



Health Newsflash

New Drugs and Indications Reviewed at the July 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

Aldurazyme [*Al-dur-aa-zime*] (0.58mg/ml of laronidase) is available from Genzyme Canada Inc. as an infusion into the vein. This is the first enzyme replacement therapy indicated in the treatment of mucopolysaccharidosis I (MPS I). MPS I is a genetic disorder where a specific enzyme is missing in the body and it leads to organ damage and eventually to death. MPS I is a rare disease, with an estimate of 1 in 25,000 births in the U.S. Previous therapies were mostly based on supportive care and on treatment of the various complications. Aldurazyme is administered as an infusion into the vein over 3 to 4 hours weekly. Infusion reactions may occur and they are sometimes severe (one case of anaphylactic reaction has been reported), therefore, it has to be administered in a hospital under medical supervision. This drug will have no impact for plan sponsors using ESI Canada Hospital Drug Program.

Forteo [*Fore-tay-oh*] (250µg/ml of teriparatide) is available from Eli Lilly Canada Inc. as an injection. This is the first synthetic parathyroid hormone (hormone involved in bone formation) issued from biotechnology. It is indicated for the treatment of severe osteoporosis in men and women. Forteo is more effective than current therapies, such as Fosamax and estrogen supplements, as it increases bone formation instead of reducing bone loss. The recommended dosage is an injection of 20 µg under the skin daily for up to 18 months. It is estimated that 8% of the population between the ages of 50 to 64 are suffering from severe osteoporosis. However, not all patients suffering from severe osteoporosis are anticipated to use injection therapy. The use of bisphosphonates (e.g. Fosamax, Actonel) is recommended after Forteo is discontinued to maintain bone mass. Forteo is significantly more expensive than current therapies at \$26.50 per day compared to Fosamax and its generics at \$1.10 to \$1.76 per day or estrogen supplements at \$0.11 to \$0.41 per day (as per Ontario pricing). Because of the additional clinical value and the cost difference of this new drug, it is anticipated that Forteo will have an intermediate impact on employer drug plans.

Aerodiol [*Air-oh-dy-ol*] (150µg of estradiol hemihydrate) is available from Servier Canada Inc. as a nasal spray. This is the first estrogen to be administered by a nasal spray. Otherwise, it is similar to conventional forms of hormone replacement therapy (HRT), such as tablets and patches. It is indicated in women for menopausal symptoms (hot flashes, vaginal dryness, etc.) and has similar efficacy. Dosing is 1 to 4 sprays per day. Adverse effects are similar to other forms of estrogen therapy but can also cause irritation at the site of application, sneezing or prickling sensations and it may have less adverse effects on the breast compared to oral estrogens. Aerodiol is not available on the market and, according to the manufacturer, there are no marketing plans in the near future. Pricing information is not available but it is anticipated to be priced similarly to estrogen patches, once marketed.

Infanrix-hexa [*Inn-fan-ricks-hex-aa*] (diphtheria, pertussis, polio, tetanus, haemophilus influenza type B, hepatitis B vaccine) is available from GlaxoSmithKline Inc. as an injection. It is a combination of 5 common childhood vaccines plus hepatitis B vaccine. The combination vaccine for the 5 diseases is available without the hepatitis B component. This will minimize the number of injections required for vaccination in prevention

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of these diseases. It has to be administered by an injection into the muscle. Vaccines are excluded by most employers drug plans therefore, it is anticipated that Infanrix-hexa will have a minimal impact. Plans for provincial funding for Infanrix-hexa are unknown at this time.

Oxytrol [*Ox-ee-trol*] (36 mg of oxybutynin) is available from Watson laboratories Inc. as a transdermal patch. It is a new dosage form for an existing agent for overactive bladder (OB). It is the first transdermal system to treat this condition. The recommended dosage is one patch to be applied twice a week and kept in place for 3 to 4 days, which will deliver 3.9 mg of oxybutynin per day. It has lower rates of dry mouth, somnolence and blurred vision than the oral form, Ditropan, but may cause itching at the application site. OB affects mostly women over 60 years old. The first line therapies in OB are oxybutynin and Detrol. Canadian pricing for Oxytrol is not available at this time but US pricing is significantly higher for Oxytrol than the tablet form Ditropan (\$82 vs. 26\$ per month). It is anticipated that the impact on employer drug plans will be minimal as most of the potential users are retired women.

Teveten Plus [*Tev-ee-ten-plus*] (600mg of eprosartan mesylate and 12.5mg of hydrochlorothiazide) is available from Solvay Pharma Inc. as an oral tablet. This is a new combination of two existing agents for treating high blood pressure in patients who require combination therapy. The recommended initial therapy is one tablet once daily. Teveten Plus is the 6th drug to combine hydrochlorothiazide and an agent from the same class as eprosartan. Similar combination drugs are Atacand Plus, Avalide, Hyzaar, Micardis Plus and Diovan HCT. All are priced similarly, between \$1.02 and \$1.10 per day (Teveten Plus \$1.02; Atacand Plus \$1.08; Avalide \$1.08; Hyzaar DS \$1.10; Micardis Plus \$1.07 and Diovan HCT \$1.05). This is another treatment option, and it is anticipated to have a minimal impact on employer drug plans.

New indications:

Aldara [*Al-dare-a*] (50mg/g of imiquimod) is available from 3M Pharmaceuticals as a topical cream. Aldara has a new indication in the treatment of actinic keratosis (AK) in adults. AK is a skin disorder (scaly, dark, mottled skin lesions) caused by long term chronic sun exposure. It can lead to skin cancer. AK is a common disorder in people over 40-50 years old. Aldara cream is to be applied locally twice a week over the course of 16 weeks. The other treatment options are mostly surgery or topical agents such as Efudex. Aldara has a significant lower rate of side effects and is better tolerated than Efudex. Aldara's previous indication was for treatment of external genital and perianal condylomas. There is a slight cost difference as one treatment with Aldara costs approximately 31.10\$ and it is 23.74 with Effudex. From the clinical study results, the benefits outweigh the additional cost. It is anticipated that this new indication will have a minimal impact on employer drug plans.

Newsworthy highlights:

The Validation committee reviewed the availability, the site of administration and the coverage of Replagal under the private drug plans. Replagal is an enzyme replacement therapy indicated in the treatment of a rare genetic disease, Fabry's disease (prevalence of 1 in 250 000 people in Canada). Replagal was approved in February 2004, and it was initially placed under ESI Canada's Hospital Drug Program because it was seen as a drug that required administration in a hospital. However, additional research indicates that Replagal can easily be given at home. Therefore, it does not fulfill the Hospital Drug Program criteria and it has been removed from this program.

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