



# The DUR Discovery

Exploring ways to improve pharmacotherapy

## Appropriate Treatment of Allergic Rhinitis

By Chris Owens, PharmD,  
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Allergic rhinitis is a common condition encountered in primary care affecting approximately 40 million people in the US. Symptoms are due to the effects of histamine, leukotrienes, and other inflammatory mediators resulting from a hypersensitivity reaction of the nasal mucosa. Historically, this condition has been treated with antihistamines and/or nasal corticosteroids, but newer agents including montelukast (Singulair®) are also commonly employed. Controversy currently exists regarding the appropriate place in therapy of older, less expensive agents vs. newer, more expensive ones.

While not intended to replace clinical judgment, a review of the literature and expert consensus yields the following key points in the appropriate management of allergic rhinitis:

- Antihistamines are the mainstay of treatment for mild-to-moderate symptoms and are best initiated PRIOR to symptom onset; if initiated after symptoms have begun, it may take days to weeks for a full effect to be realized
- A trial of an older antihistamine (i.e. chlorpheniramine) may be reasonable for many patients as they are equally efficacious to newer agents, are on average much less expensive, and tolerance to adverse effects (i.e. sedation) often develops with continued use
- Nasal steroids should be reserved for patients with more severe symptoms or those who fail other treatments

- Intranasal antihistamines (i.e. Astelin®) are more expensive and offer little therapeutic benefit over oral antihistamines
- Leukotriene inhibitors (i.e. Singulair®) have been shown to be as effective as antihistamines but less effective than nasal steroids

In a recent study conducted by the Idaho Drug Utilization Review (DUR) program, it was determined that nasal steroids and leukotriene inhibitors made up nearly 60% of all claims for allergic rhinitis treatments prescribed during last year's allergy season (April to September 2005) in patients without asthma. A survey revealed that many physicians and pharmacists are unaware of current prior authorization (PA) criteria for newer antihistamines, and among those who are aware of these criteria, controversy exists regarding their appropriateness.

Currently, Idaho Medicaid PA criteria require an ICD-9 coded diagnosis of allergic rhinitis (477.xx) or chronic urticaria (708) and a documented failure (in the clinician's judgment) of two older antihistamines before OTC loratadine will be approved for payment (with a written prescription) for patients older than 20 years of age. For younger patients, OTC loratadine is approved for payment with a coded diagnosis and a written prescription. A documented failure of OTC loratadine will allow for payment of other options (Zyrtec®, Allegra®). Proposed changes to these criteria are under discussion.

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## Recent Prior Authorization of Soma®

By Chris Owens, PharmD, BCPS

Skeletal muscle relaxants (SMRs) are agents commonly used in the treatment of spasticity or acute painful musculoskeletal conditions of local origin, such as low back pain. Agents in this group include baclofen (Lioresal®), carisoprodol (Soma®), chlorzoxazone (Parafon Forte®), cyclobenzaprine (Flexeril®), dantrolene (Dantrium®), methocarbamol (Robaxin®), metaxalone (Skelaxin®), orphenadrine (Norflex®), and tizanidine (Zanaflex®).

Abuse of SMRs has been reviewed in the literature. Soma is of particular concern and while it is unscheduled in Idaho at this time, it is a schedule IV controlled substance in several other states. Numerous case reports of physical dependence and withdrawal associated with this agent have been documented, and the US Drug Abuse Warning Network (DAWN) reported over 17,000 Soma-related emergency department (ED) visits in 2004, nearly three times the number reported from other SMRs.

According to Idaho Medicaid claims data, Soma was the most commonly prescribed SMR for musculoskeletal conditions in 2003 and the second most prescribed in both 2004 and 2005. A large percentage of patients were prescribed the agent four or more consecutive months of therapy during a six month period, a marker for potential abuse according to controlled substance patterns of utilization requiring evaluation (CS-PURE) criteria.

Despite educational efforts undertaken by the Drug Utilization (DUR) program in 2004 and 2005 designed to reduce utilization of this agent, it continued to be regularly prescribed and so was included in the state's enhanced prior authorization program (EPAP) effective December 1, 2005. At that time Soma was given non-preferred status and specific criteria were implemented including a restriction of no more than a 34 days supply allowed no more frequently than every six months.

Due to concern regarding the potential negative impact of these criteria on patients who were chronic users of Soma prior to December 2005 and who were made to undergo a therapeutic conversion as a result of it, the DUR program undertook a study to determine what agent (if any) these patients were converted to and assess any increase in healthcare utilization or costs in the months following PA implementation.

Approximately 130 patients were identified as chronic users of Soma in 2005 that had no claims for the drug in December 2005 or thereafter. Results indicated no statistically significant increase in physician office visits, ED visits, or costs for these patients in the first three months of 2006. Furthermore, only 40% of patients had claims for a different SMR (Flexeril or Robaxin predominantly) as of March 2006. A questionnaire distributed to pharmacies for the remaining 60% of former chronic Soma patients indicated a significant number continued using the agent, although they were paying out-of-pocket for it.

