Formulary Addition/Deletion

- Oncology Subcommittee
  - Nine chemotherapy medications were presented for deletion from the formulary as they were not used/ordered in the last 2 years. The medications include:
    - Aldesleukin (Proleukin®)
    - Arsenic Trioxide (Trisenox®)
    - Asparaginase (Elspar®)
    - Busulfan (Myleran®)
    - Gemtuzumab Ozogamicin (Mylotarg®)
    - Imiglucerase (Cerezyme®)
    - Melphalan (Alkeran®)
    - Streptozocin (Zanosar®)
    - Thiotepa

- Micafungin (Mycamine®) – addition – approved
- Caspofungin (Cancidas®) – deletion – approved
  
  Micafungin is an echinocandin antifungal used for the treatment of invasive Candida infections, esophageal candidiasis, and invasive aspergillosis. The medication was requested by the Infectious Diseases Division and the Pharmacy Department following review by the Antibiotic Subcommittee. Studies have demonstrated similar efficacy for micafungin compared to caspofungin and liposomal amphotericin B for the treatment of Candida infections. Micafungin has also been used in patients with invasive Aspergillus infections. A similar medication currently on formulary is caspofungin (Cancidas®). The switch from caspofungin to micafungin is associated with potential cost savings of up to $25,000/year.

Adenosine 12 mg/4 mL vials – line extension – Approved

A larger size of adenosine vials was requested by the Cardiac Cath Lab to improve efficiency when preparing the medication for myocardial perfusion studies. The Pharmacy Department currently supplies the 6 mg/2 mL vials; 15 vials are required to prepare a 90 mg bag. The use of 60 mg/20 mL or 90 mg/30 mL vials would be associated with significant additional cost. Use of the 12 mg/4 mL vials would reduce the number of vials used per bag from 15 to 8 while maintaining a comparable cost. Motion made to add adenosine 12 mg/4 mL vials to the hospital formulary. The 6 mg/2 mL vials will also remain on the formulary – approved

Off label and new FDA approved indications for formulary medications

Motion made to approve new indications for formulary medications:
- Olanzapine: treatment of schizophrenia and bipolar 1 disorder in adolescents 13 to 17 years of age
The UMDNJ/ NewarkWorks Career Fair

All in all, the career fair was a success; the youth were imparted with knowledge of what a career in the healthcare industry entails and the opportunities opened. A special thanks is extended to Lorraine Little Bell, Director, Training and Organization Development, Angela O. Adekola, MA, Training Development Specialist, and Helen Margulski, Special Projects Coordinator for making this event possible.

Contributed by:
Andy Sheu, PharmD. Candidate 2012

The dataset for the Alaris Smart Pump library was presented for review and approval. The “go-live” date for the Alaris Smart Pump is May 25, 2010. The ICU dataset has been approved by the Combined Critical Care subcommittee and the neonatal/pediatric datasets were approved by the Neonatology/Pediatric Divisions. Motion made to approve Alaris Smart Pump library dataset. No changes were noted.

Alaris Smart Pump library change algorithm and request form

The Alaris Smart Pump library change algorithm and request form were presented for review and approval. The request form will address any requested changes in the Alaris library. The algorithm details the process of implementing library changes in the Smart Pumps. Non-emergent changes will be uploaded in the dataset following P&T approval. Emergent changes that impact patient safety will be uploaded with 1 week of the request and reviewed retrospectively at P&T. Motion made to approve Alaris Smart Pump library change algorithm and request form. No changes were noted.

Rituximab: treatment of CD20-positive chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide.

Tiotropium: reduce exacerbations in patients with chronic obstructive pulmonary disease.
FDA Approves Gilenya (Fingolimod): The First Oral Drug to Reduce MS

Multiple Sclerosis (MS) is an autoimmune disease. In MS the body’s immune system gradually destroys the myelin that protects the nerve fibers in the central nervous system (CNS) leading to a wide range of neurological symptoms that can eventually progress to physical and cognitive impairment.

