



Health Newsflash

New Drugs and Indications Reviewed at the January 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.

*For the drugs listed below, we anticipate minimal impact on private drug plans (except where indicated).**

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New Prescription Drugs:

Benzaclin Topical Gel [*Ben-zah-klin*] (1% of clindamycin phosphate and 5% of benzoyl peroxide) is available as a topical gel by Dermik Laboratories Canada Inc. It is a new combination product of two existing topical agents applied to the skin twice daily to treat acne. Acne is the most common skin disease and affects 80% of the population between 12 and 25 years.

Combigan [*Com-bee-gan*] (0.2% of brimonidine and 0.5% of timolol) is available as eye drops by Allergan Inc. It is administered twice a day to lower intraocular (eye) pressure in patients with glaucoma. Combigan is a combination of two existing agents which work by different mechanisms and is used when response to a single drug is insufficient. Potential cost savings can be achieved through a decrease in dispensing fees.

Gynazole-1 [*Guy-naa-zole*] (2% of butoconazole) is available as a cream in a pre-filled vaginal syringe by Ferring Inc. It is a single dose application used for the local treatment of vaginal fungal infections (VFI). It can be applied at any time of the day due to its adhesive properties. This differs from its main comparators, Canesten and Terazol, which are usually used at bedtime. Approximately 75% of women have at least one episode of VFI in their lifetime and 45% of those will suffer a second episode. There are many treatment options available for VFI, either with or without a prescription. We anticipate Gynazole-1 to be priced competitively with similar products.

Iressa [*Ere-ress-ah*] (250 mg of gefitinib) is available as an oral tablet by AstraZeneca Canada Inc. It is the first of a new class of drugs, the tyrosine kinase inhibitors. It is given once daily, as third line therapy, for a specific type of lung cancer (locally advanced or metastatic non-small cell lung cancer). Lung cancer is the second most common cancer in Canada and the leading cause of death due to cancer. Approximately 80 to 90% of lung cancers are non-small cell lung cancer. Of these, 50 to 65% are in advanced stages. Based upon a median survival length of seven months, it would cost approximately \$17,000 per patient. (See *Health Newsflash*, Volume 5, Issue 22, December 19, 2003 for additional information). This drug was marketed in December 2003 and is anticipated to have an intermediate impact on private drug plans.*

Meningitec [*Men-inn-geh-teck*] (10mcg/0.5ml of meningococcal C oligosaccharide and 15mcg/0.5ml of corynebacterium diphtheriae CRM 197 protein) is available from Wyeth Canada as a preventative vaccine for injection into the muscle. It is used primarily in infants to provide immunity against bacteria which may cause meningitis (group C). It is similar to Menjugate, which is injected under the skin rather than into a muscle. Most meningococcal infections are due to the group B serotype (no vaccine available) but outbreaks of meningitis are more commonly caused by the groups A or C. Pricing information is not available, but Meningitec should be comparable to Menjugate. Many plan sponsors exclude vaccines from their drug plans.

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Reyataz [*Ray-ah-tazz*] (100, 150, 200 mg of atazanavir) is available as oral capsules by Bristol-Myers Squibb Canada. It is a drug for the treatment of HIV/AIDS and is taken orally once daily in combination with at least two other HIV drugs. Reyataz is one of many drugs in the protease inhibitor class and has shown less adverse effects on blood cholesterol levels. The manufacturer's price per capsule is \$9.90 with a daily cost of \$19.80 (two capsules). As Reyataz is used in combination with various other HIV drugs, the cost impact per patient will vary. At \$19.80 per day, Reyataz falls within the range of \$15.98 to \$30.72 for similar drugs in this class.

New Over-the-Counter (Non-Prescription) Drugs:

Advil Allergy Sinus Caplets (200 mg of ibuprofen, 30 mg of pseudoephedrine and 2 mg of chlorpheniramine) is available as oral caplets by Wyeth Consumer Healthcare Inc. This combination product contains an analgesic, a decongestant and an antihistamine (ibuprofen, pseudoephedrine, and chlorpheniramine) for the symptomatic relief of sinus pain, congestion, and runny nose, which are commonly seen in patients with seasonal allergies. There are several similar combination products currently available and we anticipate pricing to be comparable to these products.

Children's Advil Cold Suspension (100 mg/5 ml of ibuprofen and 15 mg/5 ml of pseudoephedrine) is available as an oral liquid by Wyeth Consumer Healthcare Inc. It is a combination product of an analgesic and a decongestant (ibuprofen and pseudoephedrine) for the treatment of cold symptoms such as fever, sinus pain and congestion in children. There are several similar combination products currently available and we anticipate pricing to be comparable to these products.

