant abstracts and articles; (3) preparing evidence tables to assess the weight of current evidence with respect to past recommendations and new and unresolved issues; (4) conducting thoughtful discussion and interpretation of findings; (5) ranking strength of evidence underlying the current recommendations that are made; (6) updating text, tables, figures, and references of the existing guidelines with new findings from the evidence review; (7) circulating a draft of the updated guidelines

through several layers of external review, as well as posting it on the National Heart, Lung, and Blood Institute (NHLBI) Web site for review and comment by the public and the National Asthma Education and Prevention Program Coordinating Committee (NAEPP CC), and (8) preparing a final-report based on consideration of comments raised in the review cycle.

Panel Discussion

The first opportunity for discussion of findings occurred within the "topic teams." Teams then presented a summary of their findings during a conference call to all members of their respective committee. A full discussion ensued on each topic, and the committee arrived at a consensus position. Teams then presented their findings and the committee position to the full Expert Panel at an in-person meeting, thereby engaging all Panel members in critical analysis of the evidence and interpretation of the data. A series of conference calls for each of the 10 committees as well as four in-person Expert Panel meetings (held in October 2004, April 2005, December 2005, and May 2006) were scheduled to facilitate discussion of findings and to dovetail with the three cycles of literature review that occurred over the 18-month period. Potential conflicts of interest were disclosed at the initial meeting.

Report Preparation

Development of the Expert Panel Report (EPR)—3: Full Report 2007 was an iterative process of interpreting the evidence, drafting summary statements, and reviewing comments from the various external reviews before completing the final report. In the summer and fall of 2005, the various topic teams, through conference calls and subsequent electronic mail, began drafting their assigned sections of the report. Members of the respective committees reviewed and revised team drafts, also by using conference calls and electronic mail. During the calls, votes were taken to ensure agreement with final conclusions and recommendations.

During the December 2005 meeting, Panel members reviewed and discussed all committee drafts. During the May 2006 meeting, the Panel conducted a thorough review and discussion of the report and reached consensus on the recommendations. For controversial topics, votes were taken to ensure that each individual's opinion was considered.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

In addition to specifying the level of evidence supporting a recommendation, the Expert Panel agreed to indicate the strength of the recommendation. When a certain clinical practice "is recommended," this indicates a strong recommendation by the panel. When a certain clinical practice "should, or may, be considered," this indicates that the recommendation is less strong.

This distinction is an effort to address nuances of using evidence ranking systems. For example, a recommendation for which clinical randomized controlled trial data are not available (e.g., conducting a medical history for symptoms suggestive of asthma) may still be strongly supported by the Panel. Furthermore, the range of evidence that qualifies a definition of "B" or "C" is wide, and the Expert Panel

considered this range and the potential implications of a recommendation as they decided how strongly the recommendation should be presented.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

In July, using conference calls and electronic mail, the Panel completed a draft of the Expert Panel Report (EPR)—3: Full Report 2007 for submission in July/August to a panel of expert consultants for their review and comments. In response to their comments, a revised draft of the EPR—3: Full Report 2007 was developed and circulated in November to the National Asthma Education and Prevention Program (NAEPP) Guidelines Implementation Panel (GIP) for their comment. This draft was also posted on the National Heart Lung and Blood Institute (NHLBI) Web site for public comment in February 2007. The Expert Panel considered 721 comments from 140 reviewers. Edits were made to the documents, as appropriate, before the full EPR—3: Full Report 2007 was finalized and published.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of the evidence (A, B, C, D) and strength of recommendations ("is recommended" and "should or may, be considered") are presented at the end of the "Major Recommendations" field.

Note from the National Asthma Education and Prevention Program (NAEPP): Panel members only included ranking of evidence for recommendations they made based on the scientific literature in the current evidence review. They did not assign evidence rankings to recommendations pulled through from the Expert Panel Report (EPR)—2 1997 on topics that are still important to the diagnosis and management of asthma but for which there was little new published literature. These "pull through" recommendations are designated by EPR—2 1997 in parentheses following the first mention of the recommendation.

Note from the NAEPP and the National Guideline Clearinghouse (NGC): The Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma have been divided into individual summaries covering assessment, education, medications, and management. In addition to the current summary, the following are available:

- Measures of asthma assessment and monitoring.
- Education for a partnership in asthma care.
- Control of environmental factors and comorbid conditions that affect asthma.

- Medications.
- Managing asthma long term in children 0-4 years of age and 5-11 years of age.
- Managing asthma long term—special situations
- Managing exacerbations of asthma.

