



## Health Newsflash

### New Drugs and Indications Reviewed at the September 2003 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:

For the new drugs listed below, we anticipate that they will have minimal impact on private drug plans due to its low utilization or similar cost as existing agents.\*

### Redefining Health Claims Solutions

**Attenade** [*At-ten-aid*] (2.5, 5 and 10mg dexamethylphenidate) available as oral tablets by Biovail Pharmaceuticals is used in the treatment of attention deficit hyperactivity disorder (ADHD). The active ingredient is similar to Ritalin and Concerta (methylphenidate). Since Attenade can be dosed twice a day, it may be useful for patients who require up to 3 times daily dosing of Ritalin (e.g., children during the school day). Attenade is an alternative to current therapy and will probably be priced at a premium; however, methylphenidate remains the current treatment of choice.

**Cetrotide** [*Ceh-trow-tyde*] (0.25 or 3.0mg per vial cetorelix) available from Serono Canada Inc., as a powder for injection, is a hormone injection given under the skin once daily for 1 to 14 days as part of infertility treatment in women. It is similar to Orgalutran. Cetrotide is another option for women who require this type of medication as part of the overall treatment regimen for assisted reproduction. Drug plan options usually define the coverage of this drug class.

**Hepsera** [*Hep-seh-rah*] (10 mg adefovir) available as an oral tablet by Gilead Sciences, Inc. is an antiviral drug for chronic hepatitis B infection which is taken once a day. Existing therapies for people infected with hepatitis B are injectable Roferon-A and oral Heptovir. Hepsera and Heptovir have fewer side effects; however, their long term efficacy and optimal treatment duration is unknown. Hepsera has been effective in patients who developed treatment resistance to Heptovir. Childhood vaccination for hepatitis B is the most effective treatment for prevention and it reduces the number of infected patients.

**Gamunex** [*Gam-mune-necks*] (10g per 100mL human immune globulin) available as a solution for injection by Bayer Inc. is an immune globulin (IVIG) that is injected into a vein. It is used in a variety of immune deficiency diseases (a group of diseases that affect the body's ability fight infections resulting in more frequent and severe infections that last longer than usual). There are currently several IVIG products available in Canada (e.g., Iivegam Immuno, Gamimune N) of which Gamunex is another option.

**Pediarix** [*Pea-dee-ah-ricks*] (diphtheria, tetanus, pertussis, hepatitis B and polio toxoid) by GlaxoSmithKline Inc. is a vaccine used to provide active immunity in infants for diphtheria, tetanus, pertussis (whooping cough), hepatitis B and polio. It is administered by injection into a muscle in 3 doses at 6 to 8 week intervals. Pediarix is the first vaccine providing immunity against hepatitis B in combination with these childhood diseases. At this point, it is not known whether provincial public health departments will provide this vaccine. We will keep our customers informed as more information becomes available.

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## Health Newsflash

### New Drugs and Indications Reviewed at the September 2003 DEC Meeting

page 2



**Pegasys** [*Peg-ah-sis*] (180 mcg per mL or per 0.5mL peginterferon alfa-2a) available as a solution for injection by Hoffmann-La Roche Limited is a pegylated interferon for treatment of chronic hepatitis C. It is self administered by injection under the skin once a week. About 0.8% of Canadians are infected with hepatitis C which is a chronic disease. Optimal therapy is oral ribavirin with interferon for 48 weeks. Pegasys does not contain ribavirin, but this component is available through Roche's access program for patients on Pegasys. Rebetron and Pegetron are alternatives which contain interferon with ribavirin. Pegetron has been available since December 2002, at a similar price. The cost per patient treated is about \$20,000/year for Pegetron or Pegasys. For the period of January to July of 2003, Pegetron accounted for 90% of the combined ingredient cost of Rebetron and Pegetron in the ESI Canada claims database.

#### *New indications:*

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

**Panto-Byk** [*Pan-toe-bick*] (20 mg pantoprazole) available as an oral enteric coated tablets by Altana Pharma AG has a new indication for prevention of gastrointestinal lesions induced by non-steroidal anti-inflammatory drugs (NSAID) in patients with a need for continuous NSAID treatment. Earlier indications were duodenal and gastric ulcers, and gastroesophageal reflux disease.

**Zithromax** [*Zith-row-macks*] (500 mg azithromycin) available as an oral tablet by Pfizer Canada Inc. has a new strength for 3 day treatment of acute respiratory infections in chronic obstructive pulmonary disease (COPD). Several antibiotics are currently available for this indication. Shorter duration of therapy with some of the newer antibiotics has shown similar efficacy to the older treatments. Zithromax is another option. Its previous indication included treatment of mild to moderate infections caused by certain microorganisms with specific duration defined.

**Avonex** [*Ave-von-necks*] (30 mcg per mL interferon beta-1a) available for injection into a muscle by Biogen Canada, Inc. has a new indication for the treatment of diagnosed multiple sclerosis after a single demyelinating event. The original indication was relapsing-remitting multiple sclerosis. Other products with the original indication include Rebif, Betaseron and Copaxone.

**Relenza** [*Rel-len-zah*] (5 mg per dose zanamivir) available as a powder for inhalation by GlaxoSmithKline Inc. has a new indication for treatment of influenza in children 7 years and older. Its original indication was influenza treatment in patients who have been symptomatic less than 2 days and are 12 years and older.

**Biaxin XL** [*Bye-axe-in*] (500mg clarithromycin) available as an oral extended-release tablet by Abbott Laboratories, Limited has a new indication for the treatment of community-acquired pneumonia. The original indication for Biaxin XL was mild to moderate infections of the respiratory tract with certain bacteria.

#### \* Minimal impact:

1. 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 (i.e., shifting of market share) or,
2. 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.



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## Health Newsflash

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page 3



#### *Reminders:*

1. On September 17, 2003, Cialis (tadalafil) for erectile dysfunction received its Notice of Compliance (NOC); however, the NOC was not available in time for September's DEC. Further information will be forthcoming in the next DEC Newsflash on New Drugs.
2. As per the e-mail message distributed to our customers in early September 2003, the Ontario Drug Benefit (ODB) program has changed its rules for the reimbursement of extemporaneous compounded injectables, effective September 4, 2003. Currently these items are not ODB benefits, but are reimbursed by ODB through the extemporaneous compounded injectable program which allows pharmacies to bill with a PIN (pseudo-DIN) and a compounded code. As a result of this change, the impact on our customers will be minimal. Based on our analysis, this change primarily affects the retiree population.

Author: Jan Demsey, Pharm.D.  
Editor: Steven Semelman, Pharm.D

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