

# Therapeutic Application and Asthma Outcomes: Louisiana and National Trends

Asthma, P7

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## Adherence to Asthma Guidelines

National standards for the diagnosis and treatment of asthma have been clearly defined<sup>1</sup> and re-evaluated<sup>2</sup> in the United States by the National Asthma Education and Prevention Program Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma in 1997 and its revised version in 2002. Measures of the long-term application and effectiveness of these guidelines have yet to be systematically assessed. Several studies, however, have attempted to evaluate guideline utilization. A pharmacoepidemiologic study of Tennessee Medicaid patients evaluated whether older patients hospitalized with asthma evaluation received appropriate outpatient asthma therapy.<sup>3</sup> The authors demonstrated poor adherence to the guidelines for prescribing as evidenced by significant underutilization of inhaled anti-inflammatory agents, beta<sub>2</sub>-agonists, and rescue corticosteroids. Reddy et al<sup>4</sup> studied guideline prescribing adherence for Connecticut Medicaid high-dose beta<sub>2</sub>-agonist use patients and determined that a high proportion of these patients were not receiving medications according to NIH guidelines. In a cross-sectional analysis in 2002, Shireman et al looked at asthma drug therapy problems as they related to preventable hospitalizations and increased health care utilization in asthmatics. It was found that a large percentage of Medicaid patients were not using asthma drugs in adherence with national guidelines.<sup>5</sup> An evaluation of consistency of care with national asthma guidelines with children in managed care populations revealed that, based on four NIH guideline parameters, approximately one-half of the recipients received care that complied with guidelines.<sup>6</sup> Opportunity for enhanced asthma care is not limited to populations in this country. A Canadian review<sup>7</sup> of the utilization of inhaled short-acting beta<sub>2</sub>-agonists (ISAB), inhaled long-acting beta<sub>2</sub>-agonists (ILAB) and inhaled corticosteroids (ICS) was completed in 2001. Relative to 1996 Canadian asthma guidelines, the study found an over-utilization of ISAB, under use of ICS, and inappro-

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ropriate use of ILAB inhalers. Using pharmacy claims data from 48,751 patients, Jones et al<sup>8</sup> evaluated the effect of the type of asthma therapy on adherence to practice guidelines. Results suggested that patients initiating leukotriene receptor antagonist (LTRAs) treatment maintained compliance with therapy at about twice the rate of those with inhaled beta<sub>2</sub>-agonists or corticosteroids.

## Asthma Outcomes

Several studies have investigated the correlation between adherence to NIH guidelines and asthma outcomes. A recent cohort study evaluated the value of guideline utilization among inner-city adults following emergency department admission for exacerbation of asthma.<sup>9</sup> Results strongly suggested that inhaled corticosteroids were effective in improving lung function and that their use should reduce morbidity in asthmatics, especially among economically disadvantaged inner-city adults. In another recent inquiry, Schatz et al looked at the effectiveness of inhaled corticosteroid use and allergy specialist care in decreasing emergency hospital use among asthma patients.<sup>10</sup> Reduced risk of asthma morbidity was related to adherence to guidelines for ICS use and improved ICS use was related to increased patient care by an allergy specialist. In a cohort study of 11,195 children the effect of inhaled anti-inflammatory therapy on emergency department visits and hospitalizations was examined. Study results indicated a significant protective effect of recommended inhaled corticosteroid and cromolyn use on the risk of ED visits and hospitalization in asthmatic children.<sup>11</sup>

