

Script Notes



The Pharmacy and Therapeutics Newsletter for AmeriHealth Mercy Health Plan Participating Providers

In This Issue:

Benign Prostatic Hyperplasia.....	1
Safety Alerts	6
Product Updates.....	8
Formulary Update.....	10
Update - Blood Glucose Monitoring Supplies	11

We welcome your thoughts, comments and/or suggestions.
Do you have an idea for a story?
Is there information we can provide to help you?

All correspondence concerning *Script Notes* should be sent to:

Paula Ang, Pharm.D.
AmeriHealth Mercy Health Plan
200 Stevens Drive
Philadelphia, PA 19113

paula.ang@performrx.com

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia or benign prostatic hypertrophy (BPH) is one of the most common health problems affecting aging men. Changes in a man's prostate initially begin after the age of 40. The prevalence of BPH in men 60 years old is greater than 50 percent and as high as 90 percent by the age of 85. The prostate is a walnut-sized gland, located in front of the rectum and just below the bladder, which forms part of the male reproductive system. While all of the prostate gland functions are not known, its main role is during sexual intercourse to release necessary fluid into the urethra as sperm passes through.

Pathophysiology:

Currently, there is no clear understanding as to why BPH occurs and no definitive risk factors have been identified. Nevertheless, two components (the static and dynamic aspect) have been recognized as causes of the symptoms of BPH. The static aspect involves the physical enlargement of the prostate. The various theories on how this occurs includes:

- The decrease in production of testosterone results in a comparatively higher percentage of estrogen. Some researchers believe that the increase in estrogen levels may have an impact on prostate growth.
- The accumulation of dihydrotestosterone (DHT), an active metabolite of testosterone, may be responsible for increasing activity of the growth-promoting genes in the prostate.
- As a man ages, some prostate cells may be "instructed" to start growing or may have increased sensitivity to certain hormones, such as estrogen or DHT.

The dynamic component relates to the increased α -adrenergic tone in the prostate, bladder and urethra. These patients may have the symptoms of BPH with a normal sized prostate. In addition certain medications, both prescription and over-the-counter, can cause urinary retention and may cause a patient to present with symptoms of BPH. These medications include antihistamines, anticholinergics, antispasmodics, tricyclic antidepressants and α -adrenergic agonists.

(continued on page 2)

Formulary Website Access

Access the AmeriHealth Mercy Website 24 hours/7 days a week at www.amerihealthmercyhp.com/pharmacy/formulary/online/index.asp

The formulary is updated on a quarterly basis.
We recommend saving it to your computer desktop for easy access.

(continued from page 1)

Symptoms:

The majority of the symptoms of BPH are due to slow loss of bladder control and obstruction of the urethra, both of which lead to incomplete emptying. The symptoms of BPH are usually associated with lower urinary tract symptoms (LUTS) and the most common are:

- Hesitation or interrupted stream
- Weak stream
- Increase in frequency especially at night
- Feeling of incomplete emptying
- Urgency
- Leaking or dribbling

While the relationship between BPH and LUTS is complex and the symptoms, at times, are similar, a diagnosis of one condition is not synonymous with the other. The extent of prostate enlargement does not always correlate with the number or severity of symptoms. If a patient has these symptoms, it is important he should be referred to a doctor. Although the majority of these cases are BPH, there is the possibility of a more serious condition, like prostate cancer, that would require immediate treatment. If the symptoms of BPH are ignored, over time they can develop into more serious problems including urinary tract infections (UTIs), bladder damage, bladder stones, incontinence, or kidney damage. If left untreated, BPH may cause permanent damage and make any possible treatment options less effective.

Diagnosis:

If BPH is suspected, the patient will usually be referred to an urologist who will then conduct specific diagnostic tests. The most common test is a digital rectal exam (DRE), which allows the doctor to examine the condition and size of the prostate. The prostate specific antigen (PSA) test is another test that can help to rule out prostate cancer as the reason for the LUTS. The American Cancer Society recommends that, beginning at the age of 50, all men with a life expectancy of at least 10 years be offered the PSA test and DRE annually to help detect prostate cancer. It is also recommended that African-

American men and those with a primary relative with prostate cancer be screened earlier.

