

### Novant Pharmacy

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### New Drugs Added to Formulary

Lori Poole, PharmD and Christy Cicarello, PharmD

#### Lurasidone (Latuda)

Lurasidone is a new 2nd generation (atypical) antipsychotic agent similar to olanzapine, quetiapine, or ziprasidone. Potential advantages of this drug are rapid onset, once-daily dosing, and minimal impact on metabolic and ECG parameters. It is indicated for the treatment of schizophrenia and is dosed at 40-80mg PO daily with food.

#### Denosumab (Prolia)

Denosumab is an injectable RANKL inhibitor indicated for treatment of osteoporosis in post-menopausal women at high risk of fracture. The drug inhibits osteoclast mediated bone resorption and osteoclast maturation/survival. Studies have shown it produces an absolute risk reduction of non-vertebral fractures of 1.5% and relative risk reduction of 20% (at 3 years vs placebo). The drug is dosed as 60mg SQ every 6 months. It is restricted to outpatient use only.

### Infectious Disease Subcommittee

Charles Hartis, PharmD and Deanna Rattray, PharmD

#### Orolabial Herpes Treatment Changes

Orolabial herpes (OLH) is an infection of the lip by herpes simplex virus (HSV-1). 80% of US adults are carriers of this virus causing nearly 50 million episodes annually. Penciclovir has been Novant's formulary agent for OLH, however product availability changes required reevaluation. Docosanol (Abreva-OTC) has been studied in OLH and is shown to reduce time to healing of lesions and cessation of pain. Novant formulary will change to use docosanol applied 5 times daily until lesions heal or max of 10 days.

#### Probiotic Formulary Changes

Lactobacillus (Lactinex) will be interchanged for Flora Q probiotic mix of Lactobacilli and non-pathogenic streptococcus. Saccharomyces boulardii will remain on formulary. As before, any probiotic should be used with caution in immune suppressed patients.

#### Novant Pneumonia Orders

Pneumonia is one of the most common reasons for hospital admission. In order to optimize both patient outcomes and compliance with CMMS guidelines, Novant has developed a corporate inpatient pneumonia order set. You may access it here: [http://intranet.novanthealth.org/PDF/Clinical\\_Resources/Novant\\_OrderSets/Novant\\_Health\\_Order\\_Sets/PneumoniaOrders-NH\\_600033.pdf](http://intranet.novanthealth.org/PDF/Clinical_Resources/Novant_OrderSets/Novant_Health_Order_Sets/PneumoniaOrders-NH_600033.pdf)

## Medication Use Policy Subcommittee

*Kathryn Montanya, PharmD, MS, FISMP*

The Medication Use Policy Subcommittee (MUPS) of Novant P&T reviewed the following policies and determined that proper front-line review and full nursing and pharmacy approval was obtained, therefore they were recommended for approval by P&T:

GWSM Policies: Automatic Stop Orders for Medications, MAC User Guide, Enteral Medication Administration, MAC Downtime Procedure, Timing of Medications, Diagnostic Skin Testing, Nutrition Support Service,

RRMC Policies: Medication Formulary Management, Procurement of Medications, Drug Recalls, Clarification of Orders in Pharmacy, Automatic Stop Orders, Investigational Drug Studies.

BNMC Policies: Pyxis Policy

GCM Policies: IV Medication Extravasation Management, Medication Administration, Medication Reconciliation, Electrolyte Replacement, Look-alike Sound-alike & High Alert, Medication Orders, Chemotherapy & Chemo Spill, Implanted Ports



## Cardiovascular Subcommittee

*Laura Frantz, PharmD*

### Dronedaronone Initiation Requirements:

When dronedarone was first approved by the FDA, telemetry monitoring was required upon initiation of the medication. As there is now more clinical experience with dronedarone, the recommendation was made to remove the requirement for telemetry monitoring upon initiation. Telemetry may be initiated at the physician's discretion.