Soma...is a schedule IV controlled substance in several other states. Numerous case reports of physical dependence and withdrawal associated with this agent have been documented.

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## Cost Corner: Nebulized Therapy in COPD

By Brooke Pugmire, PharmD

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of chronic morbidity and mortality in the United States. In efforts to increase awareness and improve treatment of COPD the Global Initiative of Obstructive Lung Disease (GOLD) was released in 2001. Key points from the GOLD report include:

- Diagnosis of COPD should be confirmed by spirometry
- Pharmacotherapy is used to decrease symptoms and complications; no drugs have been shown to modify long-term decline in lung function
- Bronchodilators ( $\beta_2$ -agonists, anticholinergics, and theophylline ) are central in treatment on an as-needed or regular basis
- Regular use of inhaled steroids should only be

used in those with a documented spirometric response or an FEV1 < 50% predicted and that have repeated exacerbations requiring antibiotics or oral glucocorticoids

- Nebulized therapy is more expensive and should be avoided in stable patients unless it has been shown to be better than conventional dose therapy

The use of nebulized therapy is of particular concern due to its high cost. Cost of drug delivery via wet nebulization is more than 2-fold higher than inhalation via an MDI for most of the commonly prescribed drugs for COPD. A cost comparison is shown in table I.

In a recent study undertaken by the Drug Utilization

(COPD continued on page 4)

**Table I:** Cost Comparison of Commonly Prescribed Drugs for COPD

Category	Agent	Common Daily Dose	Estimated Cost per Month*#
<b><math>\beta_2</math>-agonists</b>	Albuterol Inhaler (Proventil®)†	180 mcg inh qid	\$10.99
	Albuterol Neb. Solution (Proventil®)†	2.5 mg neb qid	\$94.95
	Formoterol Capsules(Foradil Aerolizer®)‡	12 mcg inh bid	\$108.17
	Levalbuterol Inhaler (Xopenex HFA®)†	90 mcg inh qid	\$48.99
	Levalbuterol Neb. Solution (Xopenex®)†	0.63 mg neb qid	\$354.20
	Metaproterenol Inhaler (Alupent®)†	1.3 mg inh q 4h	\$72.18
	Metaproterenol Neb. Solution (Alupent®)	0.2 ml 5% neb q 4h	\$75.96
	Pirbuterol Inhaler (Maxair Autohaler®)†	200 mcg inh qid	\$94.76
Salmeterol Inhaler (Serevent Diskus®)‡	50 mcg inh bid	\$104.18	
<b>Anticholinergics</b>	Ipratropium Inhaler (Atrovent®)	36 mcg inh qid	\$37.99
	Ipratropium Neb Solution (Atrovent®)	500 mcg neb qid	\$59.95
	Tiotropium Capsules (Spiriva HandiHaler®)†	18 mcg inh qd	\$129.55
<b>Inhaled Steroids</b>	Beclomethasone Inhaler (Qvar®)	80 mcg inh bid	\$73.57
	Budesonide Inhaler (Pulmicort Turbuhaler®)‡	200 mcg inh bid	\$152.56
	Budesonide Neb. Suspension (Pulmicort Respules®)‡	0.25 mg neb bid	\$298.70
	Flunisolide Inhaler (Aerobid®)†	500 mcg inh bid	\$77.55
	Fluticasone Inhaler (Flovent HFA®)‡	110 mcg inh bid	\$97.48
	Triamcinolone Inhaler (Azmecort®)†	200 mcg inh qid	\$105.99
<b>Combination Products</b>	Albuterol/Ipratropium Aerosol (Combivent®)‡	120/21 mcg inh qid	\$91.99
	Albuterol/Ipratropium Neb. Solution (DuoNeb®)‡	3/0.5 mg neb qid	\$247.46
	Fluticasone/Salmeterol Inhaler (Advair Diskus®)‡	250/50 mcg inh bid	\$151.99

\*Cost based on generic agent (if available) [www.drugstore.com](http://www.drugstore.com) (5/2006)

#Additional 30 day cost for renting nebulizer equipment is approximately \$36.50

†Idaho Medicaid preferred drug

‡Brand name only, no generic available

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### Allergic Rhinitis (from page 1)

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### COPD (from page 3)

Review (DUR) program, the implementation of selected drug-related GOLD recommendations was characterized in the Idaho Medicaid population. The main objective of the study was to evaluate the use of nebulized medications. The claims database was queried to identify patients with a coded diagnosis of COPD and who were regular users of nebulized drugs. Of the 8,385 patients with COPD identified in calendar year 2005, 267 (3%) had claims for a nebulized drug on a regular basis, indicating that routine use of nebulized drugs is a NOT a major problem in the Idaho Medicaid population.

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