



**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
**Health Care Financing Administration**

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**Center for Medicaid and State Operations**  
**7500 Security Boulevard**  
**Baltimore, MD 21244-1850**

**SMDL #01-011**

January 19, 2001

Dear State Medicaid Director:

I am writing to advise you of recent developments in the care of asthma and to stress the importance of State action to assure that Medicaid beneficiaries with asthma, particularly children, receive appropriate care. This issue is particularly important because of the increasing incidence of asthma and its prevalence among low-income populations. This letter also clarifies mandated and optional Medicaid coverage for asthma items and services.

Medicaid covers asthma-related medical services under various categories, including prescription drugs, home health services, physician services, and other licensed practitioners. Some State Medicaid programs are using disease management programs as an effective means of improving outcomes for asthma patients and reducing costs. Medicaid programs can also improve service delivery by coordinating asthma-related initiatives with other programs and addressing utilization limits with Medicaid managed care organizations and pharmacy benefit managers.

**In General**

To underscore the importance of the asthma epidemic, President Clinton signed an Executive Order in 1997, which created the Task Force on Environmental Health Risks and Safety Risks to Children. This task force is co-chaired by the Secretary of the Department of Health and Human Services (DHHS), Donna Shalala, and the Commissioner of the Environmental Protection Agency (EPA), Carol Browner, and seeks to reduce the incidence of pediatric asthma and associated medical costs by promoting additional research, programs to lessen exposure to environmental irritants, better data collection, and provider education.

The Department of Health and Human Services also recently issued "Action Against Asthma: A Strategic Plan for the Department of Health and Human Services," which is available on the Internet at <http://aspe.hhs.gov/sp/asthma/>. This action plan outlines four priority areas for investment in asthma management over the next five years: determining the cause of asthma and interventions to prevent its onset, decreasing the burden of asthma for people with the disease, eliminating the disproportionate burden of asthma in minority populations and those living in poverty, and tracking the disease and assessing the effectiveness of asthma programs. We encourage you to review this plan and help achieve progress in these priority areas.

### Epidemiological Trends

Asthma is a chronic and episodic inflammatory disease of the airways, which is often exacerbated by exposure to indoor allergens (such as tobacco smoke, pet dander, house dust mites, cockroaches, and mold), outdoor air pollutants, and upper respiratory infections. The number of Americans afflicted with asthma nearly doubled between 1980 and 1996, and the condition now affects nearly 15 million Americans, including nearly 5 million children. It is the most common chronic disease of childhood.

The illness is responsible for over 1.8 million emergency room visits, 460,000 hospitalizations and 5,000 deaths each year. Children with asthma lose an extra 10 million school days each year, and this results in an estimated \$1 billion in lost productivity from their working parents. Claims data reveal that Medicaid-eligible children under age 18 in 28 States had more than 36,000 hospitalizations costing over \$101.7 million and more than 765,000 outpatient visits costing over \$55.67 million for a primary diagnosis of asthma in 1995.

While asthma affects Americans of all ages, races, and ethnic groups, low-income and minority populations are disproportionately affected. For example, while African-Americans have only slightly higher rates of asthma than whites, they are twice as likely to die from their asthma. African-American children are four times more likely to die from asthma than white children. Pediatric asthma hospitalizations are five times higher for children in lower income families than for other children. In addition, research has indicated that low-income and minority children are less likely to have access to quality care, and are less likely to receive optimal medical therapy.

### Management of Asthma Symptoms: NIH Guidelines

Asthma can be managed most effectively by avoiding or controlling environmental and occupational factors that exacerbate the condition, taking appropriate medications, objective monitoring of the disease, and actively involving the patient and family in self-care and disease management. Effective asthma management reduces the need for hospitalizations and urgent care visits, and leads to a more full and active life.

In 1997, the National Asthma Education and Prevention Program (NAEPP), sponsored by the National Heart, Lung, and Blood Institute (NHLBI), updated “Guidelines for the Diagnosis and Management of Asthma” (Introduction including overview enclosed). The Guidelines translate research findings into recommendations for management by health care providers and for patient self-management. Although the Guidelines were widely disseminated and are recommended as standards of care, studies indicate that many professionals and affected families are not using the Guidelines. The Department’s Asthma Action Plan specifically directs HCFA to “work with...State health officials to accelerate widespread adoption of the Guidelines.” We encourage you to make your providers and beneficiaries aware of these Guidelines. The Guidelines can be accessed at <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>.

