

Pharmacy & Therapeutics Committee Updates: Drugs Added To the Formulary

March 2014:

TBO-filgrastim (Granix) was added to the formulary with the FDA indication for the reduction in duration of severe neutropenia in patients treated with chemotherapeutic agents associated with clinically significant incidence of febrile neutropenia. TBO-filgrastim has shown to have equivalent efficacy as filgrastim in reducing the duration of severe neutropenia and has shown superior efficacy compared to placebo. The most commonly reported adverse events include: bone pain, asthenia, myalgia, and diarrhea. The incidence of drug related adverse events were seen more frequently with filgrastim (39%) than TBO-filgrastim (25.7%) (p=0.0149). The usual dose is 5 mcg/kg of body weight, given no earlier than 24 hours following chemotherapy and given until the expected neutrophil nadir is passed and the neutrophil count has recovered to normal range. The cost per syringe is \$222.63/300mcg and \$356.29/480mcg. The cost savings per syringe compared to filgrastim is \$39.74/300mcg and \$61.52/480mcg. TBO-filgrastim (Granix) will be automatically substituted for all orders of filgrastim (Neupogen). Filgrastim is now off formulary and restricted to NICU and PEDS only.

February 2014:

Gadobenate Dimeglumine (MultiHance) was added to the formulary with the FDA indication for intravenous use in magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). MultiHance has been approved by the FDA based on two controlled clinical trials that compared MultiHance to non-contrast MRI in patients with suspected CNS lesions and known metastatic CNS disease. MultiHance has shown to have better visualization (border delineation, internal morphology, contrast enhancement) when compared to other gadolinium based contrast agents such as gadobutrol. The key advantage of MultiHance when compared to other gadolinium contrast agents include: a higher relativity rate which improves visualization, partial hepatobiliary excretion which allows for liver imaging and it is the only FDA approved agent for both MRI and MRA imaging. The most common adverse effects reported are headache and nausea at 1.2% and 1.3%, respectively. The recommended dosage for MultiHance is 0.1mmol/kg (0.2mL/kg) rapid IV bolus followed by 5mL saline flush. The cost to Valley hospital for 1 vial is \$38.56/20mL.

January 2014:

Fluticasone Furoate (BREO Ellipta) oral inhalation powder has been added to the formulary with the FDA indication for long term maintenance treatment of COPD, including chronic bronchitis and/or emphysema, and to reduce the number of COPD exacerbations in patients with a history of exacerbations. Fluticasone Furoate (BREO Ellipta) demonstrated efficacy in improving lung function as a long-term maintenance treatment of COPD when compared to placebo and in reducing the number of COPD exacerbations when compared to vilanterol alone. It is not indicated for acute exacerbations. Common adverse effects: nasopharyngitis, headache, upper respiratory tract infection and oropharyngeal candidiasis. Dosage: one oral inhalation (fluticasone furoate 100mcg/vilanterol trifenate 25 mcg) once daily at the same time each day, followed by a mouth rinse without swallowing to reduce the risk of oropharyngeal candidiasis. Cost: Per 100/25 mcg, \$97.02 for 14 doses using one dose per day.

LHRH Agonists (Eligard) has been added to the formulary to be used in accordance with the FDA indications including advance prostate cancer. It has been approved through the Pharmacy & Therapeutics Oncology Subcommittee by Dr. Rakowski and Dr. Fernbach. The estimated savings of Eligard compared to Lupron is \$50,000 per year.

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Pharmacy Focus

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Marian Gergis:

Clinical Pharmacist wins Prestigious Preceptor of the Year Award from the New Jersey Society of Health-System Pharmacists



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Every year, the New Jersey Society of Health-System Pharmacists (NJSHP) presents an award to a pharmacist that exemplifies the core values of being a preceptor. To be awarded as the preceptor of the year, he/she must exemplify and fulfill several different characteristics including: being a partner in education, being a role model, having a depth of experience, coaching, having enthusiasm, and professionalism. At the 2014 NJSHP annual meeting held in April, our very own Emergency Department Pharmacist, Marian Gergis was recognized for fulfilling these characteristics and was awarded the Preceptor of the Year Award.

Marian Gergis was a pharmacy practice resident at the Valley Hospital in 2007. During her residency year, she took the opportunity to do a pilot study in the Emergency Department where she performed medication reconciliations, answered drug information questions,

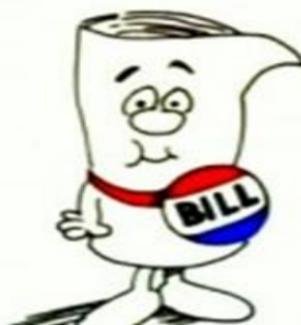
and provided several in-services to the Emergency Department team. After completion of the one year residency program, Marian was able to transition into the role of a full time Emergency Department pharmacist.

When asked about her teaching philosophy Marian states, "I've learned that you shouldn't go through life with a catcher's mitt on both hands; you need to be able to throw something back" a quote by Maya Angelou. Marian has adapted this quote into her daily life and strives to give back her wealth of knowledge to both students and residents as her preceptors and mentors did with her during her pharmacy career. Her advice for future preceptors is, "stay positive and remember the importance of teaching future pharmacists to be passionate and knowledgeable regarding our role in the health care system". Congratulations on your accomplishments Marian!

Join the Provider Status for Pharmacists Campaign!

Written by: Farah Rose Namissa, Pharm.D.

A very exciting time and opportunity has arisen for pharmacists as the HR 4190 bill is now being discussed and voted upon in Congress. The HR 4190 bill aims to give Medicare beneficiaries in underserved communities access to pharmacist provided ambulatory care services under part B of the Social Security Act. The proposal will recognize pharmacists as providers and provide a mechanism to pay for pharmacist provider services. Approval of this bill will be a great accomplishment for the pharmacy profession and reinforce the vital role that pharmacists can play as part of the health care team.



As many are well aware, pharmacists are currently the most accessible healthcare professionals. Pharmacists have a comprehensive level of training and expertise in medication use for the treatment, management, and prevention of diseases but often are limited in providing the best care to people at times due to lack of staffing and time constraints, especially in the community setting. Currently about 50% of American population, about 160 million people, takes at least 1 medication and 10%, about 31 million, are on more than 4 maintenance medications. More frightening is the impact of inappropriate medication use, which leads to more than 1.5 million preventable medication-related adverse events yearly. Medication non-adherence alone results in \$100 billion each year in excess hospitalizations. As the medication expert, the pharmacist's involvement in care and management of medications can help to alleviate this problem.

It is estimated that by 2025 there will be a deficit of primary care physicians upwards of 50,000. Because of this deficit, passage of the affordable healthcare act, and the huge financial burden of healthcare, new approaches to health care delivery are being investigated, especially a focus on preventative care. Currently, many other healthcare professionals are listed as providers under Medicare Part B including physicians, physician's assistants, certified nurse practitioners, qualified psychologists, clinical social workers, certified nurse midwives, and certified registered nurse anesthetists. If provider status is achieved, this will reinforce the value pharmacists bring to health care teams and pharmacists can work in collaboration with other healthcare professionals to improve patient quality of care and reduce overall health care costs through programs such as medication therapy management (MTM).

Recognition and coverage of pharmacist provided patient care services should create more incentives for pharmacists, pharmacy owners, and pharmacist employers to expand services offered and integrate these services into evolving care delivery models. The sad reality is, many still view pharmacists as only pill counters. Let's change that perception! In order to be successful in this pursuit, pharmacists need to be actively engaged to gain public attention for the provider status campaign.

How to become involved:

- Send a letter or schedule a meeting with your local members of Congress
- Tell your friends and family to do the same
- For more information visit: www.pharmacist.com/providerstatusrecognition or www.cqrcengage.com/ashp and follow the TAKE ACTION button

Highlights of the Pharmacy Forecast (Continued)

Summarized by: Yoohee Chu, Pharm.D.

Pharmaceutical Marketplace: It is predicted that...

Drug shortages will not likely be abated over the next 5 years

Drug shortages may decrease but still cause delays in therapy or the use of less familiar treatment regimens

Biosimilar products will replace expensive biologic products

New drugs will have accompanying diagnostic tests for optimal treatment based on pharmacogenomics

Pharmacy Department Operations: It is predicted that...

There will be an increase in the number of hospitals that compound all high risk sterile products for their patients

Pharmacy and Therapeutics Committees will have formal process for evaluating biosimilars

Hospitals will require conflict of interest disclosure by Pharmacy and Therapeutics committee members and clinicians who propose formulary addition

Pharmacy Practice Model It is predicted that...

Pharmacy students will provide essential patient care services including medical history taking and performing medication reconciliation

Pharmacy technician training programs will increase along with the requirement to complete a training program to be board certified

Standing orders for medications will be checked for accuracy and appropriateness by technology alone

Leadership: It is predicted that...