Some additional considerations relative to applications of the national guidelines for asthma therapy have been recently discussed in the literature. The marketing of fixed combination inhalation formulations of long-acting bronchodilators with corticosteroids has added to the therapeutic armamentarium for asthma. At present the only beta<sub>2</sub>-agonist/corticosteroid combination marketed in the United States is fluticasone/salmeterol (Advair Diskus®). The national guidelines, however, do not currently address these fixed combination products nor is there extensive data in this country on their utilization, therapeutic adherence or specific effect on outcome. A Canadian review found that the fixed combination of fluticasone and salmeterol is at least as effective as the respective components used separately and superior to monotherapy with salmeterol or fluticasone in both adult and pediatric groups. Investigators further concluded that this combination product reduces exacerbation rates to enhance improved cost-effectiveness.<sup>12</sup> Lyseng-Williamson et al, in a pharmaco-economic analysis, concluded that this same combination produced clinically meaningful improvements in a cost-effective manner compared to either the respective individual ingredients, to budesonide alone, to budesonide plus formoterol, to montelukast, or to montelukast plus fluticasone.<sup>13</sup> In a long-term Swedish trial, the budesonide/formoterol combination (Symbicort®) was considered to be as safe and effective as the component drugs administered separately. Outcomes also suggested an enhanced adherence rate with the fixed combination product.<sup>14</sup> An additional multicenter investigation evaluated the budesonide/formoterol combination and found it to be as effective, and as well tolerated, as budesonide plus formoterol via separate inhalers.<sup>15</sup>

The relationship of these national and international experiences to asthma outcomes in Louisiana is of interest. The accompanying data on asthma drug utilization ratios and asthma benchmarks provide some instructive baseline information relative to therapy profiles in Louisiana and their possible correlation with disease outcomes.

# Updates to Asthma Benchmarks in the Louisiana Medicaid Program

Medicaid paid claims for continuously eligible recipients with asthma were analyzed to identify changes in previously established benchmarks and measures. The benchmarks were originally established for the one-year period of July 2001 through June 2002. However, in order to provide more frequent updates, the initial benchmarks were recalculated for the two six-month periods of July through December 2001 and January through June 2002. In addition, data for July through December 2002 was analyzed. As a result, this study is comprised of the following three six-month study periods:

1. July through December 2001 - Initial Benchmarks Established.
2. January through June 2002 - Benchmark Update #1
3. July through December 2002 - Benchmark Update #2.

Claims with dates of service within the last six months were not included to allow sufficient time for submission, processing, and payment. Therefore, the study periods of January through June 2003 and July through December 2003 will be deferred to a future update.

Asthma recipients for each study period were selected using inclusion and exclusion criteria from *Respiratory Benchmarks 2000*:

- Recipients were selected if they had at least one claim with asthma as the primary or secondary diagnosis (ICD-9-CM codes of 493 - 493.1 and 493.3 - 493.9).
- Recipients meeting the criteria for chronic obstructive pulmonary disease (COPD) were excluded. COPD recipients were identified by the presence of at least one claim with a primary or secondary diagnosis code of 493.2 (chronic obstructive asthma) or by age greater than 45 years with 2 or more prescriptions for inhaled ipratropium.<sup>16</sup>

Recipients were considered continuously eligible if they were eligible for each month of the study period. They were determined to be Medicare-eligible if they had one or more Medicare-eligible claims during the study period. Table 1 contains information on the study populations for each study period.

**Table 1 – Study Population**

	<b>Jul-Dec 2001</b>	<b>Jan-Jun 2002</b>	<b>Jul-Dec 2002</b>
Total Continuously Eligible Asthma Recipients (Study Population)	28,560	32,765	34,419
Medicare-Eligible Asthma Recipients	2,055	2,272	2,279
Medicare-Eligible Percentage	7.2%	6.9%	6.6%

## Asthma Period Prevalence

The period prevalence of asthma was calculated by dividing the number of continuously eligible recipients with an asthma diagnosis by the total number of continuously eligible recipients in the Medicaid population for each study period. As shown in Table 2, the overall statewide period prevalence of asthma in the Medicaid population was 4.2% for the initial benchmark period. The prevalence increased to 4.5% during the period of January through June 2002, and remained constant for the period of July through December 2002. The prevalence of asthma in children aged 17 and under was nearly double that of adults aged 18 and over. The highest prevalence (6.3 - 6.6%) was found in children under 18 in the New Orleans region. The lowest prevalence (2.1 - 2.2%) was found in adults residing in the North Louisiana region.

