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## Special Points of Interest:

- P&T Update-Formulary Addition/Deletion
- Policy and Procedures Update
- The UMDNJ Newark – WORKS Career Fair 2012
- Meet the New Pharmacist!

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## P&T Update

### Formulary Addition/Deletion

#### Anti-Infective Subcommittee

Tramadol (Ultram®) – formulary addition – approved

Tramadol (Ultram®) is a centrally-acting analgesic approved by the FDA for the treatment of moderate to severe pain. Request for formulary addition of tramadol was initiated by the Pharmacy Dept. and supported by physicians from Emergency Medicine and Pain Management.

Ticagrelor (Brilinta™) – formulary addition-approved with restrictions to the Cardiology service.

Ticagrelor (Brilinta™) is a platelet aggregation inhibitor FDA approved to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS). Request for formulary addition of ticagrelor was submitted by the Cardiology Division.

Ticagrelor has unique pharmacologic properties that differentiate it from the current formulary antiplatelet agents (clopidogrel and prasugrel). It is a reversible P2Y<sub>12</sub>-receptor inhibitor belonging to a novel chemical class, and has demonstrated faster onset and offset of platelet aggregation inhibition. In the landmark PLATO study, ticagrelor was associated with a significantly lower incidence of the primary composite outcome (death from vascular causes, myocardial infarction, stroke) compared to clopidogrel. Safety concerns, particularly the risk of bleeding and potential interaction between aspirin and ticagrelor, were discussed. The cost of ticagrelor is slightly higher than clopidogrel or prasugrel; however, it was noted that clopidogrel is now available as a generic medication.

The committee supported the addition of ticagrelor to the hospital formulary with criteria restricting use to: 1. Patients seen by the Cardiology service, 2. Patients with suspected ACS in the Emergency Dept (one time dose only), and 3. Patients taking ticagrelor at home. The medication will be used primarily in patients unresponsive to clopidogrel or those with anticipated invasive procedures.

Radiopharmaceutical: Fludeoxyglucose F18 Diagnostic for IV administration- Formulary addition of Fludeoxyglucose F18 Diagnostic for IV is approved.

Fludeoxyglucose F18 injection is an intravenous diagnostic radiopharmaceutical for Positron Emission Tomography (PET).

Radiopharmaceutical: Sodium Fluoride F18 diagnostic for IV administration-Formulary addition of Sodium Fluoride F18 diagnostic for IV is approved.

Sodium Fluoride F18 IV is used for diagnostic purposes in conjunction with positron emission tomography (PET) and PET/computerized tomography (CT) imaging.

*(Continued on page 2)*



## **P&T Update** (Continued from page 1)

Imipenem/cilastatin (Primaxin®) – Formulary deletion – approved.

-A formulary review of carbapenem antibiotics was presented. The hospital currently has 3 carbapenem agents on formulary: meropenem, imipenem/cilastatin, and ertapenem. Meropenem is considered the carbapenem workhorse for the institution, although imipenem/cilastatin is occasionally requested (for pancreatitis, in SICU patients, etc.) and ertapenem is often used for orthopedic in patients and those with anticipated outpatient IV therapy.

Sodium Citrate 4% – Formulary addition – approved.

Sodium citrate 4% has both antithrombotic and antibacterial properties by chelating ionized calcium to disrupt normal coagulation pathway and by interfering with the formation of biofilm and bacterial cell wall. It is FDA approved for use with an apheresis device during therapeutic plasma exchange. It is not to be infused directly into the donor. Requestors seek to use sodium citrate 4% in place of heparin as an indwelling intraluminal hemodialysis (HD) locking agent.

Clopidogrel 300mg tablet (Plavix®) – Formulary deletion – approved.

Clopidogrel is a thienopyridine anti-platelet. The active metabolite irreversibly blocks the P2Y<sub>12</sub> component of ADP receptors on the platelet surface and prevents the activation of GPIIb/IIIa receptor complex, thereby reducing platelet aggregation.

Clopidogrel became generically available in mid-May. The cost of generic clopidogrel is \$0.27/75mg (\$6.26/75mg brand). There is no generic clopidogrel 300mg available and brand clopidogrel costs \$19.94/300mg. Pharmacy department proposed to delete clopidogrel 300mg/tab from UH formulary and auto-sub to 4x75mg when the 300mg dose is prescribed.

Based on 2011 UH clopidogrel purchase history, streamlining the generic cost saving opportunity for 75mg and 300mg, the projected cost saving for UH is \$74,196 per year. Cardiology department supports the recommendation to remove clopidogrel 300mg brand tablet from UH Formulary in the PCI setting.

Mecamylamine (Inversine®) 2.5mg tablet - Formulary deletion – approved.

Mecamylamine is a nicotinic acetylcholine receptor antagonist (ganglionic blocker), originally used for the treatment of severe and malignant hypertension (FDA approval 1956). This drug is not used for hypertension today because of the availability of safer and more efficacious antihypertensive agents. It is discontinued in the US. Pharmacy recommends to delete from UH Formulary.

Dimethicone 5% topical cream - Formulary deletion – approved.

Dimethicone is used as a moisturizer to treat or prevent dry, rough, scaly, itchy skin and minor skin irritations. It is discontinued in the US. Pharmacy recommends to delete from UH Formulary.

Sodium octoxynol-2 ethane (Phisoderm®) topical cleaner deletion from UH Formulary – approved.

Sodium octoxynol-2 ethane topical cleaner is discontinued in the US. Pharmacy recommends to delete from UH Formulary.

Metopirone 250mg-deletion from UH Formulary – approved.

Metopirone is an oral diagnostic agent that inhibits steroidogenesis. Specifically, metopirone works by inhibiting endogenous adrenal corticosteroid synthesis, thus decreasing the production of cortisol and corticosterone. This drug is discontinued in the US. It may still be available from the manufacturer for compassionate use.

Protirelin (Thyrel®) 0.5mg/mL injection-deletion from UH Formulary – approved.

Protirelin is a parenteral synthetic tripeptide. Although this agent is synthetic, it is structurally identical to natural thyrotropin-releasing hormone (TRH). It is FDA approved for the diagnostic assessment of thyroid function in patients with pituitary or hypothalamic dysfunction. This drug was approved by the FDA in 1976. Thyrel® TRH (Ferring) was discontinued in 2003.

Alcohol 5% in D5W IV solution-deletion from UH Formulary – approved.

Alcohol 5% in D5W IV solution is not available from Cardinal wholesaler. Dehydrated 98% alcohol is available in UH formulary.

## Policies and Procedures Update

### Intravenous drug administration guidelines for adults – 2012 annual review

The intravenous drug administration guidelines for adults were presented for annual review and approval. The guidelines were updated to accommodate IV injection of daptomycin over a 2-minute period and the formulary addition of ceftaroline.

## Ivacaftor (Kalydeco™): A Novel Treatment Option for Cystic Fibrosis

Cystic fibrosis is an inherited disease that affects about 30,000 U.S. children and adults. Cystic fibrosis is caused by a mutation in the gene that encodes the cystic fibrosis transmembrane regulator (CFTR) protein. The Delta F508 mutation accounts for about 70% of mutations observed in cystic fibrosis patients; however, more than 1,000 cystic fibrosis-associated mutations have been described. One such mutation is the G551D-CFTR mutation, which is observed in about 4% of the cystic fibrosis population and results in defective functioning of the CFTR protein.<sup>1,2,3</sup>

The clinical manifestations that result from mutations in the CFTR gene involve many organ systems, particularly the pulmonary system. Production of viscous mucus leads to airway obstruction, respiratory infections, and ultimately long-term airway destruction.<sup>2</sup> The discovery of the CFTR gene in 1989 opened the doors for researchers to pursue the discovery of agents that target this gene, thereby modifying the underlying disease processes.<sup>2,3</sup> Since there is no cure currently available, the treatment of people with cystic fibrosis has been aimed at supportive management of complications arising from the disease...until now.

Ivacaftor (Kalydeco™), a potentiator of the CFTR protein, was approved by the FDA in January 2012. It is the first drug to treat cystic fibrosis by improving the function of the defective CFTR protein in patients over 6 years old with the G551D mutation.<sup>3,4</sup> In a randomized, double-blind trial comparing ivacaftor to placebo, patients receiving 150mg of ivacaftor every 12 hours showed a statistically significant improvement in FEV<sub>1</sub> through 48 weeks, with pulmonary benefits noted as early as week 2 of treatment.<sup>5</sup> Patients receiving

ivacaftor also experienced improvement in gaining weight and a decreased risk of pulmonary exacerbations.<sup>5</sup> Ivacaftor showed no improvement in FEV<sub>1</sub> compared to placebo in patients with the more prevalent Delta F508 mutation.<sup>4</sup>

Further clinical trials are needed to determine if ivacaftor will benefit patients with mutations besides the G551D mutation. Ivacaftor is currently being studied in a Phase 2 clinical trial in patients with the Delta F508 mutation in combination with VX-809, which is an investigational drug designed to target the Delta F508 mutation.<sup>3</sup> While ivacaftor is currently only approved for use in a small population of cystic fibrosis patients, it does indicate an exciting step towards applying the concept of personalized medicine to treating the underlying cause of cystic fibrosis.<sup>3</sup>

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## The New Jersey Prescription Drug Program - Combating Medication Abuse in New Jersey

With the growing concern for drug overdose and abuse in the United States, many point at illegal drug substances such as heroin and cocaine as being the culprits of the abuse. However, it has become more apparent that the typical medicine cabinet, with its pill bottles containing prescription medications such as oxycodone, morphine, and alprazolam, is a likely source for the continued drug abuse. The Office of National Drug Control Policy cites that 2,500 youths



take a prescription analgesic in order to get their first high.<sup>1</sup> The National Survey on Drug Use and Health conducted in 2009 found that the number of American teens and adults who abuse prescription drugs exceeds those who use illegal substances such as heroin, cocaine and hallucinogens combined.<sup>1</sup> The Center for Disease Control and Prevention reports that 40 Americans die every day from a prescription pain killer overdose.<sup>1</sup> In response to these alarming findings, many states have implemented a prescription drug monitoring program (PDMP) that allows health care providers who are permitted access to a patient's protected health information to view the controlled substance use history for that patient.

The state of New Jersey continues to grapple with its staggering drug abuse statistics. In 2010, 7,328 patients were admitted to a state certified drug abuse

treatment program because of their addiction to prescription pain killers. This number is 2,000 more than the 2009 admissions and 5,000 more than the 2005 admissions.<sup>2</sup> To address the growing need for prescription drug monitoring, a bill for a PDMP in New Jersey was passed into law in 2008. In September 2011, the state of New Jersey began data collection on dispensed controlled dangerous substances (CDS). On January 18, 2012, the New Jersey Prescription Monitoring Program (NJMPMP) went in to effect, making New Jersey the fortieth state to implement a PDMP.<sup>3</sup>

A PDMP is an electronic database that collects and processes data on the dispensing of CDS in a given state. This data is forwarded to the PDMP on a regular basis by the community or outpatient hospital pharmacies that dispense the CDS. Hospitals, nursing homes, ambulatory surgical centers, and hospices are not required to report their CDS prescribing and dispensing.<sup>4</sup> State law varies in the types of substances, as well as in the frequency of required reporting. In New Jersey, all CII-V substances, as well as human growth hormone (HGH) use must be reported, and the reporting is done by dispensing pharmacists every 15 days.<sup>3</sup> The goals of the PDMP are to help identify patients who are addicted to prescription medications and to reduce the phenomenon referred to as "doctor shopping" (obtaining multiple prescriptions from different doctors for the same CDS).<sup>4</sup> As the data is collected, licensed physicians and pharmacists who register with the PDMP can access history of CDS use for an individual who they suspect may be involved in CDS abuse. An ideal PDMP would allow for easy access, standardized content, mandatory pharmacy reporting, confidentiality and security as well as the possibility of monitored access by non-health care providers such as law enforcement officials, researchers, and medical examiners.<sup>5</sup> In this way, the PDMP can be used as a vehicle to evaluate state drug abuse trends and promote public health education.

With pain assessment becoming the "fifth vital sign" and the provision for quantity limits of CII substances exceeding 120 for intractable pain, prescribers are becoming sensitized to the importance of pain

*(Continued on page 5)*

### New Jersey Prescription *(Continued from page 4)*

management. Consequently, many more prescriptions for narcotic analgesics are being prescribed, and with this comes the potential for diversion and abuse. Through the NJPMP, the pharmacist becomes the gatekeeper for the appropriate use of CDS and HGH. This heightened responsibility serves as public protection from unchecked CDS prescribing and dispensing as well as an affirmation of the vital role that pharmacists play in the health care team.

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## Ticagrelor (Brilinta®): The Latest Antiplatelet

Ticagrelor, approved by the FDA in July 2011, is the newest platelet aggregation inhibitor to reach the market. Manufactured and marketed by AstraZeneca as Brilinta®, it is available as a 90mg oral tablet. Ticagrelor carries the indication for reducing the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS), which encompasses unstable angina, ST elevation myocardial infarction (STEMI), and non-ST elevation myocardial infarction (non-STEMI). It is contraindicated in patients with severe hepatic impairment, history of intracranial hemorrhage, or active pathological bleeding such as peptic ulcers or intracranial bleeding.<sup>1</sup>

The standard dosage of ticagrelor is a loading dose of 180mg followed by a maintenance dose of 90mg twice daily with or without food. Usually, a 325mg loading dose of aspirin is taken concomitantly with ticagrelor, followed by 75mg to 100mg daily maintenance dose of aspirin. Ticagrelor carries a black box warning stating that maintenance doses of aspirin greater than 100mg/day can reduce the effectiveness of ticagrelor. Like the other antiplatelet agents, ticagrelor also carries a black box warning for causing significant, sometimes fatal, bleeding. No dosage adjustment is needed for renal impairment or mild hepatic impairment; however, ticagrelor is contraindicated in severe hepatic impairment. When possible, discontinue ticagrelor five days prior to

surgery. Ticagrelor is primarily a substrate of the CYP3A4 enzyme, which metabolizes it to an active metabolite. Furthermore, ticagrelor is a weak P-glycoprotein inhibitor.<sup>1</sup>

Similar to clopidogrel, ticlopidine, and prasugrel, ticagrelor has a mechanism of action that involves antagonizing the P2Y<sub>12</sub> adenosine-5'-diphosphate (ADP) receptor on platelets. However, ticagrelor is a reversible inhibitor, while the three aforementioned drugs irreversibly inhibit the ADP receptor.<sup>1,2</sup> Because the life of a platelet is five to seven days, patients taking irreversible inhibitors would require a week for their bodies to produce sufficient new platelets to recover function. The recovery is about twice as rapid with ticagrelor than clopidogrel,<sup>3</sup> since the reversibly-inhibited platelets can regain their function. Therefore, the need to wait for the next life cycle of platelets to recover is negated. In addition, ticagrelor is direct-acting, which allows for more rapid onset, while the others are prodrugs that require activation to their thiol metabolite.<sup>2</sup> With these two distinct characteristics of reversible inhibition and direct activity, ticagrelor has a theoretical advantage of providing a more controllable antiplatelet effect. However, the PLATO study, which compared ticagrelor to clopidogrel, showed that there was no significant difference in the rates of major

*(Continued on page 6)*

**Ticagrelor (Brilinta®)** (Continued from page 5)

bleeding and that ticagrelor had an increased rate of minor non-procedure-related bleeding (i.e. non-CABG-related).<sup>4</sup> Nonetheless, ticagrelor did demonstrate significant advantages in producing a greater reduction in cardiovascular death, myocardial infarction, and stroke than clopidogrel.<sup>4</sup> In addition, the RESPOND study found that ticagrelor has antiplatelet activity in patients that are non-responders to clopidogrel. The findings also showed that ticagrelor was associated with greater platelet inhibition than clopidogrel, regardless of the patient's responsiveness to clopidogrel.<sup>5</sup> The advantages of ticagrelor suggest a potentially unique place in ACS therapy, alongside clopidogrel and prasugrel. Considering that clopidogrel is now available generically and has convenient once daily dosing,<sup>6</sup> clopidogrel will likely remain the antiplatelet of choice, with ticagrelor being utilized only in certain cases.

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## Mirabegron (Myrbetriq®): the First FDA Approved Beta-3 Adrenergic Receptor Agonist for Urinary Incontinence, Urgency, and Frequency Associated with Overactive Bladder

Overactive bladder (OAB) is a syndrome that involves symptoms such as urinary incontinence, urinary urgency, urinary frequency, dysuria, and nocturia in the absence of a causative pathologic infection. The hallmark symptom of OAB is urinary urgency, which is defined as the sudden desire to urinate. Symptoms of OAB are mainly due to the overactivity, hyperreflexibility, and instability of the detrusor muscle that controls the contraction and relaxation of the bladder. The prevalence of OAB increases with age. Twenty percent of people 70 years or older and thirty percent of people 75 years or older reported symptoms.<sup>1,2</sup>

Treatment of OAB is aimed at decreasing the incapacitating symptoms to increase overall quality of life. The treatments of choice are anticholinergic agents, such as oxybutynin and tolterodine, which block the bladder muscarinic receptors, reducing the contractility of the detrusor muscle. However, due to several adverse effects such as dry mouth and

constipation, other treatment options have been sought. In June 2012, the FDA approved mirabegron (Myrbetriq®), the first agent in a new class of drugs, for the treatment of OAB.<sup>3</sup>

Mirabegron (Myrbetriq®) is a beta-3 adrenergic receptor agonist which relaxes the detrusor muscle during the storage phase of the bladder fill-void cycle.<sup>3</sup> This results in increased bladder capacity. The adult oral dosage for treatment of symptoms of overactive bladder is 25 mg once daily, with a maximum dose of 50 mg per day.<sup>2</sup> It is available as extended-release tablets in two strengths: 25 mg and 50 mg. Mirabegron is pregnancy category D and it should not be used in patients with severely uncontrolled hypertension. Dose adjustments are not necessary for mild hepatic or renal impairment; however with moderate impairments, the dose should not exceed 25 mg per day. In severe impairments, this drug is not recommended.<sup>3</sup>

(Continued on page 7)

### Mirabegron (Myrbetriq®) (Continued from page 6)

Mirabegron, when compared therapeutically to anticholinergic agents, has been shown to increase bladder capacity without changing micturition pressure and residual volume.<sup>4</sup> This data suggests potential for beta-3 adrenergic receptor agonists to be used as alternatives to anticholinergics in the treatment of overactive bladder symptoms.

