



**The Bulletin of  
Medicaid Drug  
Utilization Review  
in Iowa**

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**2007 Expert Panel Report Asthma Regulation  
Guidelines: Managing Asthma Long Term**

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**INTRODUCTION**

Asthma is a reversible chronic inflammatory disorder that manifests itself as a restriction to the airways of the lung, which induces symptoms such as episodic dyspnea (cough) generally associated with wheezing and shortness of breath<sup>1</sup>. This disorder is of increasing prevalence and affects an estimated 22 million people in the United States alone.<sup>2</sup> There is an alarming increase in incidence among children under the age of 17. In 1998 the estimated cost of asthma in the United States was 12.6 billion dollars. This figure includes societal burden of asthma, direct medical expenditures, emergency care of acute exacerbations and lost productivity of parents whom have to stay home with their children.

Until recently, asthma therapy has been based on The Expert Panel Report full report 1997 and the update 2002 (EPR-2 1997 and the EPR-Update 2002) guidelines. The Science Based Committee of The National Asthma Education and Prevention Program (NAEPP) published new asthma guidelines, EPR-3, in August 2007.

The following review article will concentrate on several of the key differences between the EPR-2 and EPR-2 update, versus the EPR-3, on the issues which guide the treatment of asthma in patients over 12 years of age. Please note that the treatment guidelines are different for the pediatric and young children populations (ages 0-4 and 5-11) and refer to <http://www.nhlbi.nih.gov/guidelines/asthma/index.htm> for more information.

**GUIDELINE OVERVIEW**

There are some key modifications located in the EPR-3. One of which, was an update to the labeling of the classification system that includes a new definition of asthma severity. The second key point is that the number one goal for therapy is control, which is guided by monitoring and utilizing the revised step-wise approach to adjust therapy accordingly.

**CLASSIFICATION OF SEVERITY OF ASTHMA (Chart A)**

There are still 4 classes of severity in the EPR-3, but the definitions have been modified to reflect the fact that ALL patients are potentially at risk for a severe exacerbation. More importantly, the components to define severity have been expanded in the EPR-3. Previously, severity was based solely on the number of symptoms occurring in the day/night and on PEF or FEV<sub>1</sub>. (Peak expiratory flow rate and forced expiratory volume in 1 second, respectively). According to the recent revisions, the severity of asthma is characterized in terms of two domains; impairment and risk. This was based on an effort to emphasize the need to consider asthma's effect on the present overall quality of life with the future adverse events the disease may bring forth. The EPR-3 states that severity is measured as the intrinsic intensity of the disease process, measured clinically in the untreated patients or by the least amount of medication required to achieve control.<sup>2</sup> Impairment is the frequency and intensity of symptoms and functional limitations. Specifically, the impairment component of the classification of severity is objectively measured by the number of nighttime awakenings, use of SABA for symptom control and lung function measured by FEV<sub>1</sub> and FVC (forced vital capacity).<sup>2</sup> The number of exacerbations that require oral systemic corticosteroids measures risk objectively.<sup>2</sup> These two separate domains may have implications on the differences in the response to treatment of each individual patient.

*Continued on page 2*

# 2007 Expert Panel Report Asthma Regulation Guidelines: Managing Asthma Long Term

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**Chart A: Assessing severity and initiating treatment for patients who are not currently taking long-term control medications**

Components of Severity		Classification of Asthma Severity ≥12 years of age			
		Intermittent	Persistent		
			Mild	Moderate	Severe
	Symptoms	≤2 days/week	>2 days/week but Not Daily	Daily	Throughout the day
Impairment Normal FEV <sub>1</sub> /FVC: 8-19 yr 85% 20-39 yr 80% 40-59 yr 75% 60-80 yr 70%	Nighttime awakenings	≤2x/month	3-4x/month	>1x/week but not nightly	Often 7x/week
	Short-acting beta <sub>2</sub> -agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not daily, and not more than 1x on any day	Daily	Several times per day
	Interference with normal activity	None	Minor Limitation	Some Limitation	Extremely Limited
	Lung Function	*Normal FEV <sub>1</sub> between exacerbations *FEV <sub>1</sub> >80% predicted *FEV <sub>1</sub> /FVC normal	*FEV <sub>1</sub> >80% predicted *FEV <sub>1</sub> /FVC normal	*FEV <sub>1</sub> >60% but <80% predicted *FEV <sub>1</sub> /FVC reduced 5%	*FEV <sub>1</sub> <60% predicted *FEV <sub>1</sub> /FVC reduced >5%
Risk		0-1/year (see note in full text)	≥2/year (see note in full text)		
		Consider severity and interval since last exacerbation. Frequency and severity may fluctuate over time for patients in any severity category. **Relative annual risk of exacerbations may be related to FEV <sub>1</sub> .			
Recommended Step for Initiating Therapy (See Chart B for treatment steps.)		Step 1	Step 2	Step 3	Step 4 or 5
		In 2-6 weeks, evaluate level of asthma control that is achieved, and adjust therapy accordingly.			

