Wyoming Drug Utilization Review

Asthma: Management in Pregnancy

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Asthma affects an estimated 4-8% of pregnant women in the United States.¹⁻³ Severe or uncontrolled asthma has been linked to a higher risk of complications including: perinatal mortality, intrauterine growth restriction, premature birth, low birth rate, and congenital malformations.^{1,4} The cause of these increased adverse outcomes is not well defined, however it is thought that poorly controlled maternal asthma may lead to decreased placental blood flow and fetal blood oxygen.⁴ Given this

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Edited by Aimee Lewis, PharmD Laura Miller, MS potential cause, appropriate treatment of maternal asthma could reduce risks to the fetus and improve pregnancy outcomes.¹

Pregnancy may cause existing asthma to improve, worsen, or continue unaffected.¹ The precipitating causes of these changes in severity are not known, and there are few reliable characteristics that can predict how pregnancy will affect a patient with asthma.^{1,2} Because a patient's condition may change rapidly throughout the course of pregnancy, monthly assessment of lung function and asthma symptoms should occur for pregnant patients with persistent asthma.5 Neither peak flow rates nor FEV, are altered significantly during pregnancy.1 Spirometry typically offers superior assessment of lung function, however peak flow measurement is also acceptable.⁵ The clinician should evaluate symptom frequency and severity, including frequency of rescue inhaler use, exacerbations,

and night-time symptoms.¹ These measures are similar in both pregnant and non-pregnant patients.^{1,5}

Typically, a woman will have a known history of asthma prior to pregnancy, however, diagnosis during pregnancy does occur.¹ Patients presenting with common symptoms of asthma, such as cough, wheeze, chest tightness or airway obstruction, where other causes have been ruled out, should undergo pulmonary function testing using either spirometry or peak flow measurements.¹ Women meeting the clinical picture of new onset asthma, including reduced FEV₁ and marked improvement of FEV₁ following administration of a short acting beta₂ agonist, should be appropriately treated until further testing can be performed post partum.¹

It is frequently reported that women decrease the use of asthma management medications early in pregnancy, without first consulting a health care professional, likely due to safety concerns.^{1,3} However, the risks of asthma symptoms and exacerbations to both mother and fetus outweigh any risks asthma medications may possess.⁶ A stepwise approach to asthma treatment should be employed when considering pharmacotherapy in pregnant women.⁶ Mild intermittent asthma should be managed through the use of a short-acting beta, agonist (SABA).⁶ Albuterol is preferred in the pregnant population because it has the greatest amount of safety and efficacy data available when compared to other drugs in the same class.⁶ Similarly, albuterol should also be recommended for pregnant patients experiencing exercise-induced bronchospasm.⁶ If rescue therapy is used more than twice weekly, a classification of intermittent asthma is no longer appropriate and the patient should be moved to the second step of care.⁶

All pregnant patients with a diagnosis of persistent asthma, regardless of severity, should be on a long-termcontrol medication in addition to a SABA.⁶ Mild persistent asthma should be treated with daily low-dose inhaled corticosteroids (ICS). Although safety concerns may arise, specifically concerning increased occurrences of adverse pregnancy outcomes, available evidence suggests ICS use is safe in pregnancy.³ Budesonide is currently the ICS of choice in pregnancy, due to its long history of use and the availability of encouraging safety data. Budesonide has not been proven to be safer than other ICSs; there is

P & T Committee Meeting Update

The P&T Committee met for its quarterly business meeting on February 17, 2011. Highlights of this meeting include the following.

There will be a new Director at the Wyoming Department of Health, Tom Forslund, who will begin mid-March. He will replace Dr. Sherard who will be moving to the Governor's office.

Compounds continue to be billed incorrectly. The GHS Program Integrity Pharmacist did a lot of outreach in attempt to alert pharmacies to the problems and educate on billing correctly. The Department is beginning to do recovery on those claims that are billed improperly.

Transmucosal fentanyl products will now include quantity limits and age limits were adjusted to match labeling of individual products. All continue to be approved only for cancer break-through pain.

- Abstral: Age 18 and limited to 8 doses per day.
- Actiq: Age 16 and limited to 8 doses per day.
- Fentora: Age 18 and limited to 12 doses per day.
- Onsolis: Age 18 and limited to 4 doses per day.

The following prior authorization criteria were approved.

- Cycloset: 90 day trial and failure of metformin prior to approval.
- Neudexta: Will be approved for diagnosis of pseudobulbar affect.
- Clonidine (all forms approved for hypertension) will require prior authorization. Must be on at least one other blood pressure agent. Current users will be grandfathered.
- Kapvay: 14 day trial and benefit of immediate release clonidine prior to approval.
- Natroba: Trial and failure of permethrin and lindane prior to approval.