PSA is a glycoprotein that is secreted by the prostate gland. Normal levels for a total PSA are <4 ng/ml. Because DRE and ejaculation can cause an acute increase in PSA, the PSA levels should be drawn prior to the DRE and the patient should abstain from ejaculation for 48 hours prior to the test. There are other problems that can influence PSA levels such as acute urinary retention, acute prostatitis, and BPH. Furthermore, PSA levels between 4 and 10 ng/ml cannot definitely diagnose prostate cancer or BPH. As a result, elevated PSA levels indicate the need for further examination. Urinary flow-rate monitoring (Qmax) and postvoid residual urine (PVR) are optional tests that may be performed. However, they are not usually done prior to watchful waiting or medical treatment, but may be used to predict the response to surgery.

The American Urological Association (AUA) has developed a symptom scoring system based on how the patient perceives the severity of his symptoms. The patient’s perception on the severity of the symptoms is what drives the selection of the treatment to follow.

Severity of Disease	AUA Symptom Score
Mild	0-7
Moderate	8-19
Severe	20-35

Treatment:

Once all the appropriate diagnostic tests are completed and a diagnosis of BPH is made then either a noninvasive (i.e., “watchful waiting” or medical therapy) or invasive treatment option may be used. Patients can take some simple, nonpharmacological steps on their own to reduce some of their symptoms. Patients are advised to decrease their fluid intake at bedtime and also decrease the overall amount of caffeine and alcohol that they consume. Watchful waiting is recommended for men with non-bothersome symptoms, slow and unpredictable progression, and/or reluctance to take a daily medication or undergo surgery.

(continued on page 3)

(continued from page 2)

During this period of watchful waiting, drug and procedural interventions are not initiated until the patient's symptoms become inconvenient. Once drug therapy is warranted, the selection of a medication is dependent on the patient's symptoms, medication history, and pre-existing conditions. A few over-the-counter (OTC) plant-based products, i.e., serenoa repens (Saw Palmetto) and pygeum africanum (African Plum Tree), are available for use in patients with BPH. Although some studies have shown that these products may relieve BPH symptoms, there is limited data to support such treatments. Patients who present with dynamic symptoms are often treated with alpha blockers while those who present with static symptoms are treated with 5- α reductase inhibitors.

Invasive therapy may be elective or warranted when noninvasive treatments are ineffective. Surgery is indicated for patients when they suffer complications of BPH such as hematuria, bladder stones and refractory retention.

The following tables provide a summary of the available drug therapies, OTC products, and types of procedures and surgeries recommended by AUA.

Drug Therapy for BPH

Drug	Dose	Common Side Effects	Comments
Alpha 1 Blockers			
Alfuzosin (Uroxatral®)	10 mg/day	<ul style="list-style-type: none"> • Orthostatic hypotension • Dizziness/Lightheadedness • Headache • Fatigue/Weakness 	<ul style="list-style-type: none"> • There is very little difference in the side effects of the alpha blockers, therefore all are considered equally effective in treating the urinary symptoms from BPH. • Alfuzosin is contraindicated in patients with moderate or severe hepatic insufficiency (Child-Pugh B/C) and if coadministered with potent CYP3A4 inhibitors. • Concurrent use of terazosin with phosphodiesterase-5 (PDE-5) inhibitors including sildenafil (>25 mg), tadalafil, or vardenafil is contraindicated.
Doxazosin (Cardura®)	4 - 8 mg/day		
Tamsulosin (Flomax®)	0.4 - 0.8 mg/day		
Terazosin (Hytrin®)	10 - 20 mg/day		
Silodosin (Rapaflo™)	8 mg/day		
5-α Reductase Inhibitors			
Dutasteride (Avodart®)	0.5 mg/day	<ul style="list-style-type: none"> • Impotence • Decrease in libido • Weakness • Postural hypotension • Dizziness • Ejaculation disturbances • Gynecomastia 	<ul style="list-style-type: none"> • This class of drugs is not recommended to treat lower urinary tract symptoms without enlarged prostate. • These are the only hormonal therapies that are effective and safe for treatment of BPH. • Patients may be given a 5-α reductase inhibitor to prevent progression.
Finasteride (Proscar®)	5 mg/day		

(continued on page 4)

(continued from page 3)