# Updates to Asthma Benchmarks in the Louisiana Medicaid Program

**Table 2 – Period Prevalence by Age Group and Region  
(Sorted by Descending Prevalence)**

Age Group	Region	Jul-Dec 2001	Jan-Jun 2002	Jul-Dec 2002
0-17	New Orleans	6.3%	6.6%	6.5%
0-17	Acadiana	4.8%	5.5%	5.5%
0-17	Baton Rouge	4.8%	4.9%	5.1%
0-17	North Louisiana	4.4%	4.6%	4.7%
<b>0-17</b>	<b>Statewide Prevalence</b>	<b>5.2%</b>	<b>5.5%</b>	<b>5.5%</b>
18+	New Orleans	2.9%	2.8%	3.0%
18+	Baton Rouge	2.4%	2.4%	2.5%
18+	Acadiana	2.3%	2.3%	2.2%
18+	North Louisiana	2.1%	2.2%	2.2%
<b>18+</b>	<b>Statewide Prevalence</b>	<b>2.5%</b>	<b>2.5%</b>	<b>2.5%</b>
<b>All Ages</b>	<b>Overall Statewide Prevalence</b>	<b>4.2%</b>	<b>4.5%</b>	<b>4.5%</b>

Table 3 shows the period prevalence of asthma by age group, gender, and race. Black males under the age of 18 had the highest prevalence (6.1 - 6.4%). In children under 18, the prevalence was higher in males than in females. However, in adults aged 18 and over, the prevalence of asthma was higher in females than in males.

**Table 3 – Period Prevalence by Age Group, Gender, and Race  
(Sorted by Descending Prevalence)**

Age Group	Gender	Race	Jul-Dec 2001	Jan-Jun 2002	Jul-Dec 2002
0-17	Male	Black	6.1%	6.4%	6.4%
0-17	Male	White	5.4%	6.0%	6.0%
0-17	Male	Other	4.8%	5.9%	5.4%
0-17	Female	Black	4.6%	4.7%	4.7%
0-17	Female	White	4.1%	4.5%	4.5%
0-17	Female	Other	3.2%	3.7%	4.3%
18+	Female	Black	3.0%	3.0%	3.1%
18+	Female	White	2.6%	2.6%	2.6%
18+	Female	Other	2.6%	2.8%	2.5%
18+	Male	Other	2.3%	1.4%	1.6%
18+	Male	Black	1.7%	1.6%	1.7%
18+	Male	White	1.5%	1.5%	1.5%

## Asthma Drug Utilization Ratios

Drug claims were selected using HEDIS 2003 numerator and denominator lists<sup>17</sup>. Drugs listed in the numerator list are control medications which are taken regularly to prevent asthma attacks. The denominator list contains all asthma drugs. Relief medications are used to provide immediate relief from an asthma attack. A listing of relief medications was derived using the following formula:

$$\begin{aligned} & \text{NDC Codes for Total Medications from the Denominator List} \\ & \text{Minus NDC Codes for Control Medications from the Numerator List} \\ & \text{Equals NDC Codes for Relief Medications}^{17} \end{aligned}$$

# Updates to Asthma Benchmarks in the Louisiana Medicaid Program

With increased use of control medications, the frequency of asthma attacks can be reduced. This reduces the need for relief medications and may reduce the frequency of emergency room visits and inpatient admissions. Examples of control medications include leukotriene-modifying agents, inhaled corticosteroids, xanthines, and mast cell stabilizers. Relief medications are generally classified as beta<sub>2</sub>-agonists.

Table 4 below shows the ratio of dispensing events for control medications to relief medications and for control medications to total medications. It also shows the ratio of the number of recipients on a control medication to the total number of continuously eligible recipients in the study group.

**Table 4**

	<b>Jul-Dec 2001</b>	<b>Jan-Jun 2002</b>	<b>Jul-Dec 2002</b>
Ratio of Controller to Relief Medications	0.828	0.768	0.853
Ratio of Controller to Total Medications	0.453	0.435	0.460
Ratio of Recipients on Controller Medications to Total Recipients	0.407	0.404	0.425

Note: The number of dispensing events is based on the number of 30-days supply prescriptions. For example: a prescription for a 60-day supply would be counted as two dispensing events.