Gilenya is the first in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. It is thought to reduce the immune system’s attack on the CNS by retaining certain white blood cells (WBCs) or lymphocytes in the lymph nodes. This prevents the WBCs from reaching the CNS and attacking the myelin resulting in less inflammatory damage to the nerve cells. Gilenya’s novel mechanism of action makes it the first FDA approved oral treatment for relapsing forms of MS.

Gilenya will be available in 0.5 mg capsules and can be taken once a day. Gilenya will not cure MS but it will reduce the number of MS relapses and help slow the buildup of physical problems.

Studied in over 2,600 clinical trial patients Gilenya was shown to be relatively well tolerated and safe. However, some serious side effects can include bradycardia or bradyarrhythmia, infections, macular edema, breathing problems, and liver problems. Because Gilenya has the greatest potential to affect the patient’s heart rate within the first 6 hours of taking the first dose, the first dose needs to be given under the supervision of a doctor. The doctor will monitor the patient for the first 6 hours after the first dose is taken. In a two year long placebo controlled study Gilenya showed a 54% reduction in relapse rates and a 30% reduction in overall disease progression. The role Gilenya will play in the treatment of MS is still unclear, however, Gilenya offers an attractive alternative to patients that do not want to get chronic injections.

Contributed by:
Jessica Wu, PharmD. Candidate 2011

References:

Revisiting Proton Pump Inhibitor (PPI) Usage

The recent FDA advisory published in May 2010 about increased risk of fractures of the hip, wrist, and spine with the use of proton pump inhibitors(PPI) gave us one more reason to revisit our PPI usage, besides data linking PPIs with increased incidence of C. difficile diarrhea/nosocomial pneumonia and interactions with antiplatelet agents (Plavix®). The formulary PPIs at the UH are Pantoprazole (Protonix®) which is the primary workhorse PPI and Lansoprazole (Prevacid®) (Solutabs only). If 50% of the Protonix usage from last year ($80,000) could be converted to alternate cheaper product such as Famotidine (Pepcid®), the price saving could be significant for the institution. Some of the steps that could be taken to avoid using PPIs are:

A. Consider Famotidine oral tablets or IV vials instead of Pantoprazole oral tablets or IV in the appropriate patients (e.g. Stress ulcer prophylaxis).

B. Consider stress ulcer prophylaxis (SUP) only for the patients with risk factors (Cook e al. NEJM 1994;330:377-381):
1. *Mechanical Ventilation ( > 48hrs)
2. *Coagulopathy (platelets < 50000 or INR> 1.5 or aPTT> 2 times control)

C. Consider protonix IV to oral switch for the patients who may need PPI when appropriate

D. Remove Pantoprazole from the institution ordersets.

E. Discontinue Pantoprazole drip within 48-72hrs once patient is stable and transition to oral/iv as appropriate.

Contributed by:
Nishat Faruqui, Pharm D, BCPS
Recommendations for the Management of Hypertension in Patients Receiving VEGF Inhibitors

Vascular endothelial growth factor (VEGF) inhibitors are a class of medications indicated for the treatment of a variety of cancers. These drugs include bevacizumab (Avastin), sorafenib (Nexavar), sunitinib (Sutent), and pazopanib (Votrient). VEGF inhibitors bind to VEGF and make VEGF inaccessible to its receptors, primarily VEGF receptor-2 (VEGFR2) found on the surface of endothelial cells. Inhibiting the interaction of VEGF and its receptors prevents the formation and growth of new blood vessels in the tumors thereby retarding their growth because blood vessels supply tumors with nutrients to grow.1, 2

When VEGF binds to VEGFR2, it activates the receptor’s kinase functions which trigger downstream effects. Some of the effects include increased capillary permeability, production of nitric oxide, endothelial cell proliferation, migration, and survival under stress. Hypertension therefore becomes a common mechanism-based reaction. Blocking VEGF signaling decreases the amount of nitric oxide produced thereby causing vasoconstriction of the blood vessels.2