Drug	Dose	Common Side Effects	Comments
OTC Products			
Serenoa Repens (Saw Palmetto)	320 mg/day	<ul style="list-style-type: none"> • Diarrhea • Vomiting • Nausea • Constipation • Headache • Mild sexual dysfunction • Pruritus 	<ul style="list-style-type: none"> • Because of well-documented antiandrogen and antiestrogenic activity, avoid taking with any hormone therapy. • Avoid use with anticoagulants.
Pygeum Africanum (African Plum Tree)	75 - 200 mg/day	<ul style="list-style-type: none"> • Diarrhea • Nausea • Constipation • Gastric pain 	

Invasive Therapy for BPH

Procedures/Surgery	Comments
Transurethral Microwave Heat Therapy (TUMT)	<ul style="list-style-type: none"> • Transurethral microwave heat therapy uses microwaves to heat prostatic tissue at high temperatures to produce coagulation necrosis of the tissue. • It is more effective than drug therapy but not superior to surgery in relieving BPH symptoms. • There is no evidence suggesting superiority of one specific device over another. • Irritative voiding symptoms and temporary urinary retention may occur.
Transurethral Needle Ablation (TUNA)	<ul style="list-style-type: none"> • TUNA uses radio frequency energy to heat prostatic tissue to produce coagulation necrosis. • The ideal patient for this procedure is a man with obstructive BPH, a prostate of 60 g or less with predominantly lateral lobe enlargement. • Irritative urinary symptoms and temporary urinary retention may occur.
Stents	<ul style="list-style-type: none"> • Metal or polyurethane prostatic stents are placed into the prostatic urethra under endoscopy or fluoroscopy and expand the urethra to aid in relief of obstruction. • Over time normal transitional cell epithelium cover the stents. • Stents should only be used in high-risk patients due to the serious complications such as infection, chronic pain and calcification around the area of placement.
Transurethral Resection of the Prostate (TURP)	<ul style="list-style-type: none"> • TURP removes the inner portion of the prostate via an endoscope. • Most common active treatment for symptomatic BPH. • Complications include dilutional hyponatremia, sexual dysfunction, irritative voiding symptoms, bladder neck contracture, UTI, and hematuria.

(continued on page 5)

(continued from page 4)

Procedures/Surgery	Comments
Transurethral Incision of the Prostate (TUIP)	<ul style="list-style-type: none"> • Endoscopic procedure where one or two cuts are made in the prostate and prostate capsules to reduce urethral constriction. • Limited to treating small prostates ≤ 30 g. • It is as effective as TURP but there is a higher rate of retrograde ejaculation and secondary procedures.
Transurethral Laser Coagulation	<ul style="list-style-type: none"> • Laser energy is delivered to congeal but not vaporize the prostate tissue. The tissue eventually necroses and sloughs, resulting in relief of obstruction. • There is a higher rate of postoperative urinary catheterization and irritative voiding symptoms compared to TURP.
Transurethral Laser Vaporization	<ul style="list-style-type: none"> • Laser energy is delivered to vaporize the prostate tissue. • It is as effective as transurethral electrovaporization.
Transurethral Holmium Laser Resection/Enucleation	<ul style="list-style-type: none"> • Alternative to TURP with a decreased risk of bleed and need for blood transfusions.
Open Prostatectomy	<ul style="list-style-type: none"> • Surgical removal of the prostate's inner portion by creating an incision in the lower abdominal area. • Typically performed on men with prostate volumes greater than 80 to 100 mL.

Although there are several urinary issues that may result from BPH, various drug therapies and procedures are available to help alleviate problematic symptoms commonly experienced in men with this condition and hopefully decrease the likelihood of any permanent complications.