- Freshkote eye drops: 14 day trial and failure of two different over-the-counter agents.
- Suboxone: Requires diagnosis of opioid dependence. Prescriber must have X-DEA number. Maximum dose of 24 mg/day will be allowed. Approvals will be for 24 months, after which the provider must justify continued use and provide a treatment plan. Narcotic use with Suboxone will be allowed one time for a maximum of five days.
- Subutex: Same criteria as Suboxone. Will only be allowed for pregnant or nursing women, or with a documented allergy to naloxone.
- Benzaclin: Prior authorization required for patients under the age of 12. Diagnosis of acne required.

The antidepressant step therapy was simplified as follows.

- Preferred Antidepressants: buproprion ER/SR/XL, citalopram, fluoxetine, mirtazapine 15, 30 and 45 mg, paroxetine IR/CR, sertraline, venlafaxine ER tablets.
- Non-preferred agents will require a 6 week trial of two preferred agents. Venlafaxine ER capsules require prior authorization with direction to use the tablets.

All proposed prior authorization criteria will be posted for public comment at www.uwyo.edu/DUR. Comments may be sent by email to <u>alewis13@uwyo.edu</u> or by mail to: Wyoming Drug Utilization Review Board, Dept. 3375, 1000 E. University Avenue, Laramie, WY 82071. Comments should be received prior to April 15, 2011.

The next P&T Committee meeting will be held May 19, 2011 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.

Asthma continued

simply more information available regarding its safety. No data is available indicating other ICS preparations are unsafe. Maintaining a patient who is currently controlled on another ICS rather than switching to budesonide should be considered.³ Cromolyn may be deemed an appropriate alternative in pregnant patients due to its safe historical use, however, ICSs are more efficacious.⁶

For the treatment of moderate persistent asthma, the clinician may increase ICSs to a medium dose or may maintain the ICS at a low dose and add on a long-acting beta₂-agonist (LABA).⁶ There is limited observational data available for the use of LABA in pregnancy, and no one agent is recommended over the others at this time. Increase to medium doses of ICSs and a LABA when still uncontrolled. Typically, systemic corticosteroids should be avoided, however, their use may be necessary to gain control in severe persistent asthma cases. Oral corticosteroids should be used on a short term basis. If long term therapy is required, the lowest dose possible should be utilized and attempts to reduce or discontinue therapy should be made frequently.⁶

Patients who responded well to leukotriene receptor antagonists prior to pregnancy may likely continue these medications safely during pregnancy.⁶ Sustained release theophylline preparations may be considered as alternative or adjunctive therapy for all stages of persistent asthma in pregnant patients.⁶

The pharmacological management of asthma exacerbations in a pregnant patient is the same as that of a non-pregnant patient.¹ Monitoring of a pregnant patient is, however, more intensive. Oxygen saturation should be maintained at or above 95 percent. If the pregnancy has reached a stage of viability, continuous electronic fetal monitoring, a nonstress test, or both should be considered. If maternal oxygen saturation cannot be maintained at a minimum of 95 percent, the fetus appears to be in distress, or the FEV₁ or peak flow measurements are below 70 percent of the predicted value, the mother should be hospitalized.¹

Of the asthma medications discussed here, budesonide, montelukast, zafirlukast, and cromolyn are all classified by the FDA as pregnancy category B.¹ Beclomethasone, fluticasone, salmeterol, formoterol, albuterol, and theophylline are classified as pregnancy category C.¹ No asthma medications are contraindicated while breastfeeding.⁶ Clinicians managing asthma during breastfeeding should follow the same recommendations utilized throughout pregnancy.⁶ Poorly controlled maternal asthma may negatively impact pregnancy outcomes. Patients well-controlled by a current asthma regimen should maintain that regimen. Pregnant patients experiencing symptoms should receive a step up in therapy, mirroring the treatment of nonpregnant patients. Treatment options are the same for all asthma patients, however, available evidence regarding their use in pregnancy varies. Medications such as albuterol or budesonide may be more appropriate choices for pregnant patients because more information regarding their use is available. Pregnancy can alter a patient's asthma status; monitoring should be monthly at minimum to maintain appropriate therapy. Evidence indicates that the maintenance of asthma control through asthma medications is beneficial to the growth and development of the fetus.

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2011 P & T Committee Meeting Dates

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

> Meeting time: 9 am - 3 pm

Location: Laramie County Community College, Cheyenne

All meeting dates and times are subject to change.

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