While there are other more serious adverse events such as hemorrhage, thrombosis, nephrotoxicity and cardiotoxicity, the Cardiovascular Toxicities Panel convened by the Angiogenesis Task Force of the Investigational Drug Steering Committee of the National Cancer Institute focused on hypertension due to its frequency of occurrence with VEGF inhibitor use. The panel recommended that oncologists should 1) perform and record risk assessment for potential heart complications, 2) recognize preexisting hypertension as a common event in cancer patients and address it prior to starting VEGF inhibitor therapy, 3) actively monitor the BP of patients on VEGF inhibitors with more frequent assessments during the first cycle of treatment and 4) manage BP with a goal of <140/90 mmHg for most patients.2

Of the available anti-hypertensive medications (angiotensin-converting enzyme inhibitors, diuretics, beta blockers, etc) appropriate agents should be chosen based on patient characteristics and contraindications. By increasing the physician’s awareness and properly treating hypertension in cancer patients, the therapeutic benefits of life-saving medicines can be increased.

Contributed by: Josephine Sasu-Tenkoramaa, PharmD. Candidate 2012

References:

The Pharmacy Technician Certification Board (PTCB)

The Pharmacy Technician Certification Board (PTCB) greatly appreciates the generosity of Mary Wilson, The University Hospital’s Lead Pharmacy Technician, participating in their annual Item Writers Workshop for the Pharmacy Technician Certification Exam (PTCE). This volunteer group, drawn from a variety of settings, made up of both Certified Pharmacy Technicians (CPhTs) and Pharmacists, met in Washington DC the weekend of May 14th - 15th 2010. As a participant, Ms. Wilson was afforded the opportunity to explore and maintain professional relationships with colleagues in the field of pharmacy. The pharmacy department commends Ms. Wilson’s outstanding commitment to pharmacy practice and recognizes her volunteer activities for the profession of pharmacy. Congratulations Ms. Wilson!

Contributed by: Michael Chu, Clinical Pharmacy Manager
First Generic Enoxaparin Approved by the FDA

On July 23, 2010, the Food and Drug Administration (FDA) announced its approval of the first generic version of enoxaparin sodium injection (Lovenox). Lovenox, a low molecular weight heparin that was approved by the FDA in 1993 for Sanofi-Aventis SA, is indicated for acute ST-segment elevation in myocardial infarction (STEMI), as prophylaxis for deep vein thrombosis (DVT), as treatment for acute DVT, in unstable angina, and in non-Q wave myocardial infarction. The generic enoxaparin has been approved for the 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/mL, 120 mg/0.8 mL, and 150 mg/mL strengths.

Since enoxaparin is considered a compound that is more complex than a traditional drug molecule, yet less complex than a biologic drug, the decision by the FDA seems to be a victory for generic companies in terms of what they can produce; however, the approval has not come without resistance. Prior to the ruling from the FDA, Sanofi-Aventis SA had tried unsuccessfully to extend their patent exclusivity of enoxaparin until 2012 claiming, in one instance, that enoxaparin was too difficult to copy.

The approved generic version of enoxaparin, which was developed by Momenta Pharmaceuticals Inc. and will be distributed by Sandoz, a unit of Novartis AG, has also come under scrutiny. Generic company Amphastar Pharmaceuticals Inc., who submitted their application for enoxaparin two years before Momenta, has argued that the FDA is favoring Momenta due to previous work relations between Momenta and certain FDA officials. Teva has announced that they anticipate the approval of their generic version of enoxaparin as early as the end of this year.

