



Health Newsflash - a Quarterly Publication

New Drugs and Indications Reviewed at the March to June 2006 DEC Meetings



*The Drug Evaluation Committee (DEC) of ESI Canada conducts monthly reviews of all new drugs receiving their Notices of Compliance from Health Canada, to ascertain their place 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 publication, describing new drugs of significance, is provided to our insurance customers **on a quarterly basis** as a value-added service. We hope that you will find this Health Newsflash informative, timely, and useful.*

Optimizing the Value of Drug and Dental Benefits

New Drugs:

Arestin (1, 4 mg minocycline) is available as a drug administered under the gums from Johnson & Johnson Inc. for treating adult periodontitis (gum infection) along with scaling and root planing procedures. The administration of this drug should be performed by a dentist and will most likely be dispensed by dentists. Price is unknown but this drug will likely have minimal impact on private plans.

Biphentin (10, 15, 20, 30, 40, 50, 60, 80 mg methylphenidate) is available as once daily controlled released capsules from Purdue Pharma. This drug is used to treat children, adolescents and adults with Attention Deficit Hyperactivity Disorder (ADHD). There is currently other methylphenidate containing products that are available to treat ADHD for which daily dosing is ranging from once daily up to three times daily. Pricing for Biphentin is currently unavailable. Since Biphentin is an additional option for methylphenidate containing drug for patients with ADHD, it is expected that its pricing would be in the range of currently marketed drugs, thus the impact to private drug plans should be minimal.

Revatio (20mg sildenafil) is available as oral tablets from Pfizer Canada Inc. Revatio contains the same chemical ingredient as Viagra, however it is indicated for treating pulmonary arterial hypertension (high blood pressure originating in the lungs). The tablet strength is different than Viagra, as Revatio is dosed as 20 mg three times daily versus Viagra at 25 mg to 100 mg (available as 25 mg, 50 mg, and 100 mg tablets) once before sexual activity. Other treatment options for this condition include Flolan, Remodulin, and Tracleer. Flolan and Remodulin are injectable therapies whereas Tracleer is an oral drug. The annual patient costs for current drug therapies are: Flolan- \$75,000; Remodulin- \$95,000; Tracleer- \$45,000. The annual patient cost of Revatio in the U.S. is approximately \$10,000. Current pricing is unknown, but Revatio is expected to be significantly cheaper than these other therapies. Due to the fact that PAH is a rare condition, this new drug is expected to have minimal impact to private drug plans.

Sutent (12.5, 25, 50 mg sunitinib) is available as oral capsules from Pfizer Canada Inc. Sutent is indicated for treating patients with gastrointestinal stromal tumors (GIST) that do not respond or are intolerant to imatinib (Gleevec). Sutent is dosed 50 mg once daily in 4 week cycles, with 2 weeks off treatment in between. There is an estimated 500 new cases of GIST per year in Canada. Patients with GIST that cannot tolerate imatinib or have imatinib-resistant tumors have limited treatment options. The price of Sutent is \$65.45 to \$261.79 per tablet. The annual patient cost is about \$64,000 compared to Gleevec at \$40,000-\$60,000. It is expected that Sutent will have minimal impact to private plans due to the number of patients who will actually use it as well as the fact that the annual cost is in the range of Gleevec.

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Testim 1% Gel (1% testosterone) is available as a topical gel by Auxilium Pharmaceuticals, Inc. and is indicated for the treatment of patients with hypogonadism (low testosterone levels). Another topical testosterone gel, AndroGel, is already available in Canada. AndroGel is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Testim is another option. AndroGel costs: \$3.76-10.66/day (depending on dose and dosage form used). The Canadian price for Testim is currently unknown. However, in the U.S., Testim and AndroGel have similar costs at the initial dose (50 mg testosterone per day) at \$5.45 USD and \$5.90 USD respectively.

Vantas (50 mg histrelin) is available from Paladin Labs Inc. for palliative treatment of advanced prostate cancer. This medicine is a 12 month implant that is surgically placed under the skin of the upper arm. This once-yearly implant is an alternative to other drugs for the same indication (Zoladex, Lupron, Suprefact, Eligard, Trelstar) which are administered via injection every one to six months. Vantas has been placed on ESI Canada's Hospital Drug Program (HDP); therefore it will have no impact on private plans using the HDP.

Voluven (6% hydroxyethyl starch / 0.9% sodium chloride) is available as an injection into the vein from Fresenius Kabi Deutschland GmbH for treating blood volume loss or expanding plasma volume. Voluven's administration requires constant medical surveillance and would be typically used in a hospital setting for acute hemorrhagic shock, trauma, sepsis, etc. Voluven has been placed on ESI Canada's HDP; therefore it will have no impact on private plans using the HDP.

First-Time Generics:

In this publication, we will highlight the first generics for drugs which belong to highly utilized drug classes in ESI Canada's book of business. Drug classes considered highly utilized are the ones which rank in the top 50 drug classes by ingredient costs for the previous year.

Generic Norvasc (2.5, 5,10 mg amlodipine) is now available as oral tablets from GenMed (a division of Pfizer Canada) for the treatment of hypertension and chronic stable angina. The cost for first available generics is usually about 30% less than the Brand. Norvasc costs \$1.33 to \$1.98 per tablet and the cost of the generic was not available at the time this newsletter was published. Norvasc is usually taken once daily. Norvasc belongs to the drug class, Calcium Channel Blockers (CCBs). The CCBs incurred 3.4% of ESI Canada's drug expenditure between May 2005 and May 2006. Norvasc, with the highest utilization of the drug class, made up 55% of market-share in the class. The availability of a generic will help save plans money.

New Indications:

Cerezyme (200 units/vial, 400 units/vial) is available as an injection into the vein from Genzyme Canada Inc. Cerezyme is currently indicated for Type 1 Gaucher's disease. Cerezyme has now been approved for the treatment of Type 3 Gaucher's disease. Gaucher's disease is an inherited condition found in fewer than 1 in 100,000 people in which the Type 1 is the most common. Although Cerezyme costs about \$175,000 per patient per year, it is currently placed on ESI Canada's HDP; therefore, it will have no impact on private plans using the HDP.

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Remicade (infliximab) is available as an injection into the vein from Schering Canada Inc. Remicade is currently indicated for the treatment of rheumatoid arthritis, Crohn's disease, and ankylosing spondylitis. Remicade has now been approved for the treatment of patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. This is the first biologic approved for this indication. Ulcerative colitis is a disease characterized by a chronic inflammation of the gastrointestinal tract that may affect up to 39,000 Canadians, of which 33% have moderate to severe disease. The approximate treatment cost per patient is about \$32,000. Because this drug may already be used for this indication, it should have minimal impact to private drug plans.

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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