NIH/NAEPP.Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma 2007.

\* - FEV<sub>1</sub> / FVC ratios are different for children 5-11 years of age.

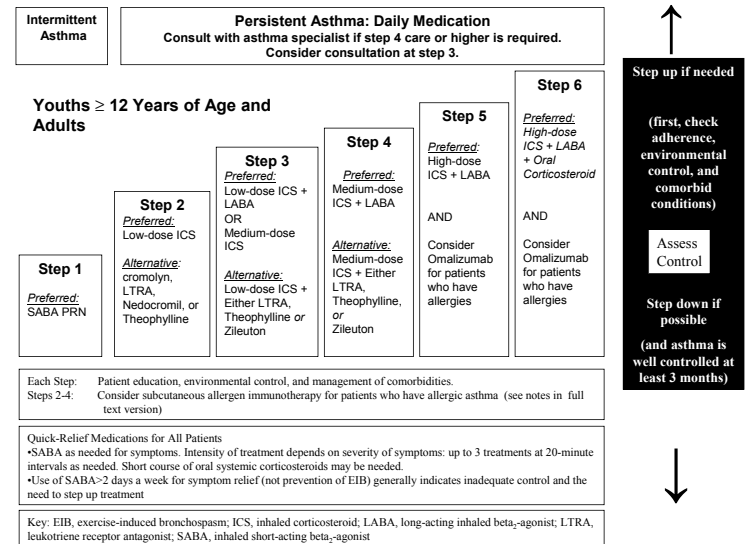
-No lung function parameters for children 0-4 years of age.

## INITIAL THERAPY A STEPWISE APPROACH (Chart B)

Previously initiating therapy was based solely on severity, which was defined by the number of symptoms in the day and night. It may be considered the most easily and directly measured value in a patient who is not currently receiving long-term control treatment. The preceding 4-step therapy was replaced with a 6-step therapy process. Short acting bronchodilators (SABA) e.g., albuterol and levalbuterol remain as the preferred treatment for “quick relief” for all patients. SABA can be used up to 3 treatments at 20-minute intervals in conjunction with a short course of oral systemic corticosteroids, if needed. Inadequate control is indicated by the use of SABA for symptom relieve greater than 2 days a week.<sup>2</sup>

ERP-3 revised Step-1 from requiring no daily medication with the use of a course of systemic corticosteroids as an option for severe exacerbations to having the preferred drug a SABA as needed. Step-3 is one of the most important changes to the step therapy with it’s revisions following the SMART study (Salmeterol Multi-center Asthma Research Trial) conducted by Nelson HS, et al.

**Chart B: A Stepwise Approach for Managing Asthma in Patients Greater 12 and Older**



NIH/NAEPP.Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma.2007.

The analysis conducted by Nelson et al. reiterated the original findings that found an increase in the primary outcome but demonstrated an increase risk of asthma-related deaths leading to a FDA mandated black box warning. (refer to Box A) The new guidelines recommend the preferred treatment for step-3 be a low-dosed ICS and a LABA or a medium-dose ICS. The advisory committee revised step-4 as an intermediate step to treat with a medium-dose ICS + LABA combination instead of jumping to a high-dose ICS + LABA as was previously recommended. Steps 5 and 6 are new additions to the step up therapy. Step-5 is also aimed at treating patients with severe persistent asthma as with step-4 but recommends that the preferred medication therapy consist of a high-dose ICS AND LABA AND considers omalizumab for patients who have allergies. (See Box B for more information on omalizumab) Step-6 goes beyond to recommend the addition of an oral corticosteroid if necessary.

#### Box A

**“Long-acting B2 agonists, such as salmeterol, one of the active ingredients in ADVAIR DISKUS may increase the risk of asthma-related death. Therefore, When treating patients with asthma, physicians should only prescribe ADVAIR DISKUS for patients not adequately controlled on other asthma-controller medications) e.g., low- to medium-dosed inhaled corticosteroids or whose disease severity clearly warrants initiation of treatment with 2 maintenance therapies...”**

#### Box B

**Eligibility for omalizumab is based on: FDA WARNING: anaphylaxis seen in  $\approx 0.2\%$**

- Use of inhaled corticosteroids
- Body weight 30-150 kg
- Serum total IgE (Immunoglobulin E) 30-700 IU/ml
- Positive test for aeroallergens

**NIH/NAEPP. Expert Panel Report 3: Guidelines for the diagnosis and Management of Asthma.2007.**

consultation during step-3. Please refer back to the full report for further information.

In addition to the newly revised 6-step program, the ERP-3 recommends throughout steps 2-4 the continuation of patient education, environmental control, and management. Also, the committee advises the patient to consult with an asthma specialist if step 4 care or higher is required and may even consider

#### ASSESSMENT AND MONITORING FOR CONTROL (A STEP DOWN APPROACH)

Previously, assessment and monitoring of asthma was based on severity only. The EPR-3 revisions include severity, control and responsiveness to treatments as tools to assess and monitor asthma. For therapeutic monitoring, control signifies the degree to which the manifestations of asthma (symptoms, functional impairments, and risk of untoward events) are minimized and the goals of therapy are met.

The expert panel emphasized the importance of having a monitoring plan in place. Key recommendation changes include the cessation of the need to assess diurnal variation when monitoring peak flow rates. Instead patients are most likely to benefit from routine peak flow monitoring throughout the day with or without regards to current symptoms.

The main goal for therapy is adequate control by reducing impairment and reducing risk. Control is defined as the degree to which the manifestations of asthma such as symptoms, functional impairment, risk of complications are minimized and the goals of therapy are met.<sup>2</sup> Whereas severity is linked to impairment, control lies within the domain of risk. The third assessment tool is responsiveness, which is the ease to which control is achieved by therapy.

Changes to follow-up visits include assessments every 2-6 weeks until control is achieved. Once control is achieved the patient should contact their healthcare provider every 3-6 months to discuss consideration for step down therapy. The patient will subsequently decrease their ICS's by 25% to 50% every 3 months until they reach a goal of the lowest effective dose.

#### SUMMARY

One key component of the therapeutic approach to asthma based on the EPR-3 guidelines consists of the balance of severity versus control. Severity is a measure of impairment, which indicates the present disease states and it's symptoms. On the other hand, control is defined by the patient's risk of a severe complication originating from the patient's history of asthma. First, the clinician must assess severity, then assign treatment based on the classification of severity, and finally assess control through continual lifelong monitoring. This drug utilization article provides a review of just some of the major elements pertaining to the 2007 asthma guidelines. Please refer back to the original full text article for more information at <http://www.nhlbi.nih.gov/guidelines/asthma/index.htm>

#### REFERENCES

- 1 American Thoracic Society (ATS) Am Rev Respir Dis. 1987;136:1299-1307.
- 2 NIH/NAEPP. Expert Panel Report 3: Guidelines for the diagnosis and management of Asthma. 2007; 1-440.



## Iowa Medicaid Drug Utilization Review

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## ANNUAL CALL FOR NEW COMMISSION MEMBERS

### ***Physicians: Are you looking for a new professional opportunity?***

According to CMS regulations, each state's medical assistance program shall assemble a group of actively practicing health care professionals to perform drug use review, as well as educational interventions, in an effort to improve medication use. In Iowa, this group is named the Iowa Medicaid Drug Utilization Review Commission. The Commission is composed of four physicians, three pharmacists, and a representative from one of the two Colleges of Pharmacy in Iowa who serve four-year staggered terms, as well as a representative from the Department of Human Services.

The Medicaid DUR Commission is an excellent opportunity to share your professional expertise and to learn from your colleagues. Most importantly, you will have an opportunity to improve the quality of care provided to this unique patient population. Past participants have expressed great admiration for work of the Commission and have described being a Commissioner as their most professionally rewarding experience. Please consider if this opportunity would fit your skills and expertise.

The DUR Commission is currently seeking a Medicaid provider specializing in internal medicine or general practice to join the committee. Any physician interested in serving in this capacity should send a resumé or curriculum vitae, as well as a letter indicating their interest, to Shelly Larson as shown below. Candidates that would like more information about the Commission or who would like to speak to a present Commissioner are also encouraged to call.

#### **The deadline for applications is May 1, 2008.**

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## Infant OTC Cough and Cold Update

By Anna Behrens, Pharm.D. Candidate

On October 11, the Consumer Healthcare Products Association (CHPA), a trade group representing the makers and distributors of over-the-counter (OTC) medicines, announced the voluntary withdrawal of oral cough and cold medications that are labeled for infant use from store shelves. The voluntary withdrawal was an action in response to reports of misuse that has led to overdose in infants. CHPA has asked the FDA to strengthen the labels on all oral OTC children's cough and cold medicines from "ask the doctor" before using to "do not use" in children under two years old. On October 18-19, two advisory committees of the U.S. Food and Drug Administration (FDA) gathered in Maryland to discuss the safety and efficacy of OTC cough and cold medicines for children. The panels, in a majority vote of 13-9, voted to recommend to the FDA that cough and cold active ingredients should no longer be available for use in children under six-years-old. The FDA will review this recommendation and all the data discussed during the advisory committee meeting to determine what actions, if any, it will take.

In response to these reports, CHPA will be launching a new, major multi-year educational campaign to build awareness among parents, other caregivers and healthcare professionals about how to safely use OTC cough and cold medicines in children, and, as importantly, when not to use them. The campaign will stress the safe use and safekeeping of OTC cough and cold medicines to prevent misuse or accidental ingestion. Harm from OTC cough and cold medicines is rare, but is almost always the result of misuse (significant overdose or accidental swallowing due to medicine not being properly stored and secured). Information from this educational program, including a list of products voluntarily withdrawn, can be found at <http://www.otcsafety.org/>.

To date, the FDA has not released any information regarding actions on the cough and cold product labeling.