Wyoming Drug Utilization Review

Asthma: Alternative and Adjunct Medications

Raven Callas, PharmD

The treatment of asthma often requires long-term control medications. Cromolyn sodium, nedocromil, and omalizumab are all examples of alternative or adjunctive asthma treatments for long-term control.[1] Cromolyn and nedocromil are both considered alternative medications in step 2 care. They are also used as preventative treatments for exercise induced bronchospasm, and can be used before unavoidable exposure to known allergens. Omalizumab is used as adjunctive therapy in step 5 or 6 care for patients who are 12 years of age or older and who have allergies.[1]

Cromolyn and nedocromil are mast cell stabilizers that have different properties, but similar anti-inflammatory actions.[2,3] They prevent the release of histamine and the slow-reacting substance of anaphylaxis of mast cells by inhibiting degranulation after contact with antigens.[2,3] The use of cromolyn in all patients and nedocromil in patients 5 years of age or greater as alternative medications for the treatment in step 2 care is considered level A evidence, having many randomized controlled trials to support their use. Both cromolyn and nedocromil have been shown to provide greater symptom control than placebo in most clinical trials.[1] In a meta-analysis of 28 trials involving children and adults, inhaled corticosteroids provided better asthma control in patients than cromolyn, making cromolyn an alternative agent, not a preferred one.[4] Nedocromil is not recommended for patients less than 5 years of age because adequate studies for safety and efficacy have not been performed in this age group.[1]

Cromolyn and nedocromil are generally well tolerated, although greater than 10% of patients experience an unpleasant taste upon administration with both agents.[2] Inhaled cromolyn is not associated with additional adverse effects. Additional adverse effects associated with nedocromil are cough (9%), pharyngitis (8%), headache(8%), rhinitis (7%), nausea (4%), vomiting (3%), dyspepsia (2%), abdominal pain (2%), and fatigue (1%).[2]

Omalizumab is a monoclonal antibody that prevents binding of IgE to receptors on basophils and mast cells.[2,3] The decrease in IgE binding leads to decreased release of mediators in response to exposure to an allergen.[2,3] Omalizumab is used as an adjunctive therapy for patients who have allergies and are not controlled with a combination of high dose inhaled corticosteroids and long acting bronchodilators in step 5 or 6 care.[1] Evidence for the use of omalizumab for these indications is considered level B evidence, having lower quality randomized controlled trials than level A evidence. Omalizumab is a subcutaneous injection and is dosed every 2 or 4 weeks based on body weight and IgE levels.[1]

Omalizumab is currently undergoing a continuous safety review by the FDA.[2] An ongoing study titled: Evaluating the Clinical Effectiveness and Long-Term Safety in Patients with Moderate

continued on page 3

Wyoming Drug Utilization Review
University of Wyoming
School of Pharmacy
Dept. 3375
1000 E. University Ave
Laramie, WY 82071
307-766-6750

www.uwyo.edu/DUR

Edited by
Aimee Lewis, PharmD
Laura Miller, MS

P & T Committee Meeting Update

The P&T Committee met for its bimonthly business meeting on August 19, 2010. Highlights of this meeting include the following.

The University of Wyoming School of Pharmacy was awarded the contract for Drug Utilization Review Program services following the request for proposals which was released in May of this year.

The Wyoming Department of Health is currently negotiating a contract with the University of Washington for pediatric psychiatry consultation services. This will consist of three separate services including a mandatory second opinion line, a voluntary provider access line and consultation with multi-disciplinary team evaluations.

The following criteria were approved:

- A prior authorization will be required for use of six or more different psychotropic medications.
- Criteria for use of **Synagis** in the 2010/2011 season was finalized. To view the proposed PA form, please visit the DUR website at www.uwyo.edu/DUR.
- Criteria for **ondansetron** was updated to allow one-dose for children under age twelve who do not have a cancer diagnosis. There will be no restrictions for those aged twelve and older or for children under age twelve with a cancer diagnosis.
- **Orbivan (butalbital/acetaminophen/caffeine)**: 30 day trial and failure of all other headache agents required prior to approval.
- **Oravig (miconazole buccal tablet):** Limit utilization to diagnosis of oral candidiasis AND diagnosis of head and neck cancer or HIV.
- **Ulesfia (benzyl alcohol):** Trial and failure of lindane and permethrin prior to approval.
- **Jalyn (dutasteride and tamsulosin):** Trial and failure of preferred single agents.
- Coverage of cough and cold products will be limited to the list of products found on the website at www.uwyo.edu/DUR.