References

1. Dipiro JT, Talbert RL, Yee GC, et al. *Pharmacotherapy: A Pathophysiologic Approach*. Seventh ed. New York, NY: McGraw Hill Medical; 2008:1387-1395.
2. Facts and Comparisons. Available at: <http://online.factsandcomparisons.com>. Accessed June 11, 2009.
3. Lexi-Comp Online. Available at: <http://online.lexi.com.db.usip.edu/crlsql/servlet/crlonline>. Accessed June 10, 2009.
4. Micromedex. Available at: <http://thomsonhc.com>. Accessed June 10, 2009.
5. Prostate Enlargement: Benign Prostatic Hyperplasia. National Kidney and Urologic Diseases Information Clearinghouse website. Available at: <http://kidney.niddk.nih.gov/kudiseases/pubs/prostateenlargement/>. Accessed June 10, 2009.
6. Prostate Cancer: Can Prostate Cancer Be Found Early? American Cancer Society. Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_Can_prostate_cancer_be_found_early_36.asp?sitearea=. Accessed June 10, 2009.
7. Roehrborn CG, McConnell JD, Barry MJ, Benaim E, Bruskewitz RC, Blute ML, et al. AUA Guideline on the Management of Benign Prostatic Hyperplasia. Available at: http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/bph-management/chapt_1_appendix.pdf. Accessed June 10, 2009.
8. SeniorCarePharmacist.com. Medications That Should Be Avoided, If Possible, When Certain Diseases Are Present. SeniorCarePharmacist website. Available at: <http://www.seniorcarepharmacist.com/diseases/>. Accessed June 10, 2009.

Safety Alerts:

Propylthiouracil-Induced Liver Failure

The FDA is notifying health care professionals of the risk of serious liver injury in adults and pediatric patients associated with the use of propylthiouracil, an anti-thyroid agent. The FDA has identified 32 cases (22 adult and 10 pediatric) of serious liver injury that were reported to FDA's Adverse Event Reporting System (AERS). Propylthiouracil is generally considered second line therapy possibly due to an increased risk of hepatotoxicity when compared to methimazole. Adult patients on propylthiouracil should be closely monitored for signs and symptoms of liver injury, especially in the first six months of therapy. Propylthiouracil should only be used in pediatric patients that are allergic to or intolerant of methimazole and no other treatment options are available.

Ongoing Safety Review of Plavix® (clopidogrel bisulfate)

In January, the FDA began working with the makers of Plavix (clopidogrel bisulfate) to conduct studies to understand the effects of genetic factors and other drugs (proton pump inhibitors [PPIs]) on the effectiveness of clopidogrel. Clopidogrel is an antiplatelet drug that is used to prevent blood clots that could lead to heart attacks or strokes in patients at risk. The varying levels of effectiveness among patients may be due to genetic differences affecting their metabolism of clopidogrel, or the use of certain drugs (such as PPIs) that may interfere with metabolism. Once this information is obtained, it could help to further understand how to optimize the use of clopidogrel. The FDA will be review the information and the public will then be informed of its conclusions and recommendations, if any. This process may take several months therefore, until further information is available, the FDA recommends the following:

1. Health care providers should continue to prescribe clopidogrel and patients should continue to take clopidogrel as directed since it has demonstrated benefits in preventing blood clots that could potentially cause heart attack or stroke.
2. Health care providers should re-evaluate the need for continuing or starting therapy with a PPI in patients taking clopidogrel.
3. Patients taking clopidogrel that are currently taking or considering taking a PPI should consult with their health care provider.

New Safety Information: Tarceva® (erlotinib)

OSI, Genentech, and the FDA notified health care professionals of additional safety information added to the WARNINGS AND PRECAUTIONS section of the prescribing information for Tarceva (erlotinib), which

is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer. Tarceva can also be used in combination with gemcitabine for the treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer. Patients taking Tarceva alone or with anti-angiogenic agents, corticosteroids, NSAIDs and/or taxane-based chemotherapy, or patients who have a history of peptic ulcers or diverticulitis are at increased risk of gastrointestinal perforation. Tarceva should be permanently discontinued if gastrointestinal perforation develops. Patients taking Tarceva may also develop bullous, blistering, and exfoliative skin conditions, including Stevens-Johnson syndrome/toxic epidermal necrolysis. If these skin conditions develop, Tarceva treatment should be interrupted or discontinued. Certain ocular disorders such as corneal perforation or ulceration, abnormal eyelash growth, keratoconjunctivitis sicca, or keratitis have been reported. Therapy with Tarceva should be interrupted or discontinued in patients who present with acute/worsening ocular disorders.