### Medicaid’s Role in Improving Asthma Management

*Access to Medicaid Services:* It has come to our attention that certain State Medicaid prescription drug and medical equipment policies could be barriers to appropriate asthma management and violate Early and Periodic Screening, Diagnostic and Treatment (EPSDT) service requirements. To avoid such barriers and violations and to contribute to the goals of the DHHS Asthma Action Plan, each State should review Medicaid utilization controls and other policies in its program that could present such obstacles. For example, State Medicaid utilization limits may prevent a child from having an inhaler whenever and wherever he or she needs it (e.g., school, caretaker’s home). Coverage policies that permit only replacement of nebulizers (used to convert medication to steam), disposable tubing, and other parts used with a nebulizer at specified time intervals may not accommodate situations in which a child requires replacement of such items more frequently.

Utilization limits on asthma-related medical equipment, including nebulizers and integral parts, peak flow meters (used to monitor degree of airflow obstruction) and spacers (used to assist in proper delivery of inhaled medication to the lungs in young children), can also be problematic. For example, limits of one peak flow meter or spacer per lifetime may prevent a child from replacing a lost or broken piece of equipment, or graduating from a child to an adult sized meter.

We remind you that the requirements of the EPSDT service do not allow such arbitrary restrictions on services provided to individuals under the age of 21. Section 1905(r)(5) requires the State Medicaid agency to provide EPSDT-eligible individuals with all medically necessary services coverable under Section 1905(a) regardless of whether the item or service is specified in the State plan or whether the State has established utilization limits for Medicaid beneficiaries generally. If a State requires prior authorization of asthma-related drugs, supplies, or equipment under EPSDT, the State must assure that these items are provided in a timely manner to Medicaid children who need them. Each State should review its prescription and medical equipment policies and make changes to assure that its policies are consistent with EPSDT requirements.

*Medicaid Coverage of Asthma-Related Services:* Individuals with asthma typically need a variety of services to manage their condition. Medicaid covers a comprehensive array of medical services required by a person with asthma, including prescription drugs and equipment to deliver those drugs, diagnostic tests and monitoring equipment, and encounters with physicians and other licensed practitioners. If a State elects to provide a drug benefit, coverage of all FDA-approved drugs, including asthma-related drugs, produced by manufacturers participating in the Medicaid drug rebate program is mandatory. Items such as inhalers are covered under the Medicaid pharmacy benefit and are also subject to the drug rebate requirements.

Asthma-related supplies and equipment, such as spacers, peak flow meters, and nebulizers, are not considered drugs and should not be covered under the prescription drug benefit, even though some of these items have a National Drug Code number and are sold through pharmacies. Neither can they be covered as “durable medical equipment” (DME) because, unlike Medicare, Medicaid law does not recognize DME as a separate coverable service.

Medicaid reimbursement is available for asthma-related supplies and equipment through the home health benefit, which allows coverage for medical supplies, equipment, and appliances that are suitable for use in the home (42 CFR 440.70(B)(3)). In accordance with these regulations, a physician must review a beneficiary's need for such supplies, equipment, or appliances annually. Although expenditures for these items should be reported to HCFA as home health services, the items can be provided by home health agencies, pharmacies, medical equipment suppliers, or other providers.

States must cover home health services for individuals entitled to nursing facility services under the State Medicaid plan. Regardless of whether they are entitled to nursing facility services, States must also cover medically necessary home health services for any EPSDT-eligible individual.

It has come to our attention that some pharmacies which do not sell medical supplies and equipment in large volume find it difficult to obtain Medicaid reimbursement for these items. To improve access for beneficiaries with asthma, you should establish procedures that allow pharmacies to be providers of medical supplies and equipment under the Medicaid home health benefit.