## Asthma Benchmarks

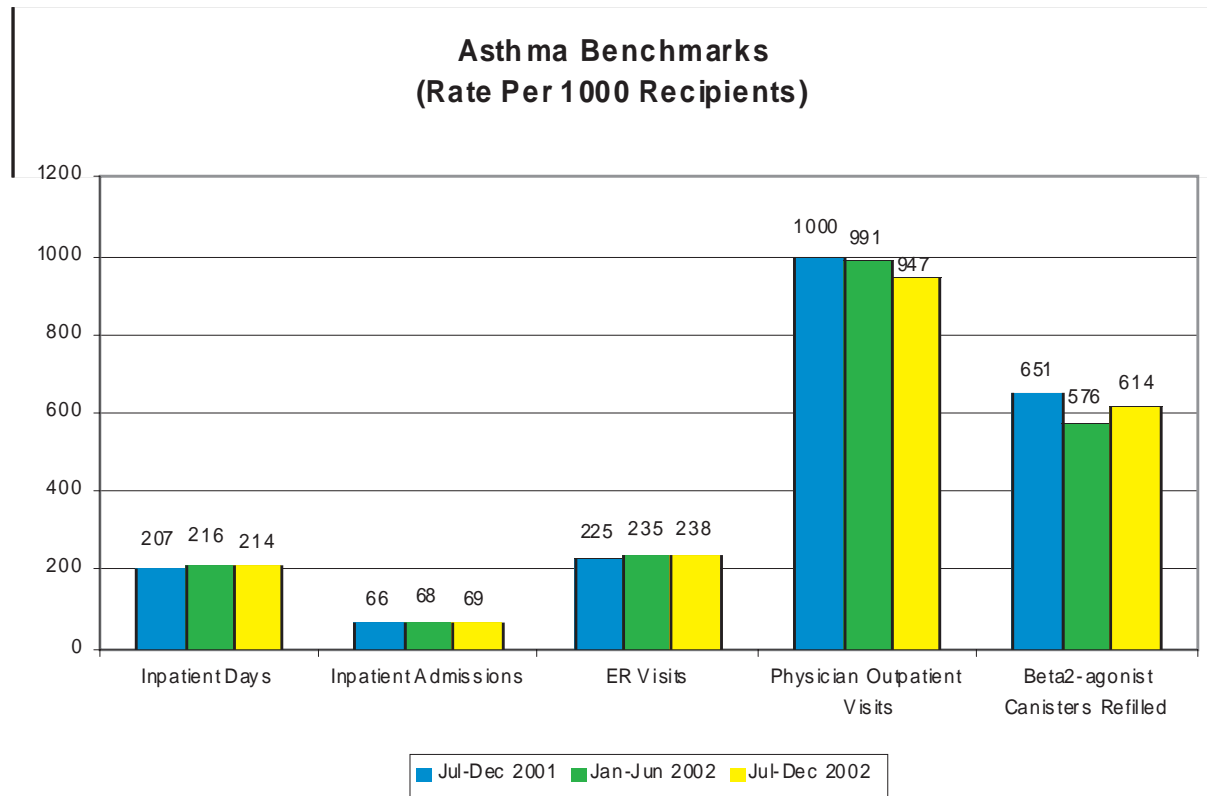
Figure 1 shows the benchmarks used as the basis for measuring the progress of asthma therapy in the Louisiana Medicaid system. These benchmarks are key measures expressed as rates per 1000 recipients. They include the number of:

- Beta<sub>2</sub>-agonist canisters refilled
- Physician outpatient visits
- Emergency room visits
- Inpatient admissions
- Inpatient days

An analysis of Figure 1 indicates that the number of beta<sub>2</sub>-agonist canisters refilled decreased slightly from the original benchmark. This could be an indication that more recipients used controller medications to prevent asthma attacks. Also, the decrease in the number of physician visits may suggest that recipients achieved better control of their asthma. However, the number of inpatient admissions, inpatient days, and emergency room visits increased slightly.

