



Health Newsflash

New Drugs and Indications Reviewed at the April 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

Levitra [*Leh-vee-tra*] (5, 10, and 20 mg of vardenafil hydrochloride) is available as an oral tablet by Bayer Inc. It is the third oral erectile dysfunction (ED) drug to be marketed in Canada, similar to Viagra and Cialis. ED generally affects men aged over 40, especially when other diseases (e.g. high blood pressure, diabetes, high cholesterol) are present. The manufacturer's prices are \$10.54, \$11.25, and \$11.70 for the 5, 10, and 20 mg tablets, respectively. These prices are similar to Viagra and less expensive than Cialis. However, Cialis has a competitive advantage over the other two drugs because of its longer duration of action. The recommended dose of Levitra for most patients is 10 mg taken orally 60 minutes prior to sexual activity. A 2003 ESI Canada study showed that this drug class can represent up to 3% of total drug expenditures for plans with ED drug coverage. We anticipate that Levitra will compete for market share with Viagra and Cialis rather than expand the overall market. Therefore, Levitra will have minimal impact to employer drug plans that currently cover oral ED drugs.

Factive [*Fact-tiv*] (320 mg of gemifloxacin mesylate) is available as an oral tablet by LG Life Sciences Ltd. It is the sixth antibiotic to be marketed in its class. Generic substitutes are currently available for Cipro and Noroxin, two agents in the same class. Factive is used for chronic bronchitis and community-acquired pneumonia. The recommended dosage is 1 tablet daily for 5 to 7 days. Although pricing is currently unavailable, it is anticipated that the impact to employer drug plans will be minimal as there are currently several other drugs in this class available and pricing will be similar.

Neulasta [*New-las-tah*] (6 mg of pegfilgrastim) is available as an injection under the skin by Amgen Inc. It is indicated for cancer patients receiving therapy. Neulasta offers similar efficacy and greater convenience than its comparator, Neupogen, which requires daily injections for up to two weeks. Neulasta can be self-administered in a single dose per chemotherapy cycle. The price of Neulasta is \$2,608 per cycle, and is comparable in price to an 11 day course of Neupogen that costs \$2,677 per cycle. It is anticipated that Neulasta will have a minimal impact on employer plans as it will gradually replace Neupogen for this condition.

Pravachol [*Praa-vaa-call*] (80 mg of pravastatin sodium) is now available as an oral 80 mg tablet in addition to the 10, 20, and 40 mg tablets marketed by Bristol-Myers Squibb Canada. Generic alternatives are available for the 10, 20, and 40 mg tablets of Pravachol. Pravachol is a drug in the statin therapy class that is used to lower cholesterol and prevent heart attacks. There are currently 6 statins available in Canada, three of which have generics – Mevacor, Zocor, and Pravachol. The lowest priced generic alternative of Pravachol 40 mg is priced at \$1.35 (Ontario). Although the price for the 80 mg Pravachol tablet is not yet available, it will likely be priced similarly to two tablets of generic pravastatin 40 mg. In ESI Canada's 2003 drug claims experience, 31% of pravastatin prescriptions were for the 40 mg tablet. The introduction of the 80 mg strength of Pravachol will likely have minimal impact on employer plans and could potentially result in cost savings.

Optimizing the Value of Drug and Dental Benefits

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Prefesta [*Pree-fess-tah*] (1 mg 17 β estradiol and 1 mg 17 β estradiol/ 90 mcg norgestimate) is oral hormone replacement therapy (HRT) by Jansen-Ortho Inc. There are two types of tablets which contain either an estrogen or an estrogen/progestin combination. Prefesta is indicated in women with an intact uterus for moderate to severe menopausal symptoms (hot flashes, vaginal dryness, etc.). According to the Women's Health Initiative study, long term HRT is no longer recommended due to an increased risk of breast cancer, heart attack and cardiovascular disease. According to the manufacturer there are no marketing plans currently anticipated for Prefesta.