Key Points: Managing Asthma Long Term in Youths >12 Years of Age and Adults

- The goal for therapy is to control asthma by **(Evidence A)**:
    - Reducing impairment
        - Prevent chronic and troublesome symptoms (e.g., coughing or breathlessness in the daytime, in the night, or after exertion)
        - Require infrequent use ($\leq$2 days a week) of inhaled short-acting beta$_2$-agonist (SABA) for quick relief of symptoms
        - Maintain (near) normal pulmonary function
        - Maintain normal activity levels (including exercise and other physical activity and attendance at work or school)
        - Meet patients' and families' expectations of and satisfaction with asthma care
    - Reducing risk
        - Prevent recurrent exacerbations of asthma and minimize the need for emergency department (ED) visits or hospitalizations
        - Prevent progressive loss of lung function; for children, prevent reduced lung growth
        - Provide optimal pharmacotherapy with minimal or no adverse effects
- A stepwise approach to pharmacologic therapy is recommended to gain and maintain control of asthma in both the impairment and risk domains **(Evidence A)**:
    - The type, amount, and scheduling of medication is dictated by asthma severity for initiating therapy and the level of asthma control for adjusting therapy **(Evidence A)**.
    - Step-down therapy is essential to identify the minimum medication necessary to maintain control **(Evidence D)**.
- Monitoring and follow up is essential **(Evidence B)**.
    - When initiating therapy, monitor at 2- to 6-week intervals to ensure that asthma control is achieved **(Evidence D)**.
    - Regular follow up contacts at 1- to 6-month intervals, depending on level of control, are recommended to ensure that control is maintained and the appropriate adjustments in therapy are made: step up if necessary or step down if possible. Consider 3-month intervals if a step down in therapy is anticipated **(Evidence D)**.
- Because asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, persistent asthma is most effectively controlled with daily long-term control medication, specifically, anti-inflammatory therapy **(Evidence A)**.
    - Inhaled corticosteroids (ICSs) are the preferred treatment option for initiating long-term control therapy **(Evidence A)**.
    - Selection of an alternative treatment option includes consideration of treatment effectiveness, the domain of particular relevance to the patient (impairment, risk, or both), the individual patient's history of

previous response to therapies, the ability of the patient and family to use the medication correctly, and anticipated patient's and family's adherence to the treatment regime **(Evidence D)**.

- Therapeutic strategies should be considered in concert with clinician-patient partnership strategies; education of patients is essential for achieving optimal pharmacologic therapy **(Evidence A)**.
- At each step, patients should be advised to avoid or control allergens **(Evidence A)**, irritants, or comorbid conditions that make the patient's asthma worse **(Evidence B)**.
- A written asthma action plan detailing for the individual patient the daily management (medications and environmental control strategies) and how to recognize and handle worsening asthma is recommended for all patients; written asthma action plans are particularly recommended for patients who have moderate or severe persistent asthma, a history of severe exacerbations, or poorly controlled asthma **(Evidence B)**. The written asthma action plan can be either symptom or peak-flow based; evidence shows similar benefits for each **(Evidence B)**.
- Referral to an asthma specialist for consultation or comanagement is recommended if there are difficulties achieving or maintaining control of asthma; if the patient requires step 4 care or higher; if immunotherapy or omalizumab are considered; or if the patient has had an exacerbation requiring hospitalization. Consider referral if the patient requires step 3 care **(Evidence D)**.
- Special considerations for youths **(EPR—2 1997)**:
    - Pulmonary function testing should use appropriate reference populations. Adolescents compare better to childhood than to adult predicted norms.
    - Adolescents (and younger children as appropriate) should be directly involved in establishing goals for therapy and developing their asthma management plans.
    - Active participation in physical activities, exercise, and sports should be promoted.
    - A written asthma management plan should be prepared for the student's school, including plans to ensure reliable, prompt access to medications. Either encourage parents to take a copy to the child's school or obtain parental permission and send a copy to the school nurse or designee.
- Special considerations for older adults **(EPR—2 1997)**:
    - Chronic bronchitis/emphysema may coexist with asthma. A trial of systemic corticosteroids will determine the presence of reversibility and the extent of therapeutic benefit.
    - Asthma medications may aggravate coexisting medical conditions (e.g., cardiac disease, osteoporosis); adjustments in the medication plan may be necessary.
    - Be aware of increased potential for adverse drug/disease interaction (e.g., aspirin, beta-blockers).
    - Review of patient technique in using medications and devices is essential; physical (e.g., arthritis or visual) or cognitive impairments may make proper technique difficult.

Treatment: Principles of Stepwise Therapy in Youths ≥12 Years of Age and Adults

The Expert Panel recommends that the goal of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimal risk for adverse effects **(Evidence A)**. Control of asthma is viewed in the context of two domains, impairment and risk, and is defined as:

- Reducing impairment
    - Prevent chronic and troublesome symptoms (e.g., coughing or breathlessness in the daytime, in the night, or after exertion)
    - Require infrequent use ($\leq$2 days a week) of SABA for quick relief of symptoms
    - Maintain (near) normal pulmonary function
    - Maintain normal activity levels (including exercise and other physical activity and attendance at work or school)
    - Meet patients' and families' expectations of and satisfaction with asthma care
- Reducing risk
    - Prevent recurrent exacerbations of asthma, and minimize the need for ED visits or hospitalizations
    - Prevent progressive loss of lung function; for youths, prevent reduced lung growth
    - Provide optimal pharmacotherapy with minimal or no adverse effects

Achieving Control of Asthma

Selecting Initial Therapy for Patients Not Currently Taking Long-Term Control Medications

The Expert Panel recommends the following actions to achieve asthma control in patients who are not currently taking long-term control medications.

- Assess asthma severity **(EPR—2 1997)**. Asthma severity is based on measurements of impairment and risk; (See figure 4–6 in the original guideline document and the discussion in the NGC summary of the NAEPP guideline Measures of Asthma Assessment and Monitoring).
- Select treatment that corresponds to the patient's level of asthma severity **(EPR—2 1997)**. (See the following in the original guideline document: figure 4–6 for the recommended step of care at different levels of severity; figure 4–5 for treatment options at each step of care; and figures 4–8 a, b, and c for usual dosages of medications.)
- If at a follow up visit in 2 to 6 weeks after starting treatment, depending on severity, asthma is not well controlled (see below), then treatment should be advanced to the next step. If uncontrolled asthma persists, then the diagnosis should be reevaluated, and, if confirmed, treatment should be advanced another step **(Evidence D)**.

Adjusting Therapy

The Expert Panel recommends that, once therapy is selected, or if the clinician sees a patient for the first time who is already taking a long-term control medication, treatment decisions are based on the level of the patient's asthma control (See figure 4–7 in the original guideline document.) **(Evidence A)**.

- Assess asthma control. As in assessment of asthma severity, asthma control can be considered in terms of impairment and risk domains **(Evidence C)**. Both domains should be addressed to select appropriate therapy; the level of control is generally judged on the most severe indicator of impairment or risk **(Evidence D)**.

Impairment Domain

This domain is multifactorial because the different manifestations of asthma do not necessarily correlate with each other, and each factor should be assessed if possible **(Evidence C)**.

Risk Domain

- Adjust therapy based on level of asthma control **(Evidence A)**. The following considerations will guide selection of therapy based on level of asthma control. Classify current level of asthma control, generally, by the most severe indicator of impairment or risk (See figure 4–7 in the original guideline document.) **(Evidence D)**.
    - If the patient's asthma is not well controlled:
        - Identify the patient's current treatment step (See figure 4–5 in the original guideline document), based on what he or she is actually taking. In general, step up one step for patients whose asthma is not well controlled. For patients who have very poorly controlled asthma, consider increasing by two steps, a course of oral corticosteroids, or both. Before increasing pharmacologic therapy, consider poor inhaler technique, adverse environmental exposures, poor adherence, or comorbidities as targets for intervention.
        - If the office spirometry suggests worse control than does the assessment of impairment based on other measures, (1) consider fixed airway obstruction as the explanation (Aburuz et al., 2005) (See the NGC summary of the NAEPP guideline, Measures of Asthma Assessment and Monitoring), and use changes from percent personal best rather than percent predicted to guide therapy; (2) reassess the other measures of impairment; and (3) if fixed airway obstruction does not appear to be the explanation, consider a step up in therapy especially if the patient has a history of frequent moderate or severe exacerbations.
        - If the history of exacerbations suggests poorer control than does the assessment of impairment, (1) reassess impairment; (2) review control of factors capable of making asthma worse (e.g., lack of adherence, adverse environmental exposure, or comorbidities); (3) review the written action plan, and be sure it includes oral prednisone for patients who have histories of severe exacerbations; and (4) consider a step up in therapy, especially if the patient has reduced forced expiratory volume in 1 second (FEV_1).
        - For troublesome or debilitating side effects, explore a change in therapy. In addition, confirm maximal efforts to control factors capable of making asthma worse. (See the NGC summary of

the NAEPP guideline, Control of Environmental Factors and Comorbid Conditions That Affect Asthma).
    - After treatment is adjusted, reevaluate in 2 to 6 weeks, depending on the level of control.
- If the patient's asthma is well controlled, see the following section on "Maintaining Control of Asthma."

Maintaining Control of Asthma

The Expert Panel recommends that regular follow up contact is essential **(Evidence B)**. Contact at 1- to 6-month intervals is recommended, depending on the level of control; consider 3-month intervals if a step down in therapy is anticipated **(Evidence D)**.

The Expert Panel recommends that, once asthma is well controlled and the control is achieved and maintained for at least 3 months, a reduction in pharmacologic therapy—a step down—can be considered. This will be helpful to identify the minimum therapy for maintaining good control of asthma **(Evidence D)**.

The Expert Panel recommends that, if asthma control is not achieved and maintained at any step of care (See figure 4–7 in the original guideline document.), several actions may be considered:

- Patient adherence and technique in using medications correctly should be assessed **(Evidence B)**. (See the NGC summary of the NAEPP guideline, Education for a Partnership in Asthma Care for discussion on assessing adherence.)
- A temporary increase in anti-inflammatory therapy may be indicated to reestablish asthma control **(Evidence D)**.
- Other factors that diminish control may have to be identified and addressed **(Evidence C)**.
- A step up to the next higher step of care may be necessary **(Evidence A)**.
- Consultation with an asthma specialist may be indicated (See the NGC summary of the NAEPP guideline, Measures of Asthma Assessment and Monitoring) **(Evidence D)**. The Expert Panel recommends referral to an asthma specialist for consultation or comanagement if: there are difficulties achieving or maintaining control of asthma; immunotherapy or omalizumab is being considered; the patient requires step 4 care or higher; or the patient has had an exacerbation requiring a hospitalization. Referral may be *considered* if a patient requires step 3 care **(Evidence D)**.

Treatment: Pharmacologic Steps

The Expert Panel recommends that specific therapy should be tailored to the needs and circumstances of individual patients. Pharmacologic therapy must be accompanied at every step by patient education and measures to control those environmental factors or comorbid conditions that can make asthma worse **(EPR—2 1997)**. (See the NGC summaries of the NAEPP guidelines, Control of Environmental Factors and Comorbid Conditions That Affect Asthma which includes discussion of the role of allergen immunotherapy, and Education for a Partnership in Asthma Care. Figure 4–5 in the original guideline document

presents treatment options for the stepwise approach for managing asthma youths ≥12 years of age and adults.

Note: The recommendations for steps of pharmacologic therapy are intended to be general guidelines for assisting, not replacing, clinical decision making. The recommendations are not intended to be prescriptions for individual treatment.

Intermittent Asthma

The Expert Panel recommends the following therapy for intermittent asthma:

Step 1 Care

- SABA taken as needed to treat symptoms is usually sufficient therapy for intermittent asthma **(EPR—2 1997)**.
- Patients who have intermittent asthma and experience exercise-induced bronchospasm (EIB) benefit from taking SABA, cromolyn, or nedocromil shortly before exercise **(EPR—2 1997)** (See "Exercise-Induced Bronchospasm" in the NGC summary of the NAEPP guideline, Managing Asthma Long Term—Special Situations).
- The following actions for managing exacerbations due to viral respiratory infections are recommended **(EPR—2 1997)**.
    - If the symptoms are mild, SABA (every 4 to 6 hours for 24 hours, longer with a physician consult) may be sufficient to control symptoms and improve lung function.
    - If this therapy must be repeated more frequently than every 6 weeks, a step up in long-term care is recommended.
    - If the viral respiratory infection provokes a moderate-to-severe exacerbation, a short course of systemic corticosteroids should be considered.
    - For those patients who have a history of severe exacerbations with viral respiratory infections, systemic corticosteroids should be considered at the first sign of the infection.
- A detailed written asthma action plan is recommended for those patients who have intermittent asthma and particularly those who have a history of severe exacerbations **(Evidence B)** (See the NGC summary of the NAEPP guideline, Education for a Partnership in Asthma Care).

Persistent Asthma

The Expert Panel recommends the following therapy for persistent asthma:

- Daily long-term control medication is recommended for patients who have persistent asthma. The long-term control medication should be one with anti-inflammatory effects. Of the available medications, ICSs are the most effective single agents **(Evidence A)** (see the NGC summary of the NAEPP guideline, Medications).
- Quick-relief medication must be available to all patients who have persistent asthma. SABA should be taken as needed to relieve symptoms **(EPR—2 1997)**. The intensity of treatment will depend on the severity of the

exacerbation (See the NGC summary of the NAEPP guideline Managing Exacerbations of Asthma).