Boxed Warning for Testosterone Gel Products (AndroGel® 1% and Testim® 1%)

The FDA is requiring that the manufacturers of topical testosterone gel products AndroGel 1% and Testim 1% include a boxed warning on their product labels. This is due to reports that children inadvertently exposed through contact with another person using these products were experiencing virilization. Signs and symptoms of virilization may include inappropriate enlargement of the penis or clitoris, premature development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases, signs and symptoms regressed once the child was no longer exposed, however, patients should still be advised to follow the following precautions in order to prevent secondary exposure to testosterone:

1. Children and women should avoid contact with application sites of AndroGel and Testim on the skin of men using these products.
2. Patients using these products should wash their hands with soap and water immediately after application.
3. The application site(s) should be covered with clothing after the gel has dried.
4. Patients should wash the application site(s) with soap and water to remove testosterone residue prior to any situation in which skin-to-skin contact may occur.
5. Should the application site come in direct contact with the skin of another person, the general area of contact should be washed with soap and water as soon as possible.

Safety Alerts:

(continued from page 6)

Possible Risk of Cancer with Lantus® Use

The FDA is currently reviewing safety data for Lantus (insulin glargine) to investigate if there is an increased risk of cancer associated with use of Lantus. Three out of four recently-published observational studies suggested that there is an increased risk. However, the FDA recommends that patients continue to take Lantus until they consult with their physician.

Boxed Warning for Chantix® and Zyban® for Serious Neuropsychiatric Symptoms

Recently, the FDA required the manufacturers of two smoking cessation products varenicline (Chantix) and bupropion (Zyban and generics) to add new boxed warnings and to develop patient medication guides highlighting the risk of serious neuropsychiatric symptoms in patients using these products. Other bupropion products (Wellbutrin and generics) that are indicated for treatment of depression and seasonal affective disorder have also made changes to the prescribing information and patient medication guides to reflect these warnings. The neuropsychiatric symptoms associated with these products include changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Patients should be advised to stop taking the medication and contact a health care professional if any symptoms occur.

Risk of Overdose in Patients Using Propoxyphene-Containing Products

Recent data has linked fatal overdoses to pain medications containing propoxyphene. In an effort to reduce the risk of overdose in patients using these products, the FDA is requiring manufacturers of propoxyphene-containing products to highlight the risk in the label's boxed warning and in medication guides for patients. Additionally, the FDA is requiring a new safety study to be conducted to evaluate the cardiovascular effects of propoxyphene when taken at higher than recommended doses. Further regulatory action may take place depending on the findings of this safety study.

References:

1. Information for Healthcare Professionals: Propylthiouracil-Induced Liver Failure. FDA Alert. June 4, 2009. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm162701.htm>. Accessed June 9, 2009.
2. Early Communication about an Ongoing Safety Review: Plavix® (clopidogrel bisulfate). FDA Alert. January 26, 2009. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm079520.htm>. Accessed June 9, 2009.
3. Information for Healthcare Professionals: Safety Information for Tarceva® (erlotinib). FDA Alert. May 8, 2009. Available at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm150596.htm>. Accessed June 9, 2009.
4. Dear Healthcare Professional Letter: Tarceva® (erlotinib). FDA Alert. April 2009. Available at: <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM150610.pdf>. Accessed June 9, 2009.
5. Testosterone Gel Safety Concerns Prompt FDA to Require Label Changes, Medication Guide. FDA News. May 7, 2009. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149580.htm>. Accessed June 10, 2009.
6. Letter for Safety Labeling Changes: AndroGel®. FDA Alert. April 2009. Available at: <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM161875.pdf>. Accessed June 10, 2009.
7. Letter for Safety Labeling Changes: Testim®. FDA Alert. April 2009. Available at: <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM161882.pdf>. Accessed June 10, 2009.
8. Postmarket Drug Safety Information for Patients and Providers: Early Communication About Safety of Lantus (insulin glargine). July 1, 2009. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm169722.htm>. Accessed July 27, 2009.
9. Information for Healthcare Professionals: Varenicline (marketed at Chantix) and Bupropion (marketed as Zyban, Wellbutrin, and generics). July 1, 2009. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm169986.htm>. Accessed July 27, 2009.
10. Safety Information: Propoxyphene-containing Products. July 7, 2009. Available at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170763.htm>. Accessed July 27, 2009.