New Indications:

Tamiflu [*Tam-eh-flu*] (75 mg, 12 mg/ml of oseltamivir phosphate) is available as oral capsules and oral liquid by Hoffmann-La Roche Limited. It is the first agent to receive this new indication for the prevention of influenza (flu) in adults and children over 13 years; however, it does not replace flu vaccination. It was previously approved to treat the flu in adults only. Therapy should start within two days of exposure and taken daily for seven days following close contact with an exposed person. However, following a community outbreak, therapy could continue for up to six weeks. Approximate drug costs would be \$30 to \$177 per patient. If governments decide to stockpile this drug in case of large flu outbreaks, there would not be enough supply for the anticipated demand. Last week, the Canadian government moved to secure some supply of the drug from Hoffman-LaRoche Limited. If physicians decide to prescribe Tamiflu for flu prevention in susceptible individuals, its utilization and cost to private drug plans would still be minimal.

Paxil CR [*Pack-sill CR*] (12.5 and 25 mg of paroxetine) is available as oral controlled-release tablets by GlaxoSmithKline Inc. It has a new indication for the treatment of social anxiety disorders, in addition to its original uses for depression and panic disorders. Compared to regular Paxil, Paxil CR has a lower incidence of nausea during the first few weeks of treatment. The regular formulation of Paxil and its generics have the same indications as Paxil CR. (See Health Newsflash, Volume 6, Issue 1 January 14, 2004 for cost analysis and additional information).

Kytril [*Keye-trill*] (1 mg/ml of granisetron hydrochloride) is available as an intravenous (into the vein) injection by Hoffmann La-Roche Limited. It has a new indication for the prevention and treatment of nausea and vomiting that occurs after surgery. Its original indication was for the prevention of nausea and vomiting associated with cancer therapies. Kytril is the second drug of its class (serotonin antagonists) to be approved for this indication.

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New Generics:

Gen-citalopram [*Jen-sit-tal-oh-pram*] (10, 20 and 40 mg of citalopram) is available as oral tablets by Genpharm Inc. As of January 2004, Celexa, a treatment for depression, lost its patent and this generic version is now available. Celexa ranks seventh in terms of drug cost in ESI Canada's database, representing 1.36% of total drug expenditures. The average prices of Celexa and Gen-citalopram are \$1.33 and \$0.98, respectively. Gen-citalopram is approximately 35% lower in cost than Celexa, resulting in potential savings for private drug plans.

Apo-omeprazole [*Ah-poe-oh-mep-pra-zole*] (20 mg omeprazole) was approved by Health Canada on January 27, 2004 and will be available as an oral capsule by Apotex Inc. This drug is a generic form of Losec by AstraZeneca. Omeprazole is used primarily for ulcers and gastro-esophageal reflux disease (GERD) and is the most prescribed drug in the proton pump inhibitors (PPI) class. As per the ESI Canada's 2003 database, Losec 20 mg tablets accounted for over 38% of prescriptions and 43% of PPI drug expenditures. It was also the fifth highest prescribed DIN and the highest DIN in total drug expenditures at 2.58%. According to Apotex Inc., the price of Apo-omeprazole 20 mg will be \$1.39 per capsule; this compares to \$2.20 per tablet for Losec 20 mg, a 37% difference. Apotex Inc. will be applying to provincial drug plans to obtain interchangeability status with Losec 20 mg tablets. If successful, this will permit pharmacists to generically substitute Apo-omeprazole 20 mg capsules for Losec 20 mg tablets, resulting in significant savings for private drug plans. We will keep you informed of the developments.

New Product Launch:

Evra [*Ev-rah*] (6 mg of norelgestromin and 0.60 mg of ethinyl estradiol) by Janssen-Ortho Inc. This is the first contraceptive skin patch to be marketed in Canada. It was approved by Health Canada on August 20, 2002; however, it is now being made available in pharmacies. Its efficacy is similar to oral contraceptives and may have a higher compliance rate due to once weekly use. One patch is to be applied on the skin and kept in place for one week and this is repeated for three weeks, followed by a patch-free week to mimic the menstrual cycle. Evra is priced at \$25.00 versus oral contraceptives which range from \$10.78 to \$21.09 per 28-day cycle. Evra has been on the market for two years in the U.S. and has captured 9.9% of the contraceptive market. Whether this trend will occur in Canada is unknown, however, it is anticipated that Evra will result in an increase to overall drug plan costs.

** 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

- The new drug has an estimated higher than average cost compared to drugs used for the medical condition or,
- The 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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