### Statin (HMG COA Reductase Inhibitor) Update:

Effective August 11th, pravastatin and rosuvastatin will become formulary statins. Atorvastatin (Lipitor) 80mg will remain on formulary but all other strengths will be therapeutically interchanged to prava- or rosuvastatin. Simvastatin will be removed from formulary, in part because of increased warnings from the FDA. For more information on recent simvastatin labeling changes look here: <http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm>

### Niacin 500mg IR Update:

Niaspan is the most common niacin formulation used. If the dose is written as 500mg daily, it is almost always intended to be Niaspan 500mg daily. Recommendation was made to therapeutically substitute Niacin 500mg daily orders to Niaspan 500mg dail unless the patient cannot receive medications via the oral route.

### Fish Oil Formulary Status:

Generic fish oil product was approved as preferred formulary agent, along with an automatic substitution of other fish oil products, including Lovaza.

## Profilnine/Novo-Seven MUE

*Jeremy Hodges, PharmD, BCPS*

**Background and Objectives:** The objectives of the MUE are to evaluate the use of the revised off-label use guidelines for rFVIIa (NovoSeven<sup>®</sup>) and Factor IX Complex (Profilnine<sup>®</sup>) to promote optimal medical therapy and evaluate medication-use practices from both patient-outcome and resource utilization perspectives. The guidelines were revised and approved April 23, 2009. Data were presented for all patients who received any amount of rFVIIa or factor IX complex from January 1 2010 - December 31, 2010. Patients are identified from drug charge data. Data collection was accomplished via retrospective chart review.

**Results:** At Forsyth Medical Center, 35 patients received at least one dose of NovoSeven or Profilnine in 2010. Data from 2010 was compared to data from as far back as 2006. There was little change in the use or outcomes of concentrated factor replacement in terms of, frequency, length of stay, or survival. The most common deviation from the guidelines included repeated doses of rFVIIa during cardiothoracic surgery, or a higher than recommended dose. The cost of concentrated factor replacement under the new guidelines compared to the projected doses of rFVIIa under the old guidelines produced a cost avoidance of \$158,832 during 2010.

**Safety:** There were no documented thromboemboli related to the administration of either drug in the charts reviewed.

**Recommendations:** Review the data on appropriate dose and need for re-dosing of rFVIIa post cardiothoracic surgery to share the information with CT surgery and anesthesia. We will continue to monitor usage and trends, and perform an ongoing MUE. Information will be presented to the P&T Committee. Guidelines will be continuously evaluated as new research and published data becomes available.

## Novant Quality Improvement Plan — 2011

*Charles Hartis, PharmD and Deanna Rattray, PharmD BCPS*

The Clinical Improvement plan is developed annually in order to reflect scope of care and corporate relationships of P&T committee as well as outlining planned steps in maintaining appropriate medication and nutrition product use. Medication Use Evaluations (MUE) play a critical role in assuring appropriate drug use. The CI plan outlines how medications for MUEs are chosen based on frequency of use, potential for toxicity or interaction, risk of a particular population, as well as those newly added to formulary. The MUE list for 2011 is below. In addition to those listed, pharmacy interventions will be summarized and their scope/impact will be presented to the committee regularly.

- Drotrecogin alfa (Xigris)
- Recombinant Factor VIIa (Novo-Seven) and Profilnine
- Methylnaltrexone (Relistor)
- Dabigatran (Pradaxa)Q
- Unfractionated Heparin IV
- Prasugrel (Effient)
- Alvimopan (Entereg)



## Medications Not Added to Formulary

*Joie Damico, PharmD and Deanna Rattray, PharmD*

### Pegloticase (Krystexxa)

Pegloticase is an antihyperuricemic agent indicated for chronic gout. It is given IV only and cannot be used if uric acid is above 6. There is a black-box warning about anaphylaxis and infusion reactions. Furthermore antibody formation has been seen resulting in reduced response rates as well as increased infusion reactions. Due to the risk/benefit profile, the committee recommended non-formulary status.

### Belimumab (Benlysta)

Belimumab is a monoclonal antibody that inhibits B-cell survival factor B-lymphocyte stimulator (BLys). It is indicated for treatment of adults with autoantibody positive systemic lupus erythematosus (SLE) who are already receiving standard therapy. Studies show a modest reduction in disease activity in a subset of those with serologically active disease. There is no data on nephritis or CNS SLE involvement nor with its use in combination with cyclophosphamide or other biologics. More patients in the belimumab group died in clinical trials. Serious infections as well as hypersensitivity reactions have been reported as well. Response rates were lower in black patients. Committee recommended non-formulary status with reevaluation in 6 months.