Product Updates:

Fanapt™ (iloperidone) is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults. The dose should be titrated slowly to a recommended dosage of 12 to 24 mg/day given twice daily in equal doses of 6 to 12 mg in order to prevent orthostatic hypotension. The dose should be started at 1 mg twice daily and increased by 4 mg daily (2 mg twice daily) until the recommended dosage range is reached. No dosage adjustments have to be made for patients with renal impairment; however, for patients with hepatic impairment, the use of Fanapt is not recommended. Fanapt is a substrate for both CYP3A4 and CYP2D6 enzymes, therefore dosage adjustments need to be made when Fanapt is administered concomitantly with strong inhibitors of CYP2D6 (e.g., fluoxetine, paroxetine) and CYP3A4 (e.g., ketoconazole). Fanapt prolongs the QT interval and can be associated with arrhythmia and sudden death, therefore the use of other drugs that prolong the QTc interval in combination with Fanapt should be avoided. Patients at risk for disturbances should have serum potassium and magnesium monitored periodically and at baseline. Fanapt is not approved for the treatment of patients with dementia-related psychosis since these patients are at increased risk of death and cerebrovascular-related adverse events, such as stroke. Common adverse reactions ($\geq 5\%$) include: dizziness, dry mouth, fatigue, nasal congestion, somnolence, tachycardia, orthostatic hypotension, and weight increase. Fanapt is available as 1, 2, 4, 6, 8, 10, and 12 mg tablets as well as a titration pack that includes two 1 mg tablets, two 2 mg tablets, two 4 mg tablets, and two 6 mg tablets.

Samsca™ (tolvaptan) is a selective vasopressin V2-receptor antagonist and is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, which includes patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH). Samsca should only be initiated and re-initiated in a hospital where serum sodium can be closely monitored. The recommended starting dose is 15 mg given orally once daily. After at least 24 hours, the dose can then be increased to 30 mg once daily. The maximum dose of Samsca is 60 mg once daily as needed to achieve the desired serum sodium level. Fluid restriction should be avoided in the first 24 hours of therapy to prevent dehydration

and hypovolemia. Samsca is a substrate for CYP3A enzymes therefore co-administration with moderate to strong inhibitors of CYP3A should be avoided. Too rapid correction of serum sodium can cause osmotic demyelination syndrome which results in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma, or death. Patients with severe malnutrition, alcoholism, or advanced liver disease are at a higher risk of osmotic demyelination syndrome and slower rates of correction may be advisable. Common adverse reactions ($\geq 5\%$) include: thirst, dry mouth, asthenia, constipation, pollakiuria or polyuria, and hyperglycemia. Samsca is available in 15 mg and 30 mg tablets.

Besivance™ (besifloxacin ophthalmic suspension) 0.6% is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: CDC coryneform group G, *Corynebacterium pseudodiphtheriticum*, *Corynebacterium striatum*, *Haemophilus influenzae*, *Moraxella lacunata*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis*, *Staphylococcus lugdunensis*, *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, and *Streptococcus salivarius*. The recommended dose for Besivance is one drop in the affected eye(s) three times a day, four to 12 hours apart for seven days. Besivance is for topical use only and should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye. The most common adverse reaction (2%) is conjunctival redness. Other less common adverse reactions ($< 2\%$) include: blurred vision, eye pain, eye irritation, eye pruritis, and headache. Besivance is available as a 7.5 ml bottle filled with 5 ml of besifloxacin ophthalmic suspension, 0.6%.

Simponi™ (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of moderate to severe rheumatoid arthritis (RA), active psoriatic arthritis (PsA), and active ankylosing spondylitis (AS) in adults. For patients with RA, Simponi should be given in combination with methotrexate.

(continued on page 9)

Product Updates:

(continued from page 8)

The recommended dose of Simponi is 50mg via subcutaneous injection once a month. Patients who take Simponi are at risk of serious infection therefore it should not be started during an active infection, and if a serious infection develops, Simponi should be discontinued. Tests for latent tuberculosis should be done prior to and during treatment with Simponi. Live vaccines should not be given while patients are on Simponi. Common adverse reactions (> 5%) include: upper respiratory infection and nasopharyngitis. Simponi is available as a 50 mg/0.5 ml single dose prefilled SmartJect autoinjector and a 50 mg/0.5 ml single dose prefilled syringe.