- Consider treating patients who may have seasonal asthma (asthma symptoms only in relation to certain seasonal molds or pollens with few symptoms the rest of the year) as having persistent asthma during the season and as having intermittent asthma the rest of the year. Confirm characteristics of intermittent asthma out of season **(Evidence D)**.
- Consider treating patients who had two or more exacerbations requiring oral corticosteroids in the past year the same as patients who have persistent asthma, even in the absence of an impairment level consistent with persistent asthma **(Evidence D)**.

Step 2 Care, Long-Term Control Medication

- Preferred treatment for step 2 care is daily ICS at a low dose **(Evidence A)**.
- Alternative, but not preferred, treatments include (listed alphabetically) cromolyn, leukotriene receptor antagonist (LTRA), nedocromil **(Evidence A)**, and sustained release theophylline **(Evidence B)**. There is insufficient evidence to recommend long-acting beta$_2$-agonists (LABA) in combination with ICS for step 2 therapy.

Step 3 Care, Long-Term Control Medications

- Consultation with an asthma specialist may be considered because the therapeutic options at this juncture pose a number of challenging risk/benefit considerations **(Evidence D)**. Before increasing therapy, however, the clinician should review the patient's inhaler technique and adherence to therapy **(Evidence B)**, as well as determine whether environmental factors, particularly allergens **(Evidence A)**, or comorbid conditions are contributing to the patient's worsening asthma **(Evidence C)**.
- Preferred step 3 care options: Two equally acceptable options are available, given the consideration of both benefits and risks for each.
    - Add a LABA to a low dose of ICS **(Evidence A)** (See Component 4 Medications, section on "Safety of Long-Acting Beta$_2$-Agonists," for a complete discussion.
        - The Expert Panel recommends that the established, beneficial effects of LABAs for the great majority of patients who have asthma not sufficiently controlled with ICS therapy alone be weighed carefully against the increased risk for potentially deleterious, although uncommon, side effects associated with the daily use of LABAs.
        - Therefore, the Expert Panel has modified its previous recommendation (EPR—Update 2002) and has now concluded that, for patients who have asthma not sufficiently controlled with a low-dose ICS alone, the step-up option to increase the ICS dose should be given equal weight to that of the addition of a LABA to ICS.

    OR

    - Continue the ICS as monotherapy by increasing the dose to the medium-dose range **(Evidence A)**.

- Alternative, but not preferred, step 3 therapy is to add (listed alphabetically) an LTRA **(Evidence A)**, theophylline **(Evidence B)**, or zileuton **(Evidence D)** to low-dose ICS.
- If an alternative, but not preferred, treatment is initially administered and does not lead to improvement in asthma control, discontinue it and use a preferred step 3 option before stepping up to step 4 **(Evidence D)**.

Step 4 Care, Long-Term Control Medications

- The preferred option is to increase the dose of ICS to the medium-dose range AND add a LABA **(Evidence B)**.
- Alternative, but not preferred, step 4 therapy includes medium-dose ICS AND either LTRA or theophylline **(Evidence B)**, or zileuton **(Evidence D)**.
- If the add-on therapy initially administered does not lead to improvement in asthma control, discontinue it and consider a trial of a different add-on therapy before stepping up **(Evidence D)**.

Step 5 Care, Long-Term Control Medications

- High-dose ICS and LABA is the preferred treatment **(Evidence B)**.
- Omalizumab may be considered at this step for patients who have sensitivity to relevant perennial allergens (e.g., dust mites, cockroach, cat, or dog) **(Evidence B)** (Bousquet et al., 2004; Humbert et al., 2005).
- Clinicians who administer omalizumab are advised to be prepared and equipped for the identification and treatment of anaphylaxis that may occur, to observe patients for an appropriate period of time following each omalizumab injection (the optimal length of the observation is not established), and to educate patients about the risks of anaphylaxis and how to recognize and treat it if it occurs (e.g., using prescription auto injectors for emergency self-treatment, and seeking immediate medical care) (see "FDA Warning/Regulatory Alert" field).
- Consultation with an asthma specialist is recommended for patients who require this step of therapy **(Evidence D)**.

Step 6 Care, Long-Term Control Medications

- Add oral corticosteroids to step 5 therapy. Patients who are not controlled on step 5 therapy may require regular oral corticosteroids to achieve well-controlled asthma **(EPR—2 1997)**.

Special Issues for Adolescents

The Expert Panel recommends that the pharmacologic management of asthma in school-age children and adolescents follows the same basic principles as those for adults, but the special circumstances of school and social development require special consideration **(EP—2 1997)**.

