



MaxorPlus Clinical Newsletter

May-June 2013

Now available

Prolensa® ([bromfenac sodium](#)) is a NSAID for once daily ophthalmic use for treatment of ocular pain and inflammation following cataract surgery. It is 0.07%. Dosing is 1 drop in affected eye(s) once daily beginning 24 hours prior to surgery and continue 14 days postop. **Bromday®** is 0.09% and is available as a generic.
AWP \$ 204.76/3 ml bottle

Osphena® ([ospemifene](#)) is an oral estrogen receptor agonist/antagonist that is used to treat women experiencing moderate to severe dyspareunia (pain during sexual intercourse) due to menopause. Dosing is once daily with food. For postmenopausal women with an intact uterus, the addition of a progestin should be considered to reduce the risk of endometrial cancer.
AWP \$ 6.32/60 mg tablet or \$ 189.60/month

Sirturo® ([bedaquiline](#)) is an anti-mycobacterial indicated for treatment of adults with pulmonary multi-drug resistant tuberculosis for which no other effective treatment regimens are available. **Sirturo®** should only be used in combination with at least 3 other drugs. Dosing is 400 mg (4 of the 100 mg tablets) once daily with food for 2 weeks. Then reduce dose to 200 mg to three times a week with food for 24 weeks.
AWP \$ 191.49/100 mg tablet or \$ 10,723.44/ 2 week loading dose

[Based on **Sirturo®** indication and cost, we recommend having a prior authorization on this medication to insure proper utilization.](#)

Signifor® ([pasireotide diaspertate](#)) is a somatostatin analog that is indicated for the treatment of adults with Cushing's disease for whom pituitary surgery is not an option or has not been curative. **Signifor®** has been granted orphan drug status. Dosing is 0.6-0.9 mg SC twice daily.
AWP \$ 287.37/either strength inj. or \$ 17,242.20/month

[Based on **Signifor®** indication and cost, we recommend restricting to a specialty pharmacy](#)

Mekinist® ([trametinib dimethyl sulfoxide](#)) is indicated for treatment of unresectable or metastatic malignant melanoma in patients with BRAF V600E or V600K mutations which must be confirmed with a test. **Mekinist®** is not indicated in patients who have received prior BRAF-inhibitor therapy (such as **Nexavar®** or **Zelboraf®**). Dosing is 2 mg orally once daily until disease progression.
AWP \$ 348.00/2 mg tablet or \$ 10,440.00/month

Based on **Mekinist®** indication and cost, we recommend restricting to a specialty pharmacy

Diclegis® ([doxylamine-pyridoxine XR 10-10mg](#)) is a combination drug indicated for the treatment of pregnancy-induced nausea or vomiting in the early stage of pregnancy, up to 14 weeks, for women who do not respond to conservative management. Dosing starts at 2 tablets orally at bedtime and may be increase up to 4 tablets daily, one morning, one mid-day, and 2 at bedtime. Tablets should not be taken as an “as needed” basis. AWP \$ 5.70/tablet

Namenda XR® ([memantine](#)) is indicated for treatment of symptoms of moderate to severe Alzheimer’s disease. Dosing is started at 7 mg once daily and titrated up to 28 mg daily. **Namenda®** is due out in a generic, but not until first quarter 2015.
AWP \$ 10.09/ for any strength capsule

Simbrinza® ([brimonidine-brinzolamide 1%-0.2%](#)) is a combination medication that is indicated to decrease intraocular pressure in patient with glaucoma. Dosing is 1 drop three times a day. [Brimonidine](#) is already available as a generic. [Brinzolamide](#), which is the active ingredient in **Azopt®**, is due out in generic this year.
AWP \$ 105.18/ 8 ml bottle

Procysbi® ([cysteamine bitartrate delayed release](#)) is used to treat nephropathic cystinosis. FDA has granted **Procysbi®** orphan drug status. Dosing is based on weight and is titrated, given every 12 hours.
AWP \$ 74.70/ for either strength capsule Average adult dose cost \$ 1,045.80/day or \$ 31,374.00/month

Based on **Procysbi®** indication and cost, we recommend restricting to a specialty pharmacy

Kcentra® ([prothrombin complex concentrate, human](#)) is indicated for the urgent reversal of vitamin K antagonists, such as warfarin. **Kcentra®** is administered with vitamin K as a measure to reverse the anticoagulation effect and prevent further bleeding. Dosing is weight based and is based on initial INR.
AWP \$ 2.17/unit Dose range from 2500-5000 units or \$ 5,425 - \$ 10,850/dose

Based on **Kcentra®** indication and cost, we recommend restricting to a specialty pharmacy

Elliotts B® ([intrathecal electrolytes w/dextrose](#)) is used as a diluent for intrathecal administration of methotrexate or cytarabine. Volume is individualized based on dose of chemotherapy agent and volume needed.