Contributed by: Richard Lem, PharmD. Candidate 2012

References:

Gold Nanoparticles: A Brighter Future for Cancer Treatments

Even with chemotherapy, surgery, and radiation therapy, cancer is still difficult to treat because of its nature. Some current therapies work because they target rapidly dividing cells, a characteristic of cancer. Unfortunately, as a result, healthy dividing cells and cancer cells are targeted alike. Studies have shown that colloidal gold can be used to make cancer treatments more selective.1,2,3

Since gold nanoparticles are inert, biocompatible, and able to be manipulated, scientists have been researching its ability to be used to detect and destroy cancer cells.1 In one study, immunolabeled gold nanoparticle biomarkers were comparable and perhaps better than the conventional methods at detecting epithelial growth factor receptor (EGFR) expression.1 More research followed with the use of hollow gold nanoshells (H AuNS) attached to monoclonal antibodies specific to EGFR. As a result, EGFR-positive A431 cancer cells could be selectively targeted and destroyed.

Since the anti-EGFR-HAuNS are only absorbed by the cancer cells and gold can absorb infrared laser, using photodynamic therapy (PDT) or photothermaltherapy (PTT), the cancer cells can be heated and killed while the surrounding normal cells are unaffected.2

It would appear that gold nanoparticles can be both a diagnostic and treatment tool. Hopefully, gold nanoparticles will be just as effective and safe as the research promises, and will soon be approved by the FDA for cancer treatment.

Contributed by: Sophia Chu, PharmD. Candidate 2012

References:
Employee of the 3rd Quarter

Josephina Versola

Josephina Versola has undeniably been chosen to be the pharmacy’s Employee of the Quarter. It may be cliche to say, but good things do come in small packages and Josephina is living proof.

Josephina is very courteous, punctual and diligent. She is always very helpful and without a doubt a joy to work with. Her colleagues have only good things to say about her. She is unique because she never has a complaint.

We are excited to award Josephina with our Essential Piece Recognition because she is truly the epitome of an essential piece in our pharmacy.

Contributed by:
Tara R. Shaw
Lead Pharmacy Technician

E-Prescriptions on the Rise

As technology improves and funding increases, more and more doctors are switching from the traditional pen and paper prescriptions to e-prescriptions. Approximately 200,000 doctors or 1 in 3 office-based doctors in the US are now using e-prescriptions compared to 156,000 last year. Also, last year, more than 47 states at least doubled their use of e-prescribing. In Massachusetts, 57 percent of doctors are e-prescribing.

A driver towards e-prescriptions is the government. In 2009, Congress, through the economic stimulus plan, is providing incentives for conversion to electronic health records. These incentives will be paid up until 2015, when providers will face penalties if they haven’t already converted.

Potential benefits for patients include: decreased chance of drug interactions and ideally ensure drugs are prescribed appropriately (e.g. weight-based dosing, renal adjustments), increased efficiency because of electronic transmission to pharmacies for pick-up, or for chronic medications, direct transmission to mail-order pharmacies, automatic formulary checking to ensure insurance coverage and decrease costs.

A major benefit for physicians is the increased efficiency gained from decreased number of calls from pharmacies. Call-backs are often made for clarification of illegible prescriptions, non-formulary drugs, drug interactions, incorrect dosages, renewals, etc. E-prescriptions would largely minimize the occurrence of calls due to these factors. Costs could also be decreased through discounts offered by malpractice insurers for the usage of electronic health records and prescribing.

Pharmacies also benefit as well. Financially, they save money through more formulary adherence, less therapeutic duplication, and complications from adverse drug events. Economically, patients are more satisfied with the ease of picking up prescriptions and more likely to stay a loyal customer. It would also help pharmacies ensure patient compliance to their medication regimen(s).

With advantages, there will also be disadvantages as well. Privacy is a factor, especially in the case of HIPAA regulations.

Patient information must be encrypted and sharing must be done with caution. These systems also need periodic maintenance and someone on-call at all times in case of problems with the system. Costs are another factor since some doctors’ practices do not have a large enough base of patients to cover the costs of switching. Some doctors are also hesitant to switch because of skepticism about the value of e-prescribing.

All-in-all, the decision to adopt electronic health records and prescribing is up to physicians. With more benefits outweighing the drawbacks, the hope is that in the future, all physicians will convert to this system to ultimately benefit the patient.

Contributed by:
Shang Jen, PharmD. Candidate 2011

References: