



## Health Newsflash

### New Drugs and Indications Reviewed at the December 2005 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.*

#### Optimizing the Value of Drug and Dental Benefits

##### **New Drugs:**

**Enablex** (7.5mg, 15mg darifenacin) is a sustained release tablet from Novartis Pharmaceuticals Canada. It is used to treat urinary incontinence due to an overactive bladder. The dose is 7.5 or 15 mg once a day. The most common side effects are related to the gastro-intestinal tract, e.g., abdominal pain, constipation, heart burn, etc. There are many drugs currently available with this indication. Many of these drugs are available as inexpensive generics. Detrol is a more expensive brand drug that is also available at about \$2.00 per day. Enablex will likely not be available for some time. Since the price is unknown at this time, there is currently insufficient information to determine the impact to private plans.

**Aptivus** (250mg tipranavir) is available by Boehringer Ingelheim (Canada) as oral capsules for the treatment of Human Immune Deficiency Virus (HIV/AIDS). It is taken twice a day in combination with another class of HIV/AIDS drug, Norvir (ritonavir). Aptivus is another option for HIV/AIDS patients. It does not have any distinct advantages over current therapies in the same class. It is expected that Aptivus will have minimal impact to private plans.

**Emtriva** (200mg emtricitabine) is available from Gilead Sciences, Inc. as oral capsules for treating HIV/AIDS. Emtriva is taken once daily in combination with other HIV drugs. Since this drug is taken once a day, this may help with compliance as HIV patients take numerous medications with varying dosing regimens. Emtriva is another option for patients. It is expected that Emtriva will have minimal impact to private plans.

##### **New Drug Combinations:**

**Caduet** (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg, 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg amlodipine/atorvastatin) is available as oral tablets by Pfizer Canada Inc. for the treatment of heart conditions. It is a combination of Norvasc (amlodipine) and Lipitor (atorvastatin). Norvasc is used to treat high blood pressure as well as angina (pain in the chest due to constriction of blood vessels in the heart); Lipitor is used to treat high cholesterol. Caduet will likely be used in patients who are stabilized on each drug individually.

The cost of Norvasc is \$1.33 and \$1.97 for the 5mg and 10mg strengths, respectively; the cost of Lipitor is \$1.76, \$2.19, \$2.36, \$2.36 for the 10, 20, 40, and 80mg strengths, respectively. The use of Caduet will require only one dispensing fee at the pharmacy instead of two. The price of Caduet is not available, so there is insufficient information to determine the impact to private plans.

##### **New Indications:**

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

**Avelox, Avelox IV** (400mg, 400mg/250mL moxifloxacin) is available as oral tablets and injectable solution by Bayer Inc., and is now indicated for treating community acquired pneumonia (CAP) that is caused by a drug

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resistant bacteria (*Streptococcus pneumoniae*). It is already indicated for treating other respiratory tract infections, including mild to moderate CAP caused by certain bacteria. The dose is 400mg once a day for 7-14 days. A number of different antibiotics are used in the treatment of CAP – Amoxil is used for mild cases and fluoroquinolones (e.g., Cipro and Avelox) are used for more resistant cases. *Streptococcus pneumoniae* accounts for about 32-55% of CAP cases.

**Lantus** (100unit/mL insulin glargine) is available as an injection under the skin by Aventis Pharma Inc., and is now indicated for treatment of pediatric patients with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. It is already indicated for treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus.

#### Optimizing the Value of Drug and Dental Benefits

**Botox Cosmetic** (100unit/vial botulinum toxin type A) is available as an injection into the muscle by Allergan Inc., and is now indicated for treating forehead lines (wrinkles) and crow's feet (wrinkles around the eyes). It was already indicated for wrinkles between the eye brows.

**Remicade** (100mg/vial infliximab) is available as an injection into the vein by Centocor Inc., and has a new indication for the treatment of fistulising Crohn's disease (CD). Remicade is already indicated for the treatment of rheumatoid arthritis (RA) and CD (non-fistulising). The dose for RA is 3mg/kg at 0, 2, and 6 weeks followed by the same dose every 8 weeks, while the dose for CD (non-fistulising) is 5mg/kg at the same dosing intervals (i.e., 0, 2, and 6 weeks and every 8 weeks thereafter). The new indication (fistulising CD) allows for the same maintenance dosing as for CD (non-fistulising) (5mg/kg every 8 weeks). The original indication was only for the 0, 2 and 6 week dosing. The increased dosing schedule may increase costs to plans, however, it is likely that Remicade is already being given according to the new dosing regimen in this patient population. It is anticipated that the new indication could possibly have an intermediate impact to private plans due to the cost of the drug.

**Lipitor** (10mg, 20mg, 40mg, 80mg atorvastatin) is available as oral tablets by Pfizer Canada Inc. It has a new indication for reducing the risk of heart attack and stroke in adult patients with type 2 diabetes and high blood pressure without clinically evident coronary heart disease, but with other risk factors (e.g., age greater or equal to 55 years, poor kidney function, high albumin levels or smoking). A lot of evidence is now available supporting the use of Lipitor for the prevention of cardiac events. Lipitor is likely already being used for this new indication. It already has the indication for treating high cholesterol.

**Nexium** (20mg, 40mg esomeprazole) is available as oral tablets by AstraZeneca Canada Inc., and has a new indication for the treatment and risk reduction of gastric ulcers associated with use of non-steroidal anti-inflammatory drugs (NSAIDs), such as naproxen. Most patients receive treatment with drugs like Nexium (a proton-pump inhibitor) following an ulcer diagnosis. Nexium is another option and is likely already being used in this manner.

#### Impact Statements

##### 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 (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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#### Intermediate Impact

1. New drug has an estimated higher than average cost compared to drugs used for the medical condition or,
2. 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.

Author: Becky Chin, B.Sc.Pharm.

Editor: Ellen Chin, B.Sc.Pharm, M.B.A.

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