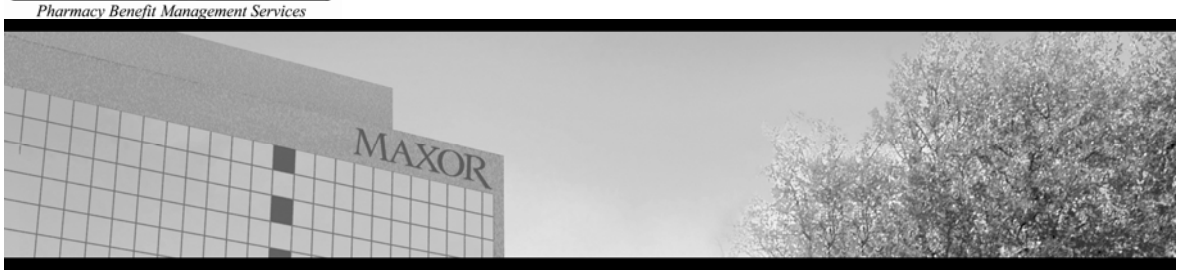
MAXORPLUS
Pharmacy Benefit Management Services



MaxorPlus Clinical Newsletter

August 2011

Now available

Solesta® (dextrabiner-sodium hyaluronate inj) is an injectable gel to treat fecal incontinence in patients for whom other therapies such as diet change, fiber therapy or anti-motility medications failed. The **Solesta**® gel is injected into a layer of tissue beneath the anus lining and may help build tissue in that area. By growing the surrounding tissue, the opening of the anus narrows and the patient may be able to better control those muscles. Dosing is two treatments, consisting of four injections each, for a total of eight injections.
AWP $ 1107/ injection or $ 8856/ treatment.

Based on **Solesta's**® indication and cost, we recommend restricting to a specialty pharmacy.

Brilinta® (ticagrelor) is an oral platelet receptor antagonist that inhibits platelet aggregation which is indicated to reduce cardiovascular death and heart attacks in patients with acute coronary syndromes (ACS). **Brilinta**® should be used in combination with aspirin and unlike clopidogrel, ticagrelor does not require hepatic activation to an active form and does not have irreversible effects on platelets. Dosing is initiated with a loading dose of ticagrelor 180 mg PO and aspirin (usually 325 mg PO). Then, give ticagrelor 90 mg PO twice a day in combination with aspirin 75—100 mg/day PO. Do not give maintenance doses of aspirin > 100 mg/day; maintenance doses of aspirin > 100 mg reduce the effectiveness of ticagrelor.
AWP $ 4.35/tablet or $130.50/month

Arcapta® (indacaterol maleate inhalation powder capusle) is indicated for the maintenance prevention of bronchospasm associated with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema. It is NOT indicated to treat acute deteriorations of COPD and should not be used for the relief of acute bronchospasm. Use a short-acting beta-agonist for rescue therapy, as appropriate. Dosing is one capsule inhaled once daily at the same time.
AWP $ 6.53/capsule or $195.90/month

New generics available:

Amethia and Camrese generic for **Seasonique**® used for birth control

alfuzosin generic for **Uroxatral**® used for the symptomatic treatment of benign prostatic hyperplasia (BPH)

fondaparinux generic for **Arixtra**® used for treatment or prophylaxis of acute pulmonary embolism (PE) or acute deep venous thrombosis (DVT)

Safety information

The U.S. Food and Drug Administration (FDA) has received reports of serious central nervous system (CNS) reactions when the antibacterial drug **Zyvox**® (linezolid) is given to patients taking psychiatric medications that work through the serotonin system of the brain (serotonergic psychiatric medications). The list of the serotonergic psychiatric medications that can interact with linezolid is long and includes most anti-depressive medications. SSRIs (ie **Prozac**®, **Lexapro**®, **Paxil**®): SRNIs (**Effexor**®, **Cymbalta**®); TCAs (amitriptyline, doxepin); MAOIs (**Nardil**®, **Emsam**®); and misc (trazodone, **Buspar**®, **Remeron**®, **Viibryd**®).

Although the exact mechanism of this drug interaction is unknown, linezolid inhibits the action of monoamine oxidase A—an enzyme responsible for breaking down serotonin in the brain. It is believed that when linezolid is given to patients taking serotonergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome—signs and symptoms include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever.

Healthcare professionals and patients may not realize that linezolid has monoamine oxidase inhibitor (MAOI) properties. Linezolid should generally not be given to patients taking serotonergic drugs. However, there are some conditions that may be life-threatening or require urgent treatment with linezolid such as when:

- Linezolid is used to treat vancomycin-resistant *Enterococcus faecium* (VRE) infections.
- Linezolid is used to treat infections such as nosocomial pneumonia and complicated skin and skin structure infections, including cases caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

Safety information about this potential drug interaction and important drug usage recommendations for emergency and non-emergency situations are being added to the drug labels for serotonergic psychiatric medications and linezolid (**Zyvox**®).

FDA med safety website 07-26-2011

In Medical News

Astrazeneca announced that they are changing the name of **Vandetanib®** to **Caprelsa®.** **Caprelsa®** is indicated for treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Concentration change

Tamiflu® (oseltamivir) will be available in a new, lower concentration to reduce the possibility of medication errors.

The **Tamiflu**® packaging of its oral suspension product says “new strength” because the concentration of medicine in the liquid has been changed from 12 mg/mL (milligrams per milliliter) to 6 mg/mL.

Tamiflu® is FDA-approved to treat adults and children older than 1 year who have had influenza symptoms for two days or less. **Tamiflu**® stops the virus from spreading in the body and can help shorten the duration of such symptoms as a stuffy or runny nose, sore throat, cough and muscle aches.

Containers of the low-concentration medication will come with new dosing instructions based on body weight.

In addition, the dosing device has been changed to a 10-milliliter oral syringe, which will make it easier to accurately measure the correct dose. The dosing device originally packaged with the 12 mg/mL suspension was marked in 30 and 45 mg, which caused confusion in measuring the liquid medication.

With both dose concentrations being available during the flu season this fall, Kendall Marcus, safety deputy in FDA’s Division of Antiviral Products, cautions that pharmacists and physicians will have to be particularly careful in prescribing and dispensing the medication.

Marcus notes that pediatric strength **Tamiflu**® capsules (30 mg and 45 mg) have not changed and are still available for children who can swallow capsules. Another option for parents is to open the capsule and mix its contents with a flavored food, like chocolate syrup.

Posted July 13,2011 FDA website