



MaxorPlus Clinical Newsletter

Sept- Oct. 2012

Now available

Aubagio® ([teriflunomide](#)) is an oral pyrimidine synthesis inhibitor indicated for the treatment of relapsing forms of multiple sclerosis. The drug contains a Boxed Warning to alert prescribers and patients to the risk of liver problems, including death. Physicians should do blood tests to check liver function before a patient starts taking **Aubagio®** and periodically during treatment.

A second Boxed Warning is an alert noting that, based on animal studies, the drug may cause fetal harm. For this reason, **Aubagio®** is labeled as Pregnancy Category X, which means women of childbearing age must have a negative pregnancy test before starting the drug and use effective birth control during treatment.

Dosing is 7 mg or 14 mg daily.

AWP \$ 148.35/either strength tablet or \$ 4153.85/month

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

Myrbetriq® ([myrabepron](#)) is a beta-2 adrenergic receptor agonist. **Myrbetriq®** is the first in this class of agents with a novel mechanism for improving the symptoms of over active bladder (OAB). By relaxing the detrusor muscle via beta-3 AR activation, bladder capacity is increased during the urine storage phase. Other agents approved for OAB treatment (i.e. [tolteradine](#), [solifenacin](#), [darifenacin](#)) exert their effect through muscarinic receptor antagonism, a mechanism that can lead to intolerable anticholinergic-based side effects. Dosing is 25 mg once daily.

AWP \$ 8.34/ 25 mg tablet

Orbivan® ([butalbital/apap/caff](#)) is indicated for treatment of tension headache or migraine headaches. APAP component is 300 mg. Dosing is 1-2 tablets every 4 hours as needed. [APAP](#) component of generics that are available is 325 mg.

AWP \$ 1.45/ tablet

Stribild® ([elvitegrav/cobicis/emtricitab/tenofovir](#)) is indicated for the treatment of HIV infection in anti-retroviral naïve patients. Dosing is one tablet daily.
AWP \$ 93.70/tablet or \$ 2,811.00/ month

Tudorza® ([aclidinium bromide aerosol powder](#)) is a respiratory antimuscarinic that acts as a bronchodilator that is indicated for long-term, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD). Dosing is 1 actuation by inhalation twice daily. This medication joins **Spiriva®** in the class of long acting muscarinic antagonist (LAMA).
AWP \$261.00/ 60 doses

Duexis® ([ibuprofen/famotidine](#)) indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and for NSAID-induced ulcer prophylaxis. Dosing is one tablet three times a day.
AWP \$ 2.11/tablet or \$189.90/month
Both ingredients are available as generics.

Qsymia® ([phentermine/topiramate](#)) Indicated for chronic weight management in adult patients with an initial body mass index (BMI) of $\geq 30 \text{ kg/m}^2$ or $\geq 27 \text{ kg/m}^2$ in the presence of at least one weight related comorbid condition (i.e. hypertension, dyslipidemia, type 2 diabetes). Four doses available for titration purposes. Evaluate weight loss 12 weeks on highest dose; if the patient has not lost at least 5% of baseline body weight, discontinue therapy, as manufacturer states that the patient is not likely to achieve and sustain meaningful weight loss with continued treatment. Discontinue the 15mg/92 mg dose gradually by dosing every other day for at least 1 week prior to stopping treatment altogether, to avoid precipitating a seizure.
AWP \$ 4.80/ 3.75-23mg strength capsule or \$ 7.36/ 15-92mg capsule which is \$ 220.80/month

Xtandi® ([enzalutamide](#)) is an androgen receptor inhibitor that is indicated for the treatment of metastatic castration-resistant prostate cancer in patients who have received prior docetaxel therapy. Dosing is 160 mg (4 x 40mg capsules) once daily.
AWP \$ 74.50/40 mg capsule or \$ 8940.00/month

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

Forfivo® ([bupropion](#)) is indicated for the treatment of major depression which is available as a 450 mg XL tablet for once daily dosing.
AWP \$ 5.40/tablet or 162.00/month

Bupropion is available as a long acting generic in a 150 mg XL or 300 mg XL strength.

Bosulif® (bosutinib) is an oral multi-tyrosine kinase inhibitor and is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. Dosing is 500 mg once daily with food. Dose may be increased to 600 mg if no response.

AWP \$ 327.25/ 500 mg tablet or \$ 9817.50/month

AWP \$ 81.81/ 100 mg tablet

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

Stivarga® (bosutinib) is an oral multikinase inhibitor and is indicated for the treatment of metastatic colorectal cancer in patients who have previously received fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-VEGF therapy; and an anti-EGFR therapy. Dosing is 160 mg once daily with low fat breakfast for 21 days then 7 days off.

AWP \$ 133.57/40 mg tablet or \$ 11,220.00/month

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

Regimex® (benphetamine) is an oral, indirect-acting sympathomimetic amine that is metabolized to various amphetamines (i.e., amphetamine and methamphetamine). **Regimex®** is used as an anorectic agent for short-term (8 to 12 weeks) adjunct treatment of exogenous obesity with an initial body mass index (BMI) of 30 kg/m² or higher. Appetite-suppression activity is believed to occur by direct CNS stimulation of the satiety center in the hypothalamic and limbic regions. **Benphetamine** has a high potential for abuse and addiction. Dosing is 25-50 mg once daily mid-morning.

AWP \$ 1.52/25 mg tablet

Benphetamine is available in a 50 mg generic.

Binosto® (alendronate effervescent tablet) indicated for treatment of osteoporosis. This dosage form is taken once weekly.

AWP \$ 42.00/ 70 mg tablet or \$ 168.00/month.

Alendronate is available as a generic 70 mg tablet.

New generics available:

[valsartain/HCTZ](#) generic for **Diovan HTC®** indicated for hypertension
[cevimeline](#) generic for **Evoxac®** indicated for xerostomia associated with Sjogren's syndrome
[spinosad](#) generic for **Natroba®** indicated for pediculosis capitis (head lice infestation)
[trospium ER](#) generic for **Sanctura XR®** indicated for treatment of overactive bladder (OAB)

New dosage form

Isentress® ([raltegravir](#)) indicated for treatment of HIV infection is now available as a chewable tablet in 25 mg or 100 mg.

In Medical News

The U.S. Food and Drug Administration (FDA) has reviewed new data that indicate [Budeprion XL 300 mg \(bupropion hydrochloride extended-release tablets\)](#), manufactured by Impax Laboratories, Inc., and marketed by Teva Pharmaceuticals USA, Inc., is **not therapeutically equivalent** to **Wellbutrin XL®** 300 mg. FDA has changed the therapeutic equivalence rating for this product in the Agency's *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book¹)* from AB to BX, signifying that [Budeprion XL 300 mg](#) fails to demonstrate therapeutic equivalence to **Wellbutrin XL®** 300 mg. Impax has requested that the Agency withdraw approval of [Budeprion XL 300 mg extended-release tablets](#). Impax and Teva have stopped shipping the product and are issuing detailed information to their customers. This announcement relates only to [Budeprion XL 300 mg](#) manufactured by Impax and marketed by Teva. It does not affect the Impax/Teva [Budeprion 150 mg](#) product or generic [bupropion](#) products made by other manufacturers.

FDA website Oct. 3, 2012