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## Elelyso® (taliglucerase alfa) approved by FDA for Gaucher's Type 1

Glucocerebrosidase deficiency, also known as Gaucher's disease, results in the accumulation of the fatty substance, glucocerebroside. In an otherwise normal individual, this lipid is degraded by the glucocerebrosidase enzyme; however, a deficit of glucocerebrosidase causes the accumulation of excessive amounts of glucocerebrosides in various organs such as the spleen, liver, and lungs. Type 1 Gaucher's accounts for the majority of the cases and can occur at any age. Signs and symptoms include osteopenia, hepatomegaly, anemia, and pingueculae (small elevations near the inner or outer margins of the cornea). These signs and symptoms can cause complications such as bone pain and an increased risk of certain cancers.<sup>1</sup>

Diagnosis and testing of Gaucher's disease can be performed using enzyme analysis via blood tests as well as less definitive tests, such as a genetic mutation analysis. If diagnosed, physicians can track progression of the disease using imaging tests, such as MRI, to look for organ enlargement.<sup>1</sup>

Elelyso® (taliglucerase alfa), which was manufactured by both Pfizer and Protalix, has been approved by the FDA for the treatment of type 1 Gaucher's disease in adults. Taliglucerase alfa replaces the missing enzyme that normally breaks down glucocerebrosides.<sup>2</sup> Elelyso® (taliglucerase alfa) works to catalyze the hydrolysis of glucocerebroside to glucose and ceramide. In clinical

trials, Elelyso decreased spleen and liver size and improved anemia and thrombocytopenia.<sup>3</sup>

The recommended dose of taliglucerase alfa is 60units/kg IV (over 60-120 minutes) every other week, although physicians can make appropriate dose adjustments. Taliglucerase alfa is available as a lyophilized powder for reconstitution in a 200 unit vial. Taliglucerase alfa should be reconstituted, diluted, and administered under the supervision of a healthcare professional. Warning and precautions include anaphylaxis, in which case taliglucerase alfa should be discontinued and immediate medical treatment should be sought. However, there are currently no contraindications for taliglucerase alfa and is marketed as pregnancy category B.<sup>3</sup>

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# The UMDNJ NewarkWORKS Career Fair 2012

On August 14, many high school students gathered at the grand foyer of the medical science building to learn about various healthcare career options. This event, called the NewarkWORKS Career Fair, is held annually and is coordinated by the Department of Human Resources Office of Training and Organizational Development with the intention of giving young students an opportunity to explore their options in the healthcare field. Such fields include human resources, radiation safety, respiratory therapy, government affairs, public safety, pharmacy, Emergency Medical Services (EMS), disaster preparedness, medicine, dentistry, food and nutritional services, and many more.

The representatives from each department excitedly set up their tables with informative flyers and souvenirs such as water bottles and t-shirts, which would later be raffled off to the students. Additionally, some departments brought special equipment they utilize in their field, such as defibrillators, ventilators and other medical equipment. Whole Foods and nutritional services were giving out freshly cooked samples of food. The pharmacy table was prepared with a mortar and pestle, a torsion balance with weights, pill crushers, empty capsules, lactose powder, and a counting tray. Tours of the dental school, kitchen, and other

departments were also available for the students.

When the students arrived, Angela O. Adekola, MA launched the career fair with opening remarks, which were followed by introductions from the representatives of each department. One by one, they gave a brief overview of their department and a snapshot of what they do, grabbing the attention and interest of all of the students. After the introduction, the students eagerly dispersed throughout the foyer to the different departments' stations.

The students who hesitantly stepped up to the pharmacy table came with little interest and knowledge about the field, but left with some insight and a big smile after Dr. Michael Chu, Pharm. D. enthusiastically exclaimed, "the starting salary for pharmacists is \$100,000!" They also showed interest in all the tools that pharmacists use to compound medications. Overall, the career fair was a great success as it provided some guidance to the students on their way to a bright, successful future in the healthcare field.

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## Meet the New Pharmacist!

**Mina M. Malaak, Pharm.D.** started working for a major retail pharmacy after receiving his Doctor of Pharmacy degree from Massachusetts College of Pharmacy & Health Sciences in May 2011. He decided to join UMDNJ for a more challenging and rewarding career. On his free time, Mina enjoys reading, playing sports, photography, and designing websites.