Exforge HCT® (amlodipine, valsartan, and hydrochlorothiazide) is an antihypertensive medication that contains a calcium channel blocker, an angiotensin receptor block and a diuretic. It is indicated for the treatment of hypertension but is not indicated for the initial therapy of hypertension. Exforge HCT is given once daily with or without food, and the dosage may be increased after two weeks of therapy. The maximum recommended dose is 10/320/25 mg. Exforge HCT should be avoided in pregnancy and discontinued immediately if pregnancy is detected. Common adverse reactions occurring in >2% of patients in clinical trials include: dizziness, edema, headache, dyspepsia, fatigue, muscle spasms, back pain, nausea and nasopharyngitis. Exforge HCT is available in five dosage strengths: 5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, and 10/320/25 mg.

Effient™ (prasugrel) is a platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome (unstable angina, non-ST-elevation myocardial infarction or ST-elevation myocardial infarction) managed with percutaneous coronary intervention. For patients ≥ 60 kg, Effient is initially given as a loading dose of 60 mg, with a maintenance dose of 10 mg once daily in combination with aspirin 75-325 mg/day. In patients weighing less than 60 kg, a maintenance dose of 5 mg once daily should be considered. The prescribing label contains a black box warning stating that Effient can cause significant, sometimes

fatal, bleeding. It should be discontinued at least seven days prior to any surgery. In addition, discontinuing Effient, particularly in the first few weeks after acute coronary syndrome, increases the risk of subsequent cardiovascular events. It is contraindicated in patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage and in patients with a history of prior transient ischemic attack or stroke. Effient is available as 5 mg and 10 mg tablets.

References:

1. Fanapt™. Prescribing Information. Vanda Pharmaceuticals Inc. May 2009.
2. Samsca™. Prescribing Information. Otsuka America Pharmaceutical, Inc. May 2009.
3. Besivance™. Prescribing Information. Bausch & Lomb Inc. April 2009.
4. Simponi™. Prescribing Information. Centocor Ortho Biotech Inc. April 2009.
5. Exforge HCT®. Prescribing Information. Novartis Pharmaceuticals Corp. April 2009.
6. Effient™. Prescribing Information. Eli Lilly and Co. July 2009.

Formulary Update: Additions to the AmeriHealth Mercy Drug Formulary

Drug	Indication	Starting Dose	Strength on Formulary
Topamax® (topiramate)	Monotherapy or adjunctive therapy for partial onset seizures and primary generalized tonic-clonic seizures; adjunctive treatment of seizures associated with Lennox-Gastaut syndrome; prophylaxis of migraine headache	100 mg - 400 mg a day in two divided doses	Tablet: 25 mg, 50 mg, 100 mg, 200 mg Sprinkle Capsule: 15 mg and 25 mg

References

1. Topamax® Tablets and Topamax® Sprinkle Capsules Prescribing Information. Ortho-McNeil Neurologics. May 2009

Update - Blood Glucose Monitoring Supplies

Daily blood glucose testing is a very important process in the management of diabetes. AmeriHealth Mercy Health Plan is committed to providing members with appropriate access to blood glucose monitoring supplies. Ascensia (Bayer) products are the preferred blood glucose monitoring products for AmeriHealth Mercy Health Plan members.

The following limits apply to the all products and claims within these limits will process without prior authorization:

- Ascensia blood glucose meter devices – one unit per 365 days
- Ascensia test strips:
 - All members – quantity sufficient to allow up to two tests per day (i.e., 50 count package will process every 25 days)
 - Members managing diabetes with insulin products – quantity sufficient to allow up to three tests per day (i.e., 100 count package will process every 30 days)
 - Members who are pregnant or managing pregnancy-induced diabetes – quantity sufficient to allow up to 10 tests per day (i.e., 300 count will process every 30 days)*

Preferred products:

Meters:

Ascensia Breeze 2

Ascensia Contour

Strips:

Ascensia Autodisc

Ascensia Breeze 2

Ascensia Contour

Ascensia Elite

** Currently the process of determining pregnancy status is not comprehensive. This may result in pregnant or pregnancy-induced diabetics receiving a rejection when attempting to fill claims for appropriate supplies. Pharmacies and providers should contact the Pharmacy Help Desk at 866-610-2774 if a member with pregnancy-induced diabetes requires an override.*

Script Notes

We welcome your thoughts, comments and/or suggestions. Do you have an idea for a story? Is there information we can provide to help you?