The next P&T Committee meeting will be held November 18, 2010 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.

PDL vs. PA

Medications are managed by the Wyoming Medicaid Pharmacy Program through various means, including:

1. Preferred Drug List with prior authorization for non-preferred medications.
2. Straight prior authorization with clinical criteria (non-PDL classes)
3. Quantity/dose limits

Drug classes not included on the Preferred Drug List may be managed through one of the other mechanisms. Please refer to the Additional Therapeutic Criteria Chart, Dosage Limitation List, Epocrates, and the Wyoming EqualityCare Provider Manual at http://wyequalitycare.org for additional criteria.

to Severe Asthma (EXCELS) has found evidence that suggests an increase in ischemic heart disease, arrhythmias, cardiomyopathy, cardiac failure, pulmonary hypertension, cerebrovascular disorders, and embolic and thrombotic events.[5] The FDA is not recommending that patients stop taking omalizumab at this time or advising the prescribing information be changed.[5]

Anaphylaxis can occur with administration of omalizumab immediately after injection or hours later.[3] Physicians who administer omalizumab should be able to recognize signs of anaphylaxis and treat patients accordingly.[1] Patients should also receive education on how to recognize and treat anaphylaxis if it occurs.[1] Omalizumab has a Black Box Warning because of the risk of anaphylaxis. A MedGuide must be provided when the drug is dispensed. The most common adverse effect experienced with omalizumab therapy is an injection site reaction, having an occurrence of 45%.[2] Most injection site reactions occur within an hour of administration and last for less than 8 days. Injection site reactions decrease with additional dosing. Other adverse reactions are viral infections (23%), upper respiratory tract infections (20%), sinusitis (16%) headache (15%), and pharyngitis (11%).[2]

Long-term control of asthma can be achieved with medications such as nedocromil and cromolyn as alternatives to inhaled corticosteroids and long acting bronchodilators. Omalizumab is used as an adjunctive therapy in patients who have allergies in addition to asthma. Nedocromil and cromolyn are both used in step 2 therapy, while omalizumab is reserved for step 5 or 6 therapy. All three medications appear to be safe and effective. Omalizumab is currently undergoing a continuous safety review; however, the FDA has not recommended a change in prescribing for this medication.

References

1. National Asthma Education and Prevention Program. Expert Panel Report 3 (EPR-3): Guidelines for the diagnosis and management of asthma-summary report 2007. J Allergy Clin Immunol. 2007. 120(5 Suppl):S94-138.
2. Lexi-Drugs Online. Lexi-Comp Online. Hudson (OH): Lexi-Comp, Inc.; 2010. Available from: http://online.lexi.com. Accessed: April 19, 2010.
3. Drug Facts and Comparisons®. Facts & Comparisons 4.0 Online®. Indy (IN): Wolters Kluwer Health Inc.; 2010. Available from: http://www.online.factsandcomparisons.com. Accessed: April 19, 2010.
4. Guevara JP, Ducharme FM, Keren R, et al. Inhaled corticosteroids versus sodium cromoglycate in children and adults with asthma. Cochrane Database of Systemic Reviews 2006, Issue 2. Art No.:CD003558. DOI: 10.1002/14651858.CDO03558.pub.2.
5. MedWatch. Early communication about an ongoing safety review of omalizumab (marketed as Xolair). (7-16-2009). U.S. Food and Administration Web site.

2011 P & T Committee Meeting Dates

February 17, 2011
May 19, 2011
August 18, 2011
November 17, 2011

Meeting time: 9 am - 3 pm
Location: Cheyenne

Wyoming Drug Utilization Review
University of Wyoming
School of Pharmacy
Dept. 3375
1000 E. University Avenue
Laramie, WY 82071

Non-Profit Organization
US Postage
Paid
Laramie WY 82070
Permit 75

Return Service Requested

September 2010

Wyoming Drug Utilization Review

In This Issue

Asthma: Alternative and Adjunct Medications
P & T Committee Meeting Update
PDL vs. PA
2011 P & T Committee Meeting Dates

Please contact WY-DUR at 307-766-6750 if you would like to have your name added or removed from our mailing list, or if you need to have your address updated. The WY-DUR newsletter is also available on-line at *www.uwyo.edu/DUR/newsletters*.