Assessment Issues

The Expert Panel recommends that pulmonary function testing should be performed by using comparison data from an appropriate reference population ("Standardization of spirometry," 1995; **EPR—2 1997**).

Treatment Issues

The Expert Panel recommends that adolescents (and younger children as appropriate) be directly involved in developing their written asthma action plans (See the NGC summary of the NAEPP guideline, Education for a Partnership in Asthma Care).

School Issues

The Expert Panel recommends that the clinician prepare a written asthma action plan for the student's school. Either encourage the youth or the parents to take a copy of the plan to the youth's school or obtain parental permission and send a copy to the school nurse or designee **(Evidence C)**.

Sports Issues

The Expert Panel recommends that clinicians encourage full participation in physical activities; physical activity at play or in organized sports is an essential part of a child's life **(EPR—2 1997)**.

Special Issues for Older Adults

Assessment Issues

The Expert Panel recommends that the extent of reversible airflow obstruction be determined because of the high prevalence of other obstructive lung disease (e.g., chronic bronchitis, emphysema) among the elderly **(EPR—2 1997)**.

Treatment Issues

The Expert Panel recommends that adjustments in therapy may be necessary because asthma medications may have increased adverse effects in the elderly patient **(EPR—2 1997)**.

- Inhaled corticosteroid. Consider concurrent treatments with calcium supplements and vitamin D, and bone-sparing medications (e.g., bisphosphonates) in patients who have risk factors for osteoporosis or low bone mineral density **(Evidence D)**.

The Expert Panel recommends that medications taken for other diseases and conditions be adjusted as necessary, because some medications may exacerbate asthma **(EPR—2 1997)**. (See the NGC summary of the NAEPP guideline, Medications for more details on drugs that can complicate asthma management.)

The Expert Panel recommends that review of the patient's technique in using medications and devices is essential **(Evidence B)**.

Definitions:

Levels of Evidence

The system* used to describe the level of evidence is as follows:

Evidence Category A: Randomized controlled trials (RCTs), rich body of data.
Evidence is from end points of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants.

Evidence Category B: RCTs, limited body of data.
Evidence is from end points of intervention studies that include only a limited number of patients, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, category B pertains when few randomized trials exist; they are small in size, they were undertaken in a population that differs from the target population of the recommendation, or the results are somewhat inconsistent.

Evidence Category C: Nonrandomized trials and observational studies.
Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.

Evidence Category D: Panel consensus judgment.
This category is used only in cases where the provision of some guidance was deemed valuable, but the clinical literature addressing the subject was insufficient to justify placement in one of the other categories. The Panel consensus is based on clinical experience or knowledge that does not meet the criteria for categories A through C.

*Source: Jadad AR, Moher M, Browman GP, Booker L, Sigouin C, Fuentes M, Stevens R. Systematic reviews and meta-analyses on treatment of asthma: critical evaluation. *BMJ* 2000;320(7234):537-40.

Strength of Recommendations

In addition to specifying the level of evidence supporting a recommendation, the Expert Panel agreed to indicate the strength of the recommendation. When a certain clinical practice "is recommended," this indicates a strong recommendation by the panel. When a certain clinical practice "should, or may, be considered," this indicates that the recommendation is less strong.

This distinction is an effort to address nuances of using evidence ranking systems. For example, a recommendation for which clinical RCT data are not available (e.g., conducting a medical history for symptoms suggestive of asthma) may still be strongly supported by the Panel. Furthermore, the range of evidence that qualifies a definition of "B" or "C" is wide, and the Expert Panel considered this range and the potential implications of a recommendation as they decided how strongly the recommendation should be presented.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Long-term control of asthma (i.e., reduced impairment and reduced risk) with the least amount of medication and hence minimal risk for adverse effects

POTENTIAL HARMS

Adverse effects of medications used for control of asthma

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines are intended to inform, not replace, clinical judgment. Of course, the clinician and patient need to develop individual treatment plans that are tailored to the specific needs and circumstances of the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides

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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Managing asthma long term in youths >=12 years of age and adults. In: National Asthma Education and Prevention Program (NAEPP). Expert panel report 3: guidelines for the diagnosis and management of asthma. Bethesda (MD): National Heart, Lung, and Blood Institute; 2007 Aug. p. 326-62. [103 references]

ADAPTATION

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

DATE RELEASED

1997 (revised 2007 Aug)

GUIDELINE DEVELOPER(S)

National Asthma Education and Prevention Program - Federal Government Agency [U.S.]
National Heart, Lung, and Blood Institute (U.S.) - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

The National Asthma Education and Prevention Program Science Base Committee is a multidisciplinary group of clinicians and scientists with expertise in asthma management. The group includes health professionals in the areas of general medicine, family practice, pediatrics, emergency and critical care, allergy, pulmonary medicine, pharmacy, and health education.

