

Preferred Drug List Advisory Committee Meeting
Tuesday February 10, 2009
Cheyenne, Wyoming
10 a.m. – 2 p.m.

Members present: Marion Smith, W. Joseph Horam, Whitney Buckley, Dean Winsch, Kevin Robinett

Members excused: Scott Johnston

Ex-officio: Antoinette Brown, Donna Artery, Roxanne Homar, James Bush

Guests: Lakhman Gondalia, Laurie Roscoe, Nikki Yost, Barbara Felt, GSK; Jeff Himmelberg, GSK; George Dela Cerda, AZ; Randy Dirks, GSK; Roy Saarg, Merck; Roy Lindfield, Schering; Dan Manning, Schering; Tim Hynek, Lilly; Todd Rodeheauer, Pfizer; Wyatt Christensen, SoP student; Chandra McCann, SoP student; Cloie Morrison-Heffern, SoP student.

Dr. Smith called the meeting to order at 10:05 a.m and reviewed the objective of the Committee.

Review of Minutes

The minutes of the October 15, 2008 meeting were approved as submitted.

Dr. Bill Harrison has resigned from the Committee, leaving a vacancy in the Vice-Chair position. Dean is interested in the position and all members were in favor of his filling the position.

Nasal Corticosteroids

Dana Selover presented the Nasal Corticosteroids DERP report. Copies of the slides are available upon request.

Public Comment:

Dan Manning (Schering-Plough) provided comments on Nasonex. Nasonex has been out since 1999. It is now scent-free and alcohol-free which reduces the frequency of side effects seen with the previous formulation. It is indicated down to the age of 2 years. It is indicated for nasal polyps and prophylaxis of seasonal allergic rhinitis. System bioavailability is less than 0.1% leading to very low risk of systemic side effects including growth and HPA axis suppression.

Barbara Felt (GlaxoSmithKline) provided comment on Veramyst. Veramyst has been on the market for two years. It is approved for seasonal and perennial allergic rhinitis in individuals two years of age and older. It is a better molecule and has better clinical

features than fluticasone. It has also been shown to decrease total ocular symptom score. Similar to other medications in the class, Veramyst can cause epistaxis. There was no difference in incidence of cataracts over placebo. There was a higher incidence of increased ocular pressure, however there have been no studies on ocular effects or growth suppression yet. The device is smaller and delivers a smaller spray volume than Flonase. It doesn't smell and has a side actuation which is helpful for parents. There is a window on the side of the device allowing a view of the amount of medication remaining.

Dr. Gondalia asked if there was any information with Nasonex regarding ocular symptoms. Dan Manning indicated that there was retrospective data showing an improvement in the total ocular symptom scores. Dr. Gondalia also noted that this device is better than the traditional devices. However, side effects are different in Wyoming than in the studies due to the very low humidity here. There is a high rate of epistaxis here.

George Dela Cerda (Astra Zeneca) gave comment on Rhinocort AQ which is approved for seasonal and perennial allergic rhinitis in individuals over the age of six. It has a unique, low-volume spray and convenient once daily dosing. Safety data shows similar adverse event profiles with placebo. Studies show no growth suppression.

Additional written public comment was reviewed.

Committee Discussion:

Dr. Gondalia disclosed that he speaks for almost all drug companies. He added that he works for his patients, not any drug companies or insurance companies.

Safety:

There is no evidence showing a significant difference between the agents in terms of safety. The AQ formulations are helpful in Wyoming, especially in the winter months. The older formulations may have a higher incidence of side effects.

Efficacy:

The existing evidence does not show a statistically significant difference in efficacy among the nasal corticosteroids.

Clinical experience:

There is a preference to have an AQ formulation available due to the advantage in decreasing incidence of epistaxis. Rhinocort and Nasonex have the most historical data for use in pediatrics. Veramyst and Nasonex are approved down to 2 years of age, Flonase to 4 years and the rest 6 years and up. Rhinocort is the only pregnancy category B agent.

The recommendations listed above were moved and seconded with all in favor.

Ophthalmic antihistamines/mast cell stabilizers

A report provided by Goold Health Systems was reviewed.

Public Comment:

There was no public comment on this class.

Committee Discussion:

Safety:

There is no evidence showing a statistically significant difference among the agents with respect to adverse effects. The biggest issue is that most of them are very irritating. Elestat and Patanol are better tolerated than the others.

