



## Health Newsflash

### New Drugs and Indications Reviewed at the May 2004 DEC Meeting



The Drug Evaluation Committee (DEC) of ESI Canada conducts a monthly review of all new drugs receiving their Notices of Compliance from Health Canada, to ascertain their places in therapy and their possible impacts on the private payer sector. Pricing information is included when the drug is available for sale. However, availability of a drug does not immediately follow its approval by Health Canada. This issue is provided to our insurance customers as a value-added service. We hope you will find this Health Newsflash informative, timely, and useful.

#### New Drugs

**Activelle** [*Act-tiv-vel*] (0.5 and 1 mg of estradiol and norethindrone acetate) is available as an oral tablet by Novo Nordisk Canada Inc. Each tablet contains a once daily dose of both an estrogen and a progestin. Activelle is the second oral combination drug for hormone replacement therapy (HRT), as Prefesta was approved last month (see May 27, 2004 Health Newsflash vol: 6 issue: 7). Activelle is used in women for treating symptoms of menopause (hot flashes, vaginal dryness, etc.). Long term HRT is no longer recommended due to increased risk of breast cancer, heart attack and stroke. The price of a 28-pack for Activelle is approximately \$32.00US (Drugstore.com). Canadian prices are not currently available for either of these two products.

**Zavesca** [*Zah-ves-kah*] (100 mg of miglustat) is available as an oral tablet by Actelion Pharmaceuticals Ltd. It is used for treating adults with Gaucher's disease, a genetic disease missing a specific enzyme responsible for the breakdown of certain fats in the body. Gaucher's disease is rare, with a worldwide prevalence of up to 1 in 40,000. At least 116 people in Canada have been diagnosed with this disease. The standard enzyme replacement therapy (ERT) for Gaucher's disease is Cerezyme. Zavesca can be used for patients who cannot tolerate standard ERT (e.g., allergy). It is given orally three times daily with an approximate cost of \$118,000 per patient per year; compared to an annual cost of \$213,000 for Cerezyme, which is infused into the vein. Cerezyme is included in ESI Canada's Hospital Drug Program (H); therefore, plans sponsors using the H program where Cerezyme is not covered, may experience an increase to drug plan costs when Zavesca is used. 2003 ESI Canada claims data revealed that one patient had 8 claims for Cerezyme for a total cost of \$54,361. The vast majority of plan sponsors should not be affected as the prevalence of this disease is very low.

**Climara Pro** [*Cly-mare-rah*] (1.39 and 4.4 mg of 17- $\beta$  estradiol and levonorgestrel) is available as a transdermal patch (absorbed through the skin) by Berlex Canada Inc. Climara Pro is a combination patch containing an estrogen and a progestin and is applied to the skin once a week. It is used in women with an intact uterus for treating symptoms of menopause. Other estrogen-progestin combination patches such as Estalis are available (\$24 per month-Ontario price), but are applied twice weekly. Although pricing information is not currently available, it is anticipated that this drug will compete with other combination patches, rather than expand the overall market, resulting in minimal impact to employer drug plans.

**Myobloc** [*My-oh-block*] (5000 units/mL solution of botulinum toxin type B) is available as an injection administered into the muscle by Elan Pharmaceuticals, Inc. Myobloc works similarly to Botox toxin. It is given every 3 to 4 months and has only one indication for treating cervical dystonia, a nerve disorder leading to abnormal movements and posture of the head and neck. Health Canada has not approved Myobloc for other conditions associated with Botox use. Pricing is currently unavailable for Myobloc. As a comparison, Botox costs approximately \$358 per vial (Ontario price). It is anticipated that the impact to employer drug plans will be minimal as the approximate prevalence of cervical dystonia is 1 in 10,000.

*Optimizing the Value of Drug and Dental Benefits*

Volume 6  
Issue 8

June 14,  
2004



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**Cipro XL** [*Sip-row*] (1000 mg of ciprofloxacin hydrochloride) is an oral extended release tablet by Bayer Inc. It is a once daily treatment for bacterial infections in the kidney and urinary tract. It is as safe and effective as regular Cipro 500 mg tablets, which are given twice daily. Generic versions of Cipro are available but are not interchangeable with Cipro XL. Cipro XL is priced at \$2.74 per tablet and is less expensive than taking two generic ciprofloxacin 500 mg tablets (\$3.51). This may result in savings to employer drug plans.

#### **New Indications**

For the drugs listed below, we anticipate that their new indications will have minimal impact on private drug plans, unless otherwise stated.

**Aspirin Extra Strength** [*As-spur-rin*] (500 mg of acetylsalicylic acid) is available as an oral tablet by Bayer Inc. Its original indications are for treating mild to moderate pain and inflammation, and at lower strengths (325, 80 and 81 mg) for preventing heart attacks and strokes. The 500 mg strength has now been approved for treating the pain associated with migraines. However, unlike the "triptan" drugs such as Imitrex, aspirin cannot be used to prevent or stop a migraine attack once it starts.

**Rythmol SR** [*Rith-maul*] (225, 325, 425 mg of propafenone hydrochloride) is available as sustained release oral capsules by Abbott Laboratories, Limited. Rythmol SR is a new formulation of Rythmol, and has a new indication for reducing recurring irregular heartbeats in certain patients. Unlike Rythmol, which is given three times a day, Rythmol SR can be taken twice a day. Generic versions of Rythmol are currently available, but are not interchangeable with Rythmol SR, as it has a different formulation (regular vs. sustained release) and indication. The manufacturer currently has no intention of marketing this product in the near future. However, when marketed, we anticipate that this new formulation will have minimal impact on employer drug plans due to its very specific indication, limiting its use.

#### **New Generics**

**Taro-Phenytoin** [*Tar-roh Fen-ni-toyn*] (125 mg/5mL of phenytoin) is available as an oral suspension by Taro Pharmaceuticals Inc. Phenytoin (brand name-Dilantin) is the standard treatment for chronic (long term) types of seizures. The dosage for phenytoin varies according to patient needs and requires close drug level monitoring. The comparable strength of Dilantin is priced at \$12.18 for the 250 mL solution. Although pricing is not currently available, generic versions are usually 30-40% less than the brand and this may result in savings to employer drug plans.

#### **Impact Statements**

##### **Minimal Impact**

- The estimated cost of the new drug is similar to existing drugs and the new drug is likely to become one of a number of existing drugs used for the medical condition (shifting of market share) or,
- The estimated cost of the new drug is similar to existing drugs and the new drug has low utilization due to either its place in therapy, its relation to other drugs or the prevalence of the medical condition.

##### **Intermediate Impact**

- New drug has an estimated higher than average cost compared to drugs used for the medical condition or,
- New drug has an anticipated higher than average utilization due to either its place in therapy, its relation to other drugs or the prevalence of medical condition

##### **No impact**

- New drug classified as a hospital drug or a diagnostic which has no impact in the private sector

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