# Updates to Asthma Benchmarks in the Louisiana Medicaid Program

**Figure 1**



**Notes to Figure 1:**

1. The number of beta2-agonist canisters equals the number of prescriptions for inhaled aerosol control medications classified as short-acting adrenergic bronchodilators by HEDIS 2003. 17
2. Physician outpatient visits are derived from the following claim types:
  - Outpatient
  - Physician
  - Medicare Crossovers - Institutional
  - Medicare Crossovers - Professional
 The physician outpatient claims also meet the following CPT code classifications:
  - Office or Other Outpatient
  - Consultations - Office or Other Outpatient
  - Domiciliary, Rest Home, or Custodial Care Services
  - Home Services
  - Preventive Medicine Services - New or Established Patient 18
3. Emergency room visits are derived from the number of claims with a CPT code designating emergency room services.
4. Inpatient admissions are calculated by counting the number of inpatient and institutional claims identified as hospital admissions.
5. Service days for claims with a claim type of inpatient or institutional are summed to provide the number of inpatient days. Claims with a CPT code designating outpatient services are excluded.

## Asthma and Influenza

The Centers for Disease Control and Prevention recommends an annual influenza vaccination for people with asthma<sup>19</sup>. There is limited data on the number of asthma patients who routinely receive influenza vaccine. A recent cross-sectional analysis of data from 1999 to 2001<sup>20</sup> found suboptimal vaccination rates among patients between the ages of 18 to 64 years old. Among patients aged 18 to 49 years of age, the average vaccination rate was 21.6% and the rate for those aged 50 to 64 years was 45.4%. Utilization rates increased with both age and level of education, while no correlation was demonstrated with gender, race, or ethnicity. While there is a paucity of evidence regarding the impact of influenza vaccination on asthma outcome, a couple of recent investigations looked at this relationship. An observational review evaluated the effectiveness of influenza vaccine in reducing severe and fatal complications in patients with asthma and/or chronic obstructive pulmonary disease (COPD).<sup>21</sup> Findings were that vaccination appeared to be associated with a clinically relevant reduction in severe asthma complications. The effectiveness of influenza vaccination in reducing asthma exacerbations was tested in a placebo-controlled trial of 696 children.<sup>22</sup> The investigators found that vaccination did not result in a significant reduction of the number, severity or duration of asthma attacks caused by influenza. Regarding vaccine safety, a cohort study of 12,000 adult subjects with asthma or COPD investigated disease worsening following influenza vaccination. Findings indicated no increased risk of adverse outcomes was associated with the vaccine for the first two weeks after vaccination.<sup>23</sup> Given concerns that influenza vaccine may exacerbate asthma attacks and may keep many asthmatic children from being immunized, Goldstein reviewed the literature relative to the safety and efficacy of influenza vaccine in asthmatic children. His findings strongly suggest the safety and efficacy of influenza vaccines in asthmatic children.<sup>24</sup>

## Recent Pharmacotherapy Notes

Magnesium and Vitamin C both have been suggested as contributing to a reduced risk of asthma based on epidemiological evidence. To test this hypothesis, a recent placebo controlled trial with 300 patients investigated the effect of both of these supplements on FEV1, FVC, airway responsiveness to methacholine, mean morning and evening peak flow rates, symptom scores and bronchodilator use as outcome measures. Data from this study demonstrated no beneficial effect of either supplement on any outcome measure employed in this trial.<sup>25</sup>

Monoclonal antibody anti-immunoglobulin E (IgE) therapy is indicated for the treatment of moderate to severe persistent asthma in adults and adolescents who have positive skin tests or in-vivo reactivity to a perennial aeroallergen, and whose symptoms are not adequately managed with inhaled corticosteroids.<sup>26</sup> Omalizumab (Xolair®), a recombinant humanized monoclonal antibody directed against IgE, is the only currently approved drug of this type indicated for adjunctive treatment of allergic asthma. Omalizumab is administered by subcutaneous and intravenous injection, although only the former route is approved in the U.S. Various recent trials<sup>27,28,29,30</sup> have demonstrated reduction of asthma exacerbations in patients with moderate to severe persistent asthma not adequately controlled with inhaled corticosteroids. Efficacy was demonstrated in these studies for up to 52 weeks in improvement in the quality of life for study subjects. Lanier et al recently completed a placebo-controlled investigation, which further demonstrated the long-term efficacy of omalizumab in reducing asthma exacerbations.<sup>31</sup>

