PROVIDENCE Tarzana Medical Center

CHAIR PERSON
Jeffery Work, M.D.

# PHARMACY AND THERAPEUTICS NEWSLETTER

VOLUME 18.2 2nd Quarter 2014 EDITORS: Jeffery Work, M.D. Susan Wee, Pharm. D.
http://www.tarzanacme.com/pharmacy_newsletter.aspx

## P&T COMMITTEE ACTIONS

### FORMULARY

**Additions:**

- Tbo-filgrastim (Granix®): FDA approved ONLY for non-myeloid malignancies. EPIC will prompt a physician to switch filgrastim (Neupogen®) to tbo-filgrastim (Granix®).

**DRUG SHORTAGE!!**

The ASHP Drug Shortage "QuickLinks" is on the front page of the hospital intranet:
http://www.ashp.org/DrugShortages/Current/

**Current Shortages Impacting PTMC**

- Ephedrine Injection
- Metronidazole (Flagyl®) Injection
- Cefazolin (Ancef®) Injection

### POLICY UPDATE

**EPIC Automatic Stop Date Policy at 30 days**

At PTMC, drugs continue for 30 days except the following medications.

Azithromycin (Zithromax®) ---------- 5 days
Ketorolac (Toradol®) ---------- 5 days
Levofloxacin (Levaquin®) for CAP ----- 5 days
Meperidine (Demerol®) ---------- 2 days
Pantoprazole (Protonix®) IV infusion -- 3 days
Tolvaptan (Samsca®) –NF ---------- 4 days

Pharmacy will send a "sticky note" to physicians for above exception medications.
In EPIC, physicians will see a clock icon next to the medication that needs renewal at 30 days.

**PTMC CME:**
**7/14/14 (Monday): Biosimilars**
**7/28/14 (Monday): EPIC Safety**

## EPIC UPDATE

### EPIC Medication Safety Tips and Tricks

1. **Order sets have an advantage over individual orders because they include** complete treatment orders, medications, and monitoring parameters. Use order-sets for the following medications:
   - Insulin Sliding Scale (Correction Scale)
   - Insulin IV protocol
   - Heparin IV protocol

2. **Therapeutic Interchange** – If a physician wishes to continue a home medication that is non-formulary in EPIC, choose the NONFORMULARY choice. It is the last item in the window of suggested formulary alternatives.

3. **Admitting physicians, please "Sign and Hold"** inpatient orders for patients in the Emergency Department (ED) waiting for admission. If the order is signed and released in the ED, all orders including admitting orders will be discontinued once the patient is admitted. This will result in patient not getting their medications as ordered.

### EPIC Exception Policy

At PTMC, the following are exceptions to the EPIC therapeutic interchanges and protocols. Pharmacist will switch to existing PTMC standards at order verification.

Therapeutic Interchanges (TI) Exception at PTMC

1. **Meropenem (Merrem®):** EPIC 500 mg IVPB q6h over 3 hours will be switched to PTMC 1gm IVPB q8h over 30 minutes.
2. **NG PPI: Zegerid (omeprazole + Na Bicarb)** will be switched to lansoprazole (Prevacid®) NG in doses and frequency equivalent.

3. **Ciprofloxacin (Cipro®):** will be switched to **levofloxacin (Levaquin®).**

# MEDICATION SAFETY

## Heparin Medication Utilization Evaluation (MUE)

The Heparin IV Protocol MUE found 93% of patients reached therapeutic anti-Xa level within 24 hours. Prescribing warfarin on the first day of IV heparin therapy improved significantly (91% vs. 27%) compared to the March 2013. Protocol compliance including laboratory turnaround time of less than one hour improved significantly compared to March 2013 (93% vs 67%). The improvement is attributed to collaborative efforts between pharmacists, nurses, education department, and laboratory department.

## Insulin MUE

The May protocol compliance overall is improving. All indicators were above 95% with exception of double signature at initiation of therapy and changing IV bag. The 80% double signature compliance significantly improved from 50% in February 2014.

## Pradaxa® (dabigatran) FDA Safety Alert – Higher Risk for GI Bleed than Warfarin

The FDA recently completed a new study in Medicare patients comparing Pradaxa® to warfarin, for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. The new study included information from more than 134,000 Medicare patients, 65 years or older, and found that among new users of blood-thinning drugs, Pradaxa® was associated with a **lower risk of clot-related strokes, bleeding in the brain, and death, than warfarin.** The study also found an **increased risk of major GI bleeding with use of Pradaxa® as compared to warfarin.** This finding is different than the landmark study, RE-LY that supported the FDA approval of Pradaxa where it showed that the bleeding rate was comparable between the two drugs. The new study is based on a much larger and older patient population than those used in FDA's earlier review of post-market data, and employed a more sophisticated analytical method to capture and analyze the events of concern.

# MEDICATION UPDATE

## Biosimilars on Formulary- Tbo filgrastim (Granix®) vs. filgrastim (Neupogen®)

Biosimilars require clinical data to support their approval due to their greater size and complexity, their intricate and variable manufacturing processes, and their potential to cause immunogenic reactions. One issue is that, unlike conventional small-molecule generic products, biotechnological medicines cannot simply be copied. One of the larger concerns of biosimilars is the potential for patients to have an immune reaction to the biosimilar medication. The result can be the loss or enhancement of efficacy, neutralization of the native protein, and general immune effects compared to the reference medication.

The FDA has two paths for a biosimilar to receive approval. The first is by Biologics License (351a), where a full clinical evaluation of purity, safety, and potency is required and the second is 351k, where evaluation of purity, safety, and potency is required, but an abbreviated process. Although 351k approval follows an abbreviated pathway, the cost of complex manufacture does not result in a significant price discount unlike generic medications.

Tbo-filgratim (Granix®), which recently received FDA approval (via 351a route) for non-myeloid malignancies, is licensed as a biosimilar in Europe, but it is a separately licensed biologic from filgrastim (Neupogen®) in the US. The NCCN updated its myeloid guideline to include the tabo-filgrastim along with filgrastim and pegfilgrastim. The questions that clinicians may have will be prescribing for non-FDA approved indications. Can the biologic be used in indications that did not have clinical trial to support the FDA approval? How will any potential differences in the potency and efficacy be evaluated for the non-approved indications? The process for adopting and introduce biosimilars will be much more complex than traditional simple molecule for generic medication. A thoughtful analysis and discussion should take place before an agent is considered as a therapeutically substituted agent for the originator.

**DIRECTOR,**
**PHARMACY SERVICES**
George Boghossian Pharm. D.