SOURCE(S) OF FUNDING

The development of this report was entirely funded by the National Heart, Lung, and Blood Institute, National Institutes of Health.

GUIDELINE COMMITTEE

National Asthma Education and Prevention Program (NAEPP) Coordinating Committee
Third Expert Panel on the Diagnosis and Management of Asthma

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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See the original guideline document for members of the National Asthma Education and Prevention Program (NAEPP) Coordinating Committee, a list of consultant reviewers, and members of the National Heart, Lung, and Blood Institute and American Institutes for Research staffs.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Development of the resource document and the guidelines report was funded by the National Heart, Lung, and Blood Institute (NHLBI), and National Institutes of Health (NIH). Expert Panel members completed financial disclosure forms, and the Expert Panel members disclosed relevant financial interests to each other prior to their discussions. Expert Panel members participated as volunteers and were compensated only for travel expenses related to the Expert Panel meetings. Financial disclosure information covering the 3-year period during which the guidelines were developed is provided for each Panel member below.

Dr. Busse has served on the Speakers' Bureaus of GlaxoSmithKline, Merck, Novartis, and Pfizer; and on the Advisory Boards of Altana, Centocor, Dynavax, Genentech/Novartis, GlaxoSmithKline, Isis, Merck, Pfizer, Schering, and Wyeth. He has received funding/grant support for research projects from Astellas, AstraZeneca, Centocor, Dynavax, GlaxoSmithKline, Novartis, and Wyeth. Dr. Busse also has research support from the NIH.

Dr. Boushey has served as a consultant for Altana, Protein Design Lab, and Sumitomo. He has received honoraria from (Boehringer-Ingelheim, Genentech, Merck, Novartis, and Sanofi-Aventis, and funding/grant support for research projects from the NIH.

Dr. Camargo has served on the Speakers' Bureaus of AstraZeneca, GlaxoSmithKline, Merck, and Schering-Plough; and as a consultant for AstraZeneca, Critical Therapeutics, Dey Laboratories, GlaxoSmithKline, MedImmune, Merck, Norvartis, Praxair, Respironics, Schering-Plough, Sepracor, and TEVA. He has received funding/grant support for research projects from a variety of Government agencies and not-for-profit foundations, as well as AstraZeneca, Dey Laboratories, GlaxoSmithKline, MedImmune, Merck, Novartis, and Respironics.

Dr. Evans has received funding/grant support for research projects from the NHLBI.

Dr. Foggs has served on the Speakers' Bureaus of GlaxoSmithKline, Merck, Pfizer, Sepracor, and UCB Pharma; on the Advisory Boards of Alcon, Altana, AstraZeneca, Critical Therapeutics, Genentech, GlaxoSmithKline, and IVAX; and as consultant for Merck and Sepracor. He has received funding/grant support for research projects from GlaxoSmithKline.

Dr. Janson has served on the Advisory Board of Altana, and as a consultant for Merck. She has received funding/grant support for research projects from the NHLBI.

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Dr. Lemanske has served on the Speakers' Bureaus of GlaxoSmithKline and Merck, and as a consultant for AstraZeneca, Aventis, GlaxoSmithKline, Merck, and Novartis. He has received honoraria from Altana, and funding/grant support for research projects from the NHLBI and NIAID.

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Dr. Nelson has served on the Speakers' Bureaus of AstraZeneca, GlaxoSmithKline, Pfizer, and Schering-Plough; and as a consultant for Abbott Laboratories, Air Pharma, Altana Pharma US, Astellas, AstraZeneca, Curalogic, Dey Laboratories, Dynavax Technologies, Genentech/Novartis, GlaxoSmithKline, Inflazyme Pharmaceuticals, MediciNova, Protein Design Laboratories, Sanofi-Aventis, Schering-Plough, and Wyeth Pharmaceuticals. He has received funding/grant support for research projects from Altana, Astellas, AstraZeneca, Behringer, Critical Therapeutics, Dey Laboratories, Epigenesis, Genentech, GlaxoSmithKline, Hoffman LaRoche, IVAX, Medicinova, Novartis, Sanofi-Aventis, Schering-Plough, Sepracor, TEVA, and Wyeth.

Dr. Platts-Mills has served on the Advisory Committee of Indoor Biotechnologies. He has received funding/grant support for a research project from Pharmacia Diagnostics.