## Recent Pharmacotherapy Notes

Current research is underway to determine the role of efalizumab, a humanized immunoglobulin G1 monoclonal antibody against the lymphocyte function antigen-1 (LFA-1) alpha chain, CD11a. Blocking of interactions between LFA-1 and intercellular adhesion molecules could inhibit asthmatic inflammation by blocking adhesion and activation of LFA-1 positive leukocytes. This recent placebo controlled trial evaluated the effect of efalizumab on allergen-induced airway responsiveness and airway inflammation. Efalizumab demonstrated effectiveness in reducing cellular inflammatory response measured in induced sputum and may attenuate the late asthmatic response.<sup>32</sup>

Melatonin levels and their relationship to overnight decline in pulmonary physiology in subjects with nocturnal asthma, non-nocturnal asthma and health controls were recently investigated.<sup>33</sup> The correlation between serum melatonin levels and overnight change in spirometry was evaluated, with the conclusion that nocturnal asthma is associated with elevation of peak serum melatonin levels. The impact of supplemental melatonin on asthma outcome awaits further clinical investigation. Supplemental melatonin is not covered by Medicaid at this time.

A Phase II randomized controlled trial is currently assessing the clinical benefits and risks of dietary borage oil containing gamma-linolenic acid and Ginkgo biloba in patients with mild persistent to moderate asthma.<sup>34</sup> The influence of these products on suppression of inflammatory leukotriene and on histamine release respectively is being evaluated. Quercetin, a constituent of Ginkgo biloba, is known to be structurally related to cromolyn sodium.

## Conclusion

There is a demonstrated correlation between adherence to NIH asthma guidelines, asthma morbidity, and reduction in the need for emergency services and hospitalization related to asthma<sup>9,10,11</sup>. However, lack of adherence to, and compliance with, these guidelines offers a significant therapeutic opportunity for both patients and providers, to substantially improve quality of care, thus positively improving associated outcomes. Various investigations have identified problems with over and underutilization of asthma medications, and other inappropriate applications of asthma care guidelines for both adults and children<sup>3,4,5,6,7,8</sup>. Medicaid data on relative use of control therapy versus relief therapy further suggest need for improvement. Application of disease state management resources and tools are essential to further understand these therapeutic deficits and to correct their impact on patient morbidity and mortality.

*Educational material provided to Louisiana Medicaid providers by the Louisiana Medicaid Pharmacy Benefit Management Program in the Department of Health and Hospitals (PBM) and developed by the University of Louisiana at Monroe School of Pharmacy.*

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# Complete Wellness: A Guide to Managing Your Health

\* The following is an abbreviated version of the education material sent to selected Medicaid recipients.

## What is Asthma?

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**A**sthma is a breathing problem that makes it hard for you to get air in and out of your lungs. Do you experience coughing, shortness of breath, wheezing, or tightness in your chest? Being aware of these symptoms may help you know if you are having an asthma attack.



## What Makes Asthma Worse?

Asthma symptoms don't just happen - Some things make asthma worse. Things that make your asthma worse are called "triggers." Asthma triggers are different for everyone. Knowing what causes your asthma attacks will help you avoid them and give you more control.

Here are some common asthma triggers:

- Pollen from plants
- Mold/mildew
- Some medications
- Animal droppings
- Cigarette smoke
- Some foods

## Staying Away From Your "Triggers" is the Key!

- Use "allergy-proof" covers for your mattresses and pillows.
- Avoid outdoor activities during allergy season.
- Avoid animals that may make your asthma/allergies worse such as dogs, cats, or birds.
- Fix any water leaks to prevent mold and mildew from growing.
- Avoid smoky places such as fireplaces, barbecue grills, or smoking areas.
- Stay away from strong odors such as perfume, paint, and hair spray.
- Change your heat/air conditioning filter at least once a month.