*Disease Management Programs:* In some Medicaid populations, nearly one-third of prescriptions for asthma medications are never filled. Covered by Medicaid under 42 CFR 440.60, disease management programs seek to address such compliance problems and improve outcomes for high-incidence or high-cost diseases by stressing state-of-the-art clinical approaches, intensive monitoring and examination of patients at frequent intervals, and patient education. Pharmacists and other non-physician practitioners are generally responsible for coordinating these programs.

States are beginning to track the effects of disease management programs on clinical outcomes and costs. A 1997 study found that total medical costs for patients with asthma and other conditions, who participated in a community pharmacy-based disease management program in the Richmond, Virginia area, were 29 percent lower than total medical costs for patients in a control group (Clinical Therapeutics, Vol. 19, No. 1, 1997)

Medicaid programs in the States of Arkansas, Delaware, Florida, Georgia, Mississippi, and Virginia have planned or implemented disease management programs for asthma. To claim Medicaid Federal financial participation for these services, you should submit a State Plan Amendment, providing a detailed description of the services to be covered and indicating which "other licensed practitioners" (e.g., pharmacists) will furnish those services. If your State practice act for pharmacists or other licensed practitioners does not encompass services provided under disease management programs, State laws must be amended if these professionals are to be reimbursed for these services under Medicaid. Practitioners planning to participate in these programs may need special training in disease management.

*Collaboration with Other Organizations:* Because beneficiaries with asthma obtain services in various settings and through different delivery systems, it is essential that you work with other organizations that serve this population to eliminate barriers to care. We encourage you to discuss

use of asthma medications in the school setting with State or local boards of education. We also urge you to review utilization limits with Medicaid managed care organizations and pharmacy benefit managers to determine whether they pose barriers to effective prevention and treatment of asthma.

By addressing the strategies discussed in this letter, you can serve in a leadership role to reduce morbidity, mortality, and the need for acute care associated with asthma, as you improve the daily lives of individuals and families who are affected by this serious health problem. We encourage you to provide us with information about your innovative approaches to addressing asthma that we can share with other States. Please contact David Greenberg by phone at (410) 786-2637 or e-mail ([dgreenberg@hcfa.gov](mailto:dgreenberg@hcfa.gov)) to furnish information about your approaches or any concerns regarding Medicaid and asthma.

Sincerely,

Timothy M. Westmoreland  
Director

Enclosure

cc:

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HCFA Associate Regional Administrators  
for Medicaid and State Operations

Lee Partridge  
Director, Health Policy Unit  
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# Guidelines for the Diagnosis and Management of Asthma

NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute

JULY 1997

## INTRODUCTION

Asthma is a chronic inflammatory disease of the airways. In the United States, asthma affects 14 million to 15 million persons. It is the most common chronic disease of childhood, affecting an estimated 4.8 million children (Adams and Marano 1995; Centers for Disease Control and Prevention 1995). People with asthma collectively have more than 100 million days of restricted activity and 470,000 hospitalizations annually. More than 5,000 people die of asthma annually. Asthma hospitalization rates have been highest among blacks and children, while death rates for asthma were consistently highest among blacks aged 15 to 24 years (Centers for Disease Control and Prevention 1996). These rates have increased or remained stable over the past decade. This report describes the appropriate use of the available therapies in the management of asthma.

To help health care professionals bridge the gap between current knowledge and practice, the National Heart, Lung, and Blood Institute's (NHLBI) National Asthma Education and Prevention Program (NAEPP) has convened two Expert Panels to prepare guidelines for the diagnosis and management of asthma. The NAEPP Coordinating Committee, under the leadership of Claude Lenfant, M.D., director of the NHLBI, con-vened the first Expert Panel in 1989. The charge to this Panel was to develop a report that would provide a general approach to diagnosing and managing asthma based on current science. The *Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma* (NAEPP 1991) was published in 1991, and the recommendations for the treatment of asthma were organized around four components of effective asthma management:

- Use of objective measures of lung function to assess the severity of asthma and to monitor the course of therapy
- Environmental control measures to avoid or eliminate factors that precipitate asthma symptoms or exacerbations
- Comprehensive pharmacologic therapy for long-term management designed to reverse and prevent the airway inflammation characteristic of asthma as well as pharmacologic therapy to manage asthma exacerbations
- Patient education that fosters a partnership among the patient, his or her family, and clinicians

The principles addressed within these four components of asthma management served as the starting point for the development of two additional reports prepared by asthma experts from many countries in cooperation with the NHLBI: the International Consensus Report on Diagnosis and Management of Asthma (NHLBI 1992) and the Global Initiative for Asthma (NHLBI/WHO 1995). The Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma (EPR-2) is the latest report from the National Asthma Education and Prevention Program and updates the 1991 Expert Panel Report. The second Expert Panel critically reviewed and built upon the reports listed above.