Dr. Schatz has served on the Speakers' Bureaus of AstraZeneca, Genentech, GlaxoSmithKline, and Merck; and as a consultant for GlaxoSmithKline on an unbranded asthma initiative. He has received honoraria from AstraZeneca, Genentech, GlaxoSmithKline and Merck. He has received funding/grant support for research projects from GlaxoSmithKline and Merck and Sanofi-Adventis.

Dr. Shapiro (deceased) served on the Speakers' Bureaus of AstraZeneca, Genentech, GlaxoSmithKline, IVAX Laboratories, Key Pharmaceuticals, Merck, Pfizer Pharmaceuticals, Schering Corporation, UCB Pharma, and 3M; and as a consultant for Altana, AstraZeneca, Dey Laboratories, Genentech/Novartis, GlaxoSmithKline, ICOS, IVAX Laboratories, Merck, Sanofi-Aventis, and Sepracor. She received funding/grant support for research projects from Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers-Squibb, Dey Laboratories, Fujisawa Pharmaceuticals, Genentech, GlaxoSmithKline, Immunex, Key, Lederle, Lilly Research, MedPointe Pharmaceuticals, Medtronic Emergency Response Systems, Merck, Novartis, Pfizer, Pharmaxis, Purdue Frederick, Sanofi-Aventis, Schering, Sepracor, 3M Pharmaceuticals, UCB Pharma, and Upjohn Laboratories.

Dr. Stoloff has served on the Speakers' Bureaus of Alcon, Altana, AstraZeneca, Genentech, GlaxoSmithKline, Novartis, Pfizer, Sanofi-Aventis, and Schering; and as a consultant for Alcon, Altana, AstraZeneca, Dey, Genentech, GlaxoSmithKline, Merck, Novartis, Pfizer, Sanofi-Aventis, and Schering.

Dr. Szefler has served on the Advisory Boards of Altana, AstraZeneca, Genentech, GlaxoSmithKline, Merck, Novartis, and Sanofi-Aventis; and as a consultant for Altana, AstraZeneca, Genentech, GlaxoSmithKline, Merck, Novartis, and Sanofi-Aventis. He has received funding/grant support for a research project from Ross.

Dr. Weiss has served on the Advisory Board of Genentech, and as a consultant for Genentech and GlaxoSmithKline. He has received funding/grant support for research projects from GlaxoSmithKline.

Dr. Yawn has served on the Advisory Boards of Altana, AstraZeneca, Merck, Sanofi-Aventis, and Schering-Plough. She has received honoraria from Pfizer and Schering-Plough, and funding/grant support for research projects from the Agency for Healthcare Research and Quality, the CDC, the NHLBI, Merck, and Schering-Plough.

Financial disclosure information covering a 12 month period prior to the review of the guidelines is provided in the original guideline document for each consultant reviewer.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: National Asthma Education and Prevention Program Expert Panel Report: guidelines for the diagnosis and management of asthma update on selected topics-2002. J Allergy Clin Immunol 2002 Nov;110(5 pt 2):S141-219.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Heart, Lung, and Blood Institute Web site.

Print copies: Available from NHLBI Information Center, P.O. Box 30105, Bethesda, MD 20824-0105; e-mail: nhlbiic@dgsys.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidelines for the diagnosis and management of asthma. Summary report 2007. Bethesda (MD): National Heart, Lung, and Blood Institute; 2007. Available from the National Heart, Lung, and Blood Institute Web site.
- Overall methods used to develop this report. Electronic copies: Available from the National Heart, Lung, and Blood Institute Web site.
- Search strategies. Electronic copies: Available from the National Heart, Lung, and Blood Institute Web site.
- Evidence tables. Electronic copies: Available from the National Heart, Lung, and Blood Institute Web site.
- Lung diseases information. Information for health professionals. Electronic copies: Available from the National Heart, Lung, and Blood Institute Web site.

Print copies: Available from NHLBI Information Center, P.O. Box 30105, Bethesda, MD 20824-0105; e-mail: nhlbiic@dgsys.com.

PATIENT RESOURCES

The following is available:

- Lung diseases information. Information for patients and the public.

Electronic copies: Available from the National Heart, Lung and Blood Institute Web site.

Print copies: Available from NHLBI Information Center, P.O. Box 30105, Bethesda, MD 20824-0105; e-mail: nhlbiic@dgsys.com.

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 summary was completed by ECRI on January 5, 1999. The information was verified by the guideline developer on April 30, 1999. This summary was updated by ECRI on January 31, 2003. This information was not verified by the guideline developer. This summary was updated by ECRI on December 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on long-acting beta2-adrenergic agonists (LABA). This NGC summary was updated by ECRI Institute on January 16, 2008.

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Date Modified: 10/13/2008