## Low-Dose Vitamin K

*Lisa Brennan, PharmD BCPS*

In patients on long-term warfarin therapy with difficult to control INRs even with excellent medication and dietary compliance or in patients with vitamin K absorption issues, low-dose vitamin K (100 to 200 mcg) can be recommended. ADEKs (oral vitamins A,D,E, and K) have been discontinued by the manufacturer. The committee approved adding a generic vitamin K 100mcg to formulary for this indication.



## Insulin U-500 Use and Safety Plan

*Bridget Dumont, PharmD*

Patients with severe insulin resistance associated with diabetes and obesity may require up to 2 units of insulin per kg of body weight daily or >200 units of insulin daily to meet their insulin needs, and insulin doses may exceed 100 units in a single injection. Highly concentrated Insulin U-500 contains 500 units/ml instead of standard 100 units/ml.

There is a significant error risk with U-500 insulin. Administration and dispensing errors are the most common (82% of cases), with hypoglycemia occurring in over one-third of reports. Novant has developed a thorough, system-wide process to ensure safe use of this product. Key points are outlined below.

- The drug will not be **started** in the hospital. Only patient on it prior to admission will receive the drug
- Pharmacists will verify home doses through direct patient interview using a standard verification tool
- All doses will be drawn up by pharmacy and dispensed labeled for the individual patient and hand-delivered to the patient's nurse
- Pharmacy will keep this product segregated from all other insulins



## Formulary Reconciliation—Class Reviews

*Amanda Edwards, PharmD*

This committee will reconcile the formularies across the system by comparing all of the existing formulary agents by AHFS classification and retaining a group of drugs that is determined to be the most beneficial for our patients and will meet the needs of all facilities across the system. Class reviews will be preformed by teams of clinical pharmacists from all facilities across the system. The order in which the drug classes will be reviewed was determined by a decision matrix that scored each section by safety, ease and cost. Formulary reconciliation will be remain a constant item in this newsletter until the process is complete in 2011.

- |                                    |  |
|------------------------------------|--|
| 1. Beta-adrenergic blocking agents | 10. Miscellaneous cardiac medications              |
| 2. Glycogenolytic agents           | 11. Proton Pump Inhibitors                         |
| 3. Miotics                         | 12. Anti-inflammatory agents (skin/mucus membrane) |
| 4. Propylamine derivatives         | 13. Protectants                                    |
| 5. Contraceptives                  | 14. Antimanic agents                               |
| 6. Loop diuretics                  | 15. Centrally-acting skeletal muscle relaxants     |
| 7. Potassium-sparing diuretics     | 16. 1st Gen. antihistamine derivatives             |
| 8. Calcium-channel blocking agents |  |
| 9. Direct vasodilators             |  |

### Formulary Class Review Teams:

Medicine Team I: Andrea Fender, Lorie Poole, Deanna Rattray, Christina Roels

Medicine Team II: Lisa Brennan, Gwen Mitchell, Chue Lee, Kristine Vaden

Medicine Team III: Sara Shields, Lauren Gurganus, Michael Evans

Medicine Team IV: Brock Harris, Amy Holmes, Allison Gaddy, Cam Haskett, Randi Bridges

Surgery/Critical Care Team I: Sara Szafran, Susan Smith, Jackie Olin, Patricia Pinder

Surgery/Critical Care Team II: Jeremy Hodges, Susan Wilson, Laura Bruner, Kevin Morris

Infectious Disease Team: Charles Hartis, Susan Smith

Oncology Team: Christina Ciccarello

Pediatrics Team: Amy Holmes, Brock Harris, Shannon Williams

Cardiology Team: Laura Frantz, Ryan Kammer

### P&T Spotlight

#### New Pharmacy Residents are Here!

Presbyterian and Forsyth both have new PGY1 Pharmacy residents. They will have significant involvement with P&T matters in the coming year, so please help welcome them!



#### Presbyterian



Catherine Sury

#### Forsyth Medical Center



Amanda Edwards



Rachel Holland



Sahal Khoshhal



#### August Events:

CV Subcommittee: August 25

Novant P&T Committee: August 25