Efficacy:

There is no evidence showing a statistically significant difference in terms of efficacy. Cromolyn is the best agent for prophylaxis as it is a true mast cell stabilizer.

Clinical experience:

The committee would like an agent that is used twice daily or less. Alomide is approved down to the age of two and cromolyn to age 4. Cromolyn, Emadine, Alomide and Alocril are Pregnancy Category B.

There was a motion for approval of the recommendation which was seconded with all in favor.

Asthma agents

The DERP report on Asthma agents was presented by Laura Morgan. Slides are available upon request.

Public comment:

Dan Manning (Schering-Plough) provided comment on Asmanex which is available in two different strengths. It is approved down to the age of four years old. It has proven safety and tolerability, is a simple device and is approved for once daily use. The flow rate required to get a full dose is similar to sipping a juice box.

Barbara Felt (GlaxoSmithKline) presented comment on Advair and Flovent. Flovent has been on the market for greater than ten years. It has an FDA-approved superiority claim over beclomethasone, triamcinolone and montelukast. Advair is very versatile and is available in two forms. Most patients prefer the diskus, however, if there are oral side effects from the diskus, the HFA is a good option. Both will have a dose counter soon. There is better compliance with the combination product than Flovent alone. Advair is approved for COPD, with a number needed to treat of 2.1. Pneumonia was shown to occur more often in COPD patients taking the 500/50 dose (which is not approved for COPD in the US).

Roy Saari (Merck) provided comment on Singulair. This is only leukotriene modifier used extensively in Wyoming. It is approved for exercise-induced asthma in individuals 15 and older, perennial allergic rhinitis for ages six months and older, and seasonal allergic rhinitis for ages two and older. It is a once-daily tablet with many formulations. The FDA has indicated that they do not see a correlation between suicide and suicidal behavior and they continue to review the data.

George Dela Cerda (Astra Zeneca) provided comment on Pulmicort and Symbicort. Pulmicort is budesonide, and is approved for maintenance of asthma in those 12 months old and older. It is a pregnancy category B and adverse effects are similar to placebo. Symbicort is budesonide and formoterol. Formoterol has a very rapid onset of action, within 15 minutes. Symbicort is available in two strengths and is approved for management of persistent asthma in those twelve years and older.

Committee Discussion:

Safety:

There is no evidence of any difference in safety in any of the asthma classes reviewed with the exception of the leukotriene modifiers. There is an increased risk of hepatotoxicity with zileuton.

Because of warnings of increased risk of asthma-related deaths, it may not make sense clinically to have a long-acting beta agonist on the preferred drug list for asthma.

Efficacy:

There is no evidence showing a statistically significant difference among the reviewed classes with regard to efficacy.

Clinical Experience:

The Committee requested that at least one inhaled corticosteroid with twice daily or less frequent dosing be available. A variety of formulation options should be available. Ciclesonide (Alvesco) should be considered specifically for those who experience oral candidiasis with other agents. Long acting beta agonists should not be used alone.

Leukotriene modifiers are not generally very effective as monotherapy. Pulmicort and Singulair are approved down to 12 months of age. Advair, Flovent and Serevent are approved for 4 years and up. Singulair has dosage flexibility.

There was a motion, second and all were in favor of the above recommendations.

The committee recommended education on the NAEPP guidelines and effective use of Singulair which will be done through the DUR Program.

Quick relief asthma agents:

The DERP report on quick relief asthma agents was presented by Susan Norris.

Public Comment:

Dan Manning (Schering-Plough) gave comment on Proventil HFA which is indicated down to the age of four.

Barbara Felt (GlaxoSmithKline) gave comment on Ventolin HFA. A study showed that one-fourth of patients find that their medication is gone when they need it for rescue. Determining the amount of medication is extremely difficult now. Ventolin HFA is the only agent in the class which has a dose counter.

Committee Discussion:

Safety:

There is no evidence indicating a difference in adverse effects among the class.

Efficacy:

There is no evidence of a difference in efficacy among the class.

Clinical experience:

The nebulizer formulation should be available for children. Ventolin HFA may have a benefit related to the dose counter. Ipratropium is only appropriate for emergent use in children, and should not be used chronically. Utilization will be reviewed through DUR to determine appropriateness in this age group.

There was a motion, second and all were in favor of the above recommendations.

There being no further business, Dr. Smith adjourned the meeting at 2:15 p.m.

Respectfully submitted,

Aimee Lewis, PharmD
DUR Manager