Contributions of the pharmacy department will be made more visible to patients through awareness brochures highlighting pharmacy services

Pharmacy leaders in the hospital setting will be evaluated and incentivized based on their department's contribution to achieving long term goals rather than routine operations

Ambulatory Care: It is predicted that...

The number of pharmacists practicing in ambulatory care settings will increase

A dedicated pharmacist working in the hospital setting will be responsible for patient's drug therapy management after discharge

There will be an increase in the number of hospitals providing outpatient pharmacy services (including: bedside delivery of discharge medications, medication reconciliation, and transition of care)



For more information on Pharmacy Forecast visit:

<http://www.ashpfoundation.org/pharmacyforecast>

Original biologic

Biosimilars



Generic drugs are often major cost savers for hospitals and patients as well as lucrative for the pharmaceutical industry, which makes one question why we do not have access to generic versions of biologic drugs such as Herceptin, Insulin, and Epogen.

The term "generic" should not be used to describe a similar biologic product. The more appropriate term is "biosimilar", which describes a biologic product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components. Compared to biosimilars, "generic" products are the exact same as the brand in the dosage, safety, strength, quality, and contains the identical amount of the same active ingredient(s) as the brand.

One major challenge in manufacturing biosimilars is the proprietary nature of the process for developing and manufacturing the original product. The biologic manufacturing process cannot be exactly duplicated by another manufacturer, thus the active ingredient can only closely resemble the original biologic but may not be identical.

Although the Biologics Price Competition and Innovation Act of 2010 allow the FDA to develop pathways to approve biosimilar products, the guidelines are still in development as to exactly how a biosimilar will be assessed and approved. These factors make the production of biosimilars a challenge for pharmaceutical companies.

In 2012, Teva successfully filed for approval of TBO-Filgrastim or Granix, which is modeled after Amgen's Neupogen. TBO-Filgrastim is a leukocyte growth factor indicated to reduce the duration of severe neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Since the laws of biosimilar approval is still in development, Teva utilized a full biologics licensed application (BLA) process and marketed TBO-filgrastim as a new drug in order to get it approved.

The Valley Hospital Pharmacy and Therapeutics Committee have approved the automatic conversion of Neupogen (Filgrastim) to Granix (TBO-Filgrastim) since May 2014. With the addition of Granix to the formulary, The Valley Hospital is on the forefront of the biosimilar movement.

Analysts estimate that there are approximately \$54 billion worth of biological patents expiring by 2020, with the cost saving ultimately being passed down to the patient through the health system. It will be interesting to see how the health system will handle the issues with biosimilar approval and regulations on product interchangeability, but one thing is for sure, biosimilars are on the horizon.

Written by:
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PHARMACY FORECAST 2014-2018:

STRATEGIC PLANNING ADVICE FOR
PHARMACY DEPARTMENTS IN
HOSPITALS AND HEALTH SYSTEMS



Pharmacy Forecast is a trends report from the American Society of Health-System Pharmacists that predicts important developments and challenges that are likely to arise for health system pharmacists in the near future. The reported trends are based on the responses of Forecast Panelists (made of health-system pharmacists who are experts in their area of pharmacy practice) who complete a questionnaire that discusses the developments in pharmacy predicted to occur over the next five years. The Pharmacy Forecast report is used by health systems pharmacy practice leaders to make strategic plans and improvements in their departments based on the emerging trends. Here is a summary of the 8 topic areas covered in the 2014-2018 Pharmacy Forecast which include: Fiscal Issues, Quality of Care, Health Care Analytics, Pharmaceutical Market Place, Pharmacy Practice Model, Ambulatory Care, Pharmacy Department Operations, and Leadership.

Fiscal Issues: It is predicted that...

Medicaid coverage will increase by $\geq 25\%$ over the next five years

Most hospital patients will participate in an Accountable Care Organization reimbursement plan

Most hospitals will be involved in the bundle reimbursement plan

Quality of Care: It is predicted that...

The Pharmacy department will be accountable for contributing to the improvement of performance in quality and safety

Pharmacists will be responsible for solving medication access issues before patient discharges

Pharmacist will have the authority to write discharge prescriptions

Hospitals will contract with retail pharmacy chains to ensure medication adherence by discharged patients

Health Care Analytics: It is predicted that...

Pharmacists will adopt new ways to improve quality of medication related data analysis

Medication Use Evaluations will be continuous and hospital protocols and guidelines will be refined based on the findings

IT analytics will be used to automatically detect ADRs, notify RPh for clinical interventions, prioritize patients in need of pharmacy care, and analyze cost and quality outcomes data

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