This report presents basic recommendations for the diagnosis and management of asthma that will help clinicians and patients make appropriate decisions about asthma care. Of course, the clinician and patient need to develop individual treatment plans that are tailored to the specific needs and circumstances of the patient. The NAEPP, and all who participated in the development of this latest report, hope that the patient with asthma will be the beneficiary of the recommendations in this document. This report is not an official regulatory document of any Government agency.

## METHODS USED TO DEVELOP THIS REPORT

The NAEPP Coordinating Committee established a Science Base Committee of U.S. asthma experts who began work in early 1994 to monitor the scientific literature and advise the Coordinating Committee when an update of the 1991 *Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma* was needed. The Science Base Committee, along with international members of the Global Initiative for Asthma, examined all the relevant literature on asthma in human subjects published in English between 1991 and mid-1995, obtained through a series of MEDLINE database searches. More than 5,000 abstracts were reviewed. In 1995, the Science Base Committee recommended to the NAEPP Coordinating Committee that sufficient new information had been published since 1991 to convene a panel of experts to update the first Expert Panel Report.

The second Expert Panel is a multidisciplinary group of clinicians and scientists with expertise in asthma management. The Panel includes health professionals in the areas of general medicine, family practice, pediatrics, emergency medicine, allergy, pulmonary medicine, nursing, pharmacy, and health education. Among the Panel members are individuals who served on either the Science Base Committee or the 1991 Expert Panel. Other members were chosen based on names submitted by NAEPP Coordinating Committee member organizations. Several Expert Panel members are themselves members of the Coordinating Committee. Representatives from several Federal agencies also have participated.

The charge to the Panel was to prepare recommendations for use by clinicians working in diverse health care settings that address the practical decisionmaking issues in the diagnosis and management of asthma. The Panel also was requested to develop specific aids to facilitate implementation of the recommendations.

Panel members were asked to base their recommendations on their review of the scientific literature and to cite studies that support the recommendations. When a clear recommendation could not be extracted from the studies (e.g., studies were not available, were conflicting, or were equivocal), the Panel was asked to label the recommendation as "based on the opinion of the Expert Panel," "recommended by the Expert Panel," or similar terminology. When a whole section was "based on the opinion of the Expert Panel," this was indicated at the beginning of the section (e.g., see component 1-Initial Assessment and Diagnosis).

This report was prepared in a systematic and iterative process. In addition to the Science Base Committee review of the scientific literature, the Panel conducted in-depth reviews of the literature in selected areas it considered controversial. In interpreting the literature, the Panel considered the nature and quality of the study designs and analyses. Given the complexities of several issues, the Panel chose not to use the strict evidence ranking system used in the guidelines development procedures of the U.S. Preventive Services Task Force. However, this procedure was applied in the area of peak flow monitoring. The Panel submitted their interpretation of the literature and related recommendations for multiple reviews by their fellow Expert Panel members and outside reviewers.

The development of EPR-2 was directed by an Executive Committee; each member of the Executive Committee headed a subcommittee assigned to prepare a specific chapter. Each member of the Panel was assigned to one of the subcommittees. The sub-committees were responsible for reviewing the pertinent literature and drafting the recommendations with the supporting evidence for the full Panel to review. Once the subcommittee reports were prepared, the full Panel critically reviewed the evidence and rationale for each recommendation, discussed revisions, and reached final agreement on each recommendation. A vote was taken to confirm the consensus of the Panel. The final report was approved by the NAEPP Coordinating Committee via mail. Box 1 summarizes the draft, review, and consensus-building process.

The development of this report was *entirely* funded by the National Heart, Lung, and Blood Institute, National Institutes of Health. Panel members and reviewers participated as volunteers and were compensated only for travel expenses related to the two Expert Panel meetings and the Executive Committee meetings.

#### **BOX 1. MAJOR EVENTS IN THE DEVELOPMENT OF THE EXPERT PANEL REPORT -**

First Expert Panel meeting June 1995

Executive Committee meeting November 1995

Executive Committee meeting (by phone) February 1996

Second Expert Panel meeting and review by outside experts May 1996

Review by NAEPP Coordinating Committee member organizations August 1996

Executive Committee meeting October 1996

Mail Review, Expert Panel December 1996

Mail Review and Approval, NAEPP Coordinating Committee January 1997

The goal of the *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma* is to serve as a comprehensive guide to diagnosing and managing asthma.

Implementation of EPR-2 recommendations is likely to increase some costs of asthma care by increasing the number of primary care visits for asthma and the use of asthma medications, environmental control products and services, and equipment (e.g., spacer/holding chamber devices). However, asthma diagnosis and management are expected to improve, which should reduce the numbers of lost school and work days, hospitalizations and emergency department visits, and deaths due to asthma. A net reduction in total health care costs should result. The NAEPP encourages research to evaluate the impact of implementing the recommendations in this report.

## **OVERVIEW OF THE REPORT**

Each section of EPR-2 begins with a list of "Key Points" and "Differences From 1991 Expert Panel Report." A brief overview of each section is provided below.

### **Pathogenesis and Definition**

In the 1991 Expert Panel Report, the role of inflammation in the pathogenesis of asthma was emphasized although the scientific evidence for the involvement of inflammation in asthma was just emerging. Now in 1997, although the role of inflammation is still evolving as a concept, a much firmer scientific basis exists to indicate that asthma results from complex interactions among inflammatory cells, mediators, and the cells and tissues resident in the airways.

Thus, asthma is now defined as a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular, mast cells, eosinophils,

T lymphocytes, neutrophils, and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and cough, particularly at night and in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. The inflammation also causes an associated increase in the existing bronchial hyperresponsiveness to a variety of stimuli.

#### COMPONENT 1:

### Measures of Assessment and Monitoring

#### *Initial Assessment and Diagnosis of Asthma*

Making the correct diagnosis of asthma is extremely important. Clinical judgment is required because signs and symptoms vary widely from patient to patient as well as within each patient over time. To establish the diagnosis of asthma, the clinician must determine that:

- Episodic symptoms of airflow obstruction are present.
- Airflow obstruction is at least partially reversible.
- Alternative diagnoses are excluded.

This section differs from the 1991 Expert Panel Report in several ways. Asthma severity classifications have been changed from mild, moderate, and severe to mild intermittent, mild persistent, moderate persistent, and severe persistent to more accurately reflect the clinical manifestations of asthma. The Panel emphasizes that patients at any level of severity can have mild, moderate, or severe exacerbations. In addition, information on wheezing in infancy and vocal cord dysfunction has been expanded in the differential diagnosis section in component 1. Situations that may warrant referral to an asthma specialist have been refined with input from specialty and primary care physicians.

#### *Periodic Assessment and Monitoring*

To establish whether the goals of asthma therapy have been achieved, ongoing monitoring and periodic assessment are needed. The goals of asthma therapy are to:

- Prevent chronic and troublesome symptoms
- Maintain (near) "normal" pulmonary function
- Maintain normal activity levels (including exercise and other physical activity)
- Prevent recurrent exacerbations of asthma and minimize the need for emergency department visits or hospitalizations
- Provide optimal pharmacotherapy with minimal or no adverse effects
- Meet patients' and families' expectations of and satisfaction with asthma care

Several types of monitoring are recommended: signs and symptoms, pulmonary function, quality of life/functional status, history of asthma exacerbations, pharmacotherapy, and patient-provider communication and patient satisfaction.

The Panel recommends that patients, especially those with moderate-to-severe persistent asthma or a history of severe exacerbations, be given a written action plan based on signs and symptoms and/or peak expiratory flow. As in the 1991 report, daily peak flow monitoring is

recommended for patients with moderate-to-severe persistent asthma. In addition, the Panel states that any patient who develops severe exacerbations may benefit from peak flow monitoring. A complete review of the literature on peak flow monitoring was conducted, evidence tables were prepared, and the results of this analysis are summarized in the report.

#### C O M P O N E N T 2 :

### **Control of Factors Contributing to Asthma Severity**

Exposure of sensitive patients to inhalant allergens has been shown to increase airway inflammation, airway hyperresponsiveness, asthma symptoms, need for medication, and death due to asthma. Substantially reducing exposures significantly reduces these outcomes. Environmental tobacco smoke is a major precipitant of asthma symptoms in children, increases symptoms and the need for medications, and reduces lung function in adults. Increased air pollution levels of respirable particulates, ozone, SO<sub>2</sub>, and NO<sub>2</sub> have been reported to precipitate asthma symptoms and increase emergency department visits and hospitalizations for asthma. Other factors that can contribute to asthma severity include rhinitis and sinusitis, gastroesophageal reflux, some medications, and viral respiratory infections. EPR-2 discusses environmental control and other measures to reduce the effects of these factors.

#### C O M P O N E N T 3 :

### **Pharmacologic Therapy**

EPR-2 offers an extensive discussion of the pharmacologic management of patients at all levels of asthma severity. It is noted that asthma pharmacotherapy should be instituted in conjunction with environmental control measures that reduce exposure to factors known to increase the patient's asthma symptoms.

As in the 1991 report, a stepwise approach to pharmacologic therapy is recommended, with the type and amount of medication dictated by asthma severity. EPR-2 continues to emphasize that persistent asthma requires daily long-term therapy in addition to appropriate medications to manage asthma exacerbations. To clarify this concept, the EPR-2 now categorizes medications into two general classes: *long-term-control medications* to achieve and maintain control of persistent asthma and *quick-relief medications* to treat symptoms and exacerbations.

Observations into the basic mechanisms of asthma have had a tremendous influence on therapy. Because inflammation is considered an early and persistent component of asthma, therapy for persistent asthma must be directed toward long-term suppression of the inflammation. Thus, EPR-2 continues to emphasize that the most effective medications for long-term control are those shown to have anti-inflammatory effects. For example, early intervention with inhaled corticosteroids can improve asthma control and normalize lung function, and preliminary studies suggest that it may prevent irreversible airway injury.

An important addition to EPR-2 is a discussion of the management of asthma in infants and young children that incorporates recent studies on wheezing in early childhood. Another addition is discussions of long-term-control medications that have become available since 1991—long-acting inhaled beta<sub>2</sub>-agonists, nedocromil, zafirlukast, and zileuton.

Recommendations for managing asthma exacerbations are similar to those in the 1991 Expert Panel Report. However, the treatment recommendations are now on a much firmer scientific basis because of the number of studies addressing the treatment of asthma exacerbations in children and adults in the past 6 years.

#### **COMPONENT 4:**

#### **Education for a Partnership in Asthma Care**

As in the 1991 Expert Panel Report, education for an active partnership with patients remains the cornerstone of asthma management and should be carried out by health care providers delivering asthma care. Education should start at the time of asthma diagnosis and be integrated into every step of clinical asthma care. Asthma self-management education should be tailored to the needs of each patient, maintaining a sensitivity to cultural beliefs and practices. New emphasis is placed on evaluating outcomes in terms of patient perceptions of improvement, especially quality of life and the ability to engage in usual activities. Health care providers need to systematically teach and frequently review with patients how to manage and control their asthma. Patients also should be provided with and taught to use a written daily self-management plan and an action plan for exacerbations. It is especially important to give a written action plan to patients with moderate-to-severe persistent asthma or a history of severe exacerbations. Appropriate patients should also receive a daily asthma diary. Adherence should be encouraged by promoting open communication; individualizing, reviewing, and adjusting plans as needed; emphasizing goals and outcomes; and encouraging family involvement.

In summary, the 1997 *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma* reflects the experience of the past 6 years as well as the increasing scientific base of published articles on asthma. The Expert Panel hopes this new report will assist the clinician in forming a valuable partnership with patients to achieve excellent asthma control and outcomes.

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