



MaxorPlus Clinical Newsletter

July- August 2012

Now available

Elelyso® ([taliglucerase alfa](#)) is an enzyme using plant cell culture (carrot) to treat patients with Gaucher's disease. Gaucher's disease is a generic disease in which a fatty substance accumulates in cells and certain organs. **Elelyso®** was approved under orphan status. Dosing is 60 units/kg IV infusion every 2 weeks.
AWP \$ 714.00/ 200 unit vial monthly cost for average adult \$ 16,491.00

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

Sorilux® ([calcipotriene](#) foam) used in the treatment of plaque psoriasis. Dosing is twice daily to affect areas.

AWP \$ 480.00/ 60gm tube

[Calcipotriene](#) is available as a generic in a solution, ointment and cream.

Dymista® ([azelastine/fluticasone nasal spray](#)) is indicated for seasonal allergic rhinitis. Dosing is 1 spray per each nostril twice daily.

AWP \$ 173.75/ 23gm spray. Both [azelastine](#) and [fluticasone](#) are available as generics in nasal sprays.

Zetonna® ([ciclesonide nasal spray](#)) is indicated for seasonal allergic rhinitis. Dosing is 1 spray in each nostril once daily. **Zetonna®** is 37 mcg/spray and is the same generic as **Omnaris®**, which is 50 mcg/spray. The generic for Omnaris is due on the market around Jan. 2013

AWP \$ 136.85/ 6.1gm

Pertzye® ([pancrelipase](#)) is indicated for pancreatic insufficiency as seen in patients with cystic fibrosis or chronic pancreatitis. Dosing is individualized.

AWP \$ 1.98/ 8000 unit capsule or \$ 3.98/ 16,000 unit capsule

Perjeta® ([pertuzumab](#)) is a humanized recombinant monoclonal antibody that blocks human epidermal growth factor receptor-2 (HER2). It is approved for the first-line treatment of HER2- positive metastatic breast cancer in combination with [trastuzumab](#) and [docetaxel](#). Dosing is 840 mg IV loading dose, then 420 mg every 3 weeks. AWP \$ 4,890.79/ 420 mg vial

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

Neupro® ([rotigotine patch](#)) is indicated for the treatment of Parkinson's disease and restless leg syndrome. Available in strengths 1- 8mg/24 hours patches. Dosing is once daily. Neupro was available in 2007, but removed from the market in 2008 because some of the medicine crystalized on the patch and did not get absorbed well through the skin. These problems have been addressed with the new patches per the FDA. AWP \$ 5.10/1 mg patch and \$ 15.00/8 mg patch

Zaltrap® ([ziv-aflibercept](#)) is a humanized recombinant fusion protein that inhibits angiogenesis. It is indicated for the treatment of metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen. Dosing is 4mg/kg every 2 weeks prior to the FOLFIRI regimen. AWP \$ 1,920.00/ 400 mg vial or \$ 3,840.00/month

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

New generics available:

[Myorisan](#) generic for **Accutane®** indicated for severe recalcitrant cystic acne vulgaris

[nevirapine](#) generic for **Viramune®** indicated for HIV

[abacavir](#) generic for **Ziagen®** indicated for HIV

[olanzapine/fluoxetine](#) generic for **Symbyax®** indicated for depression associated with bipolar disorder

[montelukast](#) generic for **Singulair®** indicated for asthma

[desloratadine](#) generic for **Clarinet®** indicated for seasonal allergies

[tolterodine](#) generic for **Detrol®** indicated for overactive bladder

[pioglitazone](#) generic for **Actos®** indicated for type II diabetes

[pioglitazone/metformin](#) generic for **Actoplus Met®** indicated for type II diabetes

New indication

Afinitor® is now indicated for advanced breast cancer. Previously approved to treat kidney and pancreatic cancer, **Afinitor®** is the first 'proliferation signal inhibitor to be approved for breast cancer.

Reuters July 2012

Truvada® is now indicated to prevent HIV infections in people having sex with infected individuals. When taken daily, **Truvada®** (emtricitabine/tenofovir disoproxil fumarate) reduced the risk of HIV infection by 42 percent compared with a placebo. That was in a clinical trial where HIV-negative individuals had unprotected sex with multiple partners, including some HIV carriers. Another trial involving heterosexual couples where one partner was infected, and condoms were used routinely, found that **Truvada®** reduced the risk of infections by 75 percent. **Truvada®** is already approved to be used in combination with other antiretroviral drugs for the treatment of HIV.

FDA press release website July 16,2012

In Medical News

FDA approves first over-the-counter home-use rapid HIV test

The U.S. Food and Drug Administration today approved the **OraQuick In-Home HIV Test**, the first over-the-counter home-use rapid HIV test kit to detect the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2). HIV is the virus that causes acquired immune deficiency syndrome (AIDS).

The **OraQuick In-Home HIV Test** is designed to allow individuals to collect an oral fluid sample by swabbing the upper and lower gums inside of their mouths, then place that sample into a developer vial, and obtain test results within 20 to 40 minutes. A positive result with this test does not mean that an individual is definitely infected with HIV, but rather that additional testing should be done in a medical setting to confirm the test result.

Similarly, a negative test result does not mean that an individual is definitely not infected with HIV, particularly when exposure may have been within the previous three months. The test has the potential to identify large numbers of previously undiagnosed HIV infections especially if used by those unlikely to use standard screening methods. The Centers for Disease Control and Prevention estimates that 1.2 million people in the United States are living with HIV infection. About one in five are not aware they are infected. There are about 50,000 new HIV infections every year. Many of these new infections are transmitted from people who are unaware of their HIV status.

OraSure Technologies, the manufacturer of the **OraQuick In-Home HIV Test** will have a consumer support center with bilingual in English and Spanish that is available via phone and will be open 24 hours a day, seven days a week. The center will be operational and available to educate users with information about HIV/AIDS, the proper method for administering the test and guidance on what to do once results have been obtained once the manufacturer makes the product available for sale to the public. Information about the consumer support center and contact information is included in the test kit.

The company is not announcing a price yet, but said it would be less than \$60.

FDA press release website July 3, 2012