All correspondence concerning *Script Notes* should be sent to:

Paula Ang, Pharm.D.
AmeriHealth Mercy Health Plan
200 Stevens Drive
Philadelphia, PA 19113

paula.ang@performrx.com

Perform_{Rx}
The Next Generation PBM

The Quarterly Pharmacy and Therapeutics Newsletter for AmeriHealth Mercy Health Plan Participating Providers

Steven Feinstein, M.D.
P&T Committee Chair

Andrew Maiorini, Pharm.D.
Manager, Formulary

Editors:

Paula Ang, Pharm.D.
Clinical Pharmacist, Formulary

Margaret Shepherd, R.Ph.
Director, Clinical Services

Jamila J. Jorden, Pharm.D.
Clinical Pharmacist, Formulary

Contributing Editors:

Norbert Becker, R.Ph.
Clinical Pharmacist, Formulary

Lauren Brophy, Pharm.D.
Clinical Pharmacist, Formulary

Nicole F. Campese, Pharm.D.
Clinical Pharmacist, Formulary

Angela Guldin, Pharm.D.
Clinical Pharmacist, Formulary

Jeffrey Kreitman, Pharm.D.
Regional Clinical Pharmacist

Kristina Ortiz, Pharm.D. Candidate
University of the Sciences, Philadelphia, PA

Timothy Poole, Pharm.D. Candidate
University of the Sciences, Philadelphia, PA

Jeeja Thomas, Pharm.D. Candidate
University of the Sciences, Philadelphia PA

200 Stevens Drive
Philadelphia, PA 19113

A Program of AmeriHealth First and Mercy Health Plan



Script Notes

Pharmacist Corner



The Pharmacy and Therapeutics Newsletter for AmeriHealth Mercy Health Plan Participating Providers

The CDC states that, “antibiotic resistance has been called one of the world’s most pressing public health problems.” Patients who go to the doctor when they are sick have an expectation that they will receive treatment (i.e., a prescription) to make them feel better. When the suspected diagnosis is of viral origin, the treatment may only include rest and fluids leaving the patient wondering where the “real” treatment is. AmeriHealth Mercy covers a wide variety of OTC cough, cold, and antipyretic medications for patients over the age of 2 with a prescription. Effective use of these agents provides a valuable tool for prescribers to fulfill patients’ expectations to receive treatment for their illness while avoiding unnecessary antibiotic therapy.

If an antibiotic is required, it is important to select one that is narrow spectrum, such as penicillin VK, amoxicillin, first generation cephalosporins, or erythromycin for penicillin allergic patients, and emphasize the need to take it for the full duration to ensure its efficacy. In addition, encouraging the use of appropriate measuring devices for liquids is important for patients to receive accurate dosing. There are numerous oral syringes available as well as the option for the pharmacy to order private label measuring devices to advertise their pharmacy.

Our most current formulary can be found online at: <http://www.amerhealthmercyhp.com/pharmacy/formulary/online/index.asp>. This tool can be used to search for individual medications as well as by therapeutic categories, e.g., first generation cephalosporins. Below is a list of some common, formulary OTC cough, cold and antipyretic medications:

- Guaifenesin liquid and tablets
- Guaifenesin/Dextromethorphan liquid
- Guaifenesin/Phenylephrine liquid
- Pseudoephedrine 60mg tablets
- Oxymetazoline 0.05% Nasal Spray
- Phenylephrine 0.25% and 1% Nasal Spray
- Infant and Children’s acetaminophen
- Infant and Children’s acetaminophen
- Dextromethorphan 15mg/5ml

We are currently in the process of analyzing our medical and pharmacy data to identify prescribers who appear to be prescribing antibiotics to patients with diagnoses that are consistent with viral infections. Prescribers who are “outliers” in the data analysis will receive more specific information to help them evaluate and potentially modify their prescribing patterns.

Finally, the CDC’s Get Smart Campaign (<http://www.cdc.gov/drugresistance/community/>) also provides a valuable resource for patient education, handouts, waiting room materials, etc. Implementing measures to curb the over-prescribing of unnecessary antibiotic therapy will help reduce antibiotic resistance and the spread of resistant bacteria to naïve patients. Working together, we can make sure our patients get the most appropriate care.

Please feel free to contact me with your comments and suggestions at 1-877-693-8271 x83566 or via email at jeffrey.kreitman@amerihealthmercyhp.com.

Sincerely,
Jeffrey Kreitman, Pharm.D.
Regional Clinical Pharmacist