## Can My Asthma Be Treated?

Yes! Your asthma can be treated. Asthma symptoms can be prevented or controlled with the right medications. There are two main groups of asthma medications.

Fast-acting medications are used to provide relief for a short period of time. These "rescue medications," help open up the airway to let more air get to the lungs. They help stop asthma attacks after they have started. These medicines usually begin to work 5-10 minutes after you take them. They should be taken within 5 minutes after symptoms begin. This class of drugs includes:

- **Albuterol**
- **Combivent®**

Long-acting medications are used to help prevent asthma attacks from starting. These "control medications" help keep your airways open all the time so that you don't have an attack. This class of drugs includes:

- **Accolate®**
- **Advair®**
- **Cromolyn**
- **Flovent®**
- **Pulmicort®**
- **Serevent®**
- **Singulair®**
- **Theo-Dur®**

The long-acting medications should be taken every day to prevent an asthma attack, even if you do not have symptoms. Your doctor will decide which medications are right for you. You may be taking one or more medicines to help control your asthma. It is very important that you learn when to use your fast-acting medication for relief to help stop an attack and how to use your long-acting medication for control to help prevent an attack from occurring. If you only have a long-acting medication and not a fast-acting medication, talk to your doctor about the importance of having a "rescue medication" for your asthma attacks.

## What Should I Do If I Have An Asthma Attack?

Asthma attacks can happen very suddenly. Attacks can be severe, moderate, or mild. During any kind of attack, only take medicines that your doctor has given you for your asthma. During a mild or moderate attack, you will feel tightness in your chest and you might make a whistling sound when you breathe. These types of attack are more common. If you have a mild or moderate attack, take your asthma medication as directed by your doctor. In a severe attack, you will become breathless and have trouble talking. Get help right away! Go to your doctor's office, or to an emergency room



## Tips for Using Your Inhaler:

Hold your breath for 10 seconds after inhalation.

- Wait one minute between puffs.
- Do not block inhaler with your tongue.
- Do not use inhalers with gum or other objects in your mouth.
- Wash mouth out with water after using long-acting inhalers to prevent fungal infections in your mouth and throat.
- Spacers help to get more medicine to your lungs. Ask your doctor, pharmacist, or nurse for more information.



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*Ask your doctor, nurse, and/or pharmacist about the information contained in this brochure*

## How Can I Tell If My Medication is Working?

Using a peak flow meter to see how well air flows from your lungs can help you control your asthma. Your doctor can use the measurements to figure out what asthma medications are right for you. A peak flow meter can help you know if you are using your medications correctly, and warn you of an asthma attack even before you feel the symptoms. You can also use your meter during asthma attacks to see how bad the attack is. Talk with your doctor, pharmacist, or nurse to get more information on using a peak flow meter.

## Learn to Control Your Asthma So That It Doesn't Control You.

- Figure out what triggers your asthma symptoms and try to stay away from these things.
- Learn the correct way to use your inhaler.
- Find out how a spacer and a peak flow meter will help you control your asthma.
- It is important to understand when to use your fast-acting "rescue medications," to help stop an attack, and when to use your long-acting "control" medications to help prevent an attack.
- Don't use your fast-acting medication more often than what your doctor prescribed without talking to your doctor.

## Helpful Information for You!

If you would like additional information on asthma, you can contact one of the following:

### **The American Lung Association®**

61 Broadway, 6th Floor  
New York, NY 1000  
Phone: 1-800-LUNG-USA  
(1-800-586-4872) <http://www.lungusa.org>

### **American Academy of Allergy, Asthma & Immunology**

611 East Wells Street;  
Milwaukee, WI 53202  
Phone: (800) 822-2762 [info@aaaai.org](mailto:info@aaaai.org)

### **National Heart, Lung & Blood Institute-Health Information Center**

P. O. Box 30105  
Bethesda, MD 20824-0105  
Phone:(301) 592-8573 [nhlbiinfo@rover.nhlbi.nih.gov](mailto:nhlbiinfo@rover.nhlbi.nih.gov)

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