AWP \$ 81.47/10 ml vial

Belviq® ([lorcaserin](#)) is a serotonin 2C receptor agonist indicated for treatment of obesity as an adjunct to a reduced-calorie diet and exercise. Indicated for patients with BMI greater than 30. Dosing is 10 mg twice daily. Re-evaluate in 12 weeks. If patient has not lost at least 5% of baseline body weight, discontinue.

AWP \$ 3.99/ 10 mg tablet or \$ 239.40/month

New generics available:

- [cecpalexin 750 mg](#) generic for **Keflex 750 mg®** indicated for treatment of infection
- [zolmitriptan](#) generic for **Zomig®** indicated for treatment of migraines
- [candesartan](#) generic for **Atacand®** indicated for treatment of hypertension
- [zenzedi](#) generic for **Dexedrine®** indicated for treatment of ADHD
- [riluzole](#) generic for **Rilutek®** indicated for treatment of ALS

New strength

Afinitor® now available in 2 mg and 3mg

Revlimid® now available in 20 mg

New indication

On May 15, 2013, the U.S. Food and Drug Administration approved a new use for **Simponi®** ([golimumab](#)) injection to treat adults with moderate to severe ulcerative colitis.

Simponi® works by blocking tumor necrosis factor (TNF), which plays an important role in causing abnormal inflammatory and immune responses. Previously approved to treat rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis (arthritis affecting the joints in the spine and the pelvis), **Simponi®** is now approved to treat adults with moderate to severe ulcerative colitis that is resistant (refractory) to prior treatment or requires continuous steroid therapy.

Ulcerative colitis is a chronic disease that affects about 620,000 Americans. It causes inflammation and ulcers in the inner lining of the large intestine and is one of two main forms of chronic inflammatory bowel disease. The inflammation can lead to abdominal discomfort, gastrointestinal bleeding, production of pus and diarrhea.

In Medical News

Zyprexa Relprevv® (olanzapine pamoate): Drug Safety Communication - FDA Investigating Two Deaths Following Injection

AUDIENCE: Health Professional, Pharmacy, Patient

ISSUE: FDA is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug **Zyprexa Relprevv® (olanzapine pamoate)**. The patients died 3-4 days after receiving an appropriate dose of the drug, well after the 3-hour post-injection monitoring period required under the **Zyprexa Relprevv® Risk Evaluation and Mitigation Strategy (REMS)**. Both patients were found to have very high **olanzapine** blood levels after death.

BACKGROUND: Under the REMS, patients are required to receive the **Zyprexa Relprevv®** injection at a REMS-certified health care facility, to be continuously monitored at the facility for at least 3 hours following an injection, and to be accompanied home from the facility. The **Zyprexa Relprevv®** label contains warnings about the risk of post-injection delirium sedation syndrome (PDSS), a serious condition in which the drug enters the blood too fast following an intramuscular injection, causing greatly elevated blood levels with marked sedation (possibly including coma) and/or delirium

RECOMMENDATION: FDA is providing this information to health care professionals while it continues its investigation. If therapy with **Zyprexa Relprevv®** is started or continued in patients, health care professionals should follow the REMS requirements and drug label recommendations. Patients and caregivers should talk to their health care professional(s) about any questions or concerns.

FDA safety website 6/18/13

FDA approves first genotyping test for patients with hepatitis C virus

The U.S. Food and Drug Administration today approved a test that identifies the genotype of hepatitis C virus (HCV) that a patient is carrying. The Abbott **RealTime HCV Genotype II**, which can differentiate genotypes 1, 1a, 1b, 2, 3, 4, and 5, using a sample of an infected patient's blood plasma or serum, will aid health care professionals in determining the appropriate approach to treatment. Because the various HCV genotypes respond differently to available drug therapies, knowing the type of HCV a person is infected with can result in better patient outcomes.

FDA website 6/20/13