Bonviva [*Bon-vee-vaah*] (2.5 mg of ibandronate sodium) is available as an oral tablet by Hoffmann-La Roche Ltd. Bonviva is used to treat or prevent osteoporosis in postmenopausal women. It is taken once a day. Fosamax and Actonel are other agents in this class (bisphosphonates). Unlike Bonviva which is taken once daily, its comparators are available in once-a-week oral tablets. According to the manufacturer, there are no marketing plans currently anticipated for Bonviva.

Lescol XL [*Less-call XL*] (80 mg of extended-release fluvastatin sodium) is available as an oral tablet by Novartis Pharmaceuticals Canada Inc. Lescol is a statin which is used to lower cholesterol and prevent heart attacks. Lescol XL 80 mg, priced at \$1.30 per tablet, is less expensive than taking two Lescol 40 mg capsules, which is priced at \$2.10. There are currently no generics on the market for Lescol.

New Indications

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

Climara [*Klye-meer-rah*] (2, 3.9, 5.7, 7.8 mg of estradiol hemihydrate) is available as a transdermal patch (absorbed through the skin) by Berlex Canada Inc. Climara is the first once-a-week hormone replacement therapy (HRT) available as a transdermal patch to be approved for prevention of osteoporosis. Other options for the prevention of osteoporosis include oral HRT, bisphosphonates, Evista, and calcium supplements. Climara was previously approved for relief of menopausal symptoms for women who had surgical removal of the uterus and ovaries. Currently there are no marketing plans for the 5.7 mg strength. The 2, 3.9, and 7.8 mg strengths are priced at \$4.56, \$4.88, and \$5.50 respectively.

Levaquin [*Lev-ah-kwin*] (250, 500, 750 mg, 25 mg/ml, 5 mg/ml IV of levofloxacin) is available as oral tablets, an oral liquid, and as an injection into the vein by Janssen-Ortho Inc. Levaquin is now indicated for the treatment of chronic bacterial prostatitis (long-term infection of the prostate). The dose of Levaquin for this new indication is 500 mg a day for 28 days. Levaquin was previously indicated for various types of upper-airway, lung, skin, and urinary tract infections. It is in the same class as Cipro (ciprofloxacin) and Floxin (ofloxacin), both of which are also indicated for infection of the prostate. Equivalent dosing of Levaquin (\$5.01/day) is less expensive than Cipro (\$5.50/day) but more expensive than generic Floxin (\$4.86/day) for this indication.

Zocor [*Zoe-core*] (5, 10, 20, 40, 80 mg of simvastatin) is available as oral tablets by Merck Frosst Canada Inc. It is a statin used to lower cholesterol and prevent heart attacks. The new indication for Zocor is for patients who have a high risk for heart attack even if their cholesterol levels are normal. In light of recent studies, it has been suggested that current cholesterol target levels should be lower than currently recommended. However, this is controversial and large clinical trials are currently underway to examine clinical outcomes in patients with cardiovascular disease. Zocor was the agent studied in a landmark study (The Heart Protection Study) that suggests that lowering cholesterol in patients with normal cholesterol levels reduces their risk for heart attacks. However, Canadian cholesterol management guidelines (October 2003) do not advocate this practice. The potential target population is significant as statins represent the highest utilized class in terms of costs. Without additional studies, we cannot predict the utilization for this new indication. We will keep our readers informed of new developments.



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New Generics

Gen-Clarithromycin [*Gen-clare-rith-row-my-sin*] (250, 500 mg clarithromycin) is available as oral tablets by Genpharm Inc. Clarithromycin is an antibiotic used to treat various respiratory infections, including pneumonia and sinus infections. It is dosed twice daily for 7 to 14 days. Biaxin is the brand name for clarithromycin, which is manufactured by Abbot Laboratories Ltd. In 2003, Biaxin ranked 23rd for drug cost in ESI Canada's drug claims experience and was the most commonly used drug in its therapy class. The comparable brand strengths of Biaxin are priced at \$1.53 and \$3.23 for the 250 and 500 mg strengths respectively. Although pricing is currently not available, generic versions are usually 30 to 40% less than the brand and this may result in savings to employer drug plans.

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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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