



Health Newsflash - a Quarterly Publication

New Drugs and Pipeline Drugs Reviewed at the July to September 2007 DEC Meeting



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, the 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.

New Drugs

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Elapraxe™ (2 mg/mL idursulfase injection; Shire Human Genetic Therapies Inc.) is the first enzyme replacement therapy for the treatment of Hunter syndrome (Mucopolysaccharidosis II, MPS II). Hunter syndrome is a rare genetic disease (affecting approximately 30 to 40 males in Canada) that is caused by the absence or insufficient levels of an enzyme called lysosomal enzyme iduronate-2-sulfatase. Without this enzyme, cellular waste products accumulate in tissues and organs, causing them to malfunction. Elapraxe is the only treatment option that may slow the progression of the disease; all other treatment options are symptomatic and supportive. Elapraxe is given by intravenous infusion at a dose of 0.5 mg/kg weekly. Serious and life-threatening allergic reactions have been observed with Elapraxe; therefore, it should be administered under the supervision of a physician or other experienced health care provider. The yearly cost per patient is approximately \$525 000. Because this drug should be administered in a hospital setting, it is not expected to have an impact on the private sector. Funding decisions by federal and provincial governments are expected in December 2007.

Eloxatin® (50 & 100 mg/vial, 5mg/mL oxaliplatin injection; sanofi-aventis Canada Inc.) is indicated for use in combination with 5-fluorouracil (5-FU) and leucovorin for the treatment of metastatic colorectal cancer. For both previously treated and untreated patients, the recommended dose of Eloxatin is 85 mg/m² infused over 2 hours on Day 1, every 2 weeks. Pricing for Eloxatin is currently not available but it is not anticipated to have an impact on the private sector because it is intravenous cancer chemotherapy and should be administered under supervision of a health care provider.

Thelin™ (100 mg sitaxsentan sodium oral tablet; Encysive Pharmaceuticals Inc.) is the first oral endothelin-A (ETA) receptor antagonist indicated for the treatment of primary pulmonary arterial hypertension (PAH) or PAH due to connective tissue disease in patients with WHO functional class III who have not responded to conventional therapy. Thelin is also indicated in patients with WHO functional class II who do not respond to conventional therapy and for whom no appropriate alternative can be identified. PAH is a condition that involves high blood pressure and structural changes in the walls of the pulmonary (lung) arteries and capillaries, resulting in shortness of breath, limited activity, and decreased life expectancy. In Canada, there are approximately 480 to 640 persons living with the disease. The recommended dosage of Thelin is 100 mg once daily. The drug will be used as an alternative oral agent to Tracleer® (bosentan, a non-selective endothelin antagonist) and to Revatio® (sildenafil, a phosphodiesterase-5 inhibitor). Current Thelin pricing (\$126.00 per 100 mg tablet or approximately \$50 000 per year of therapy) is on par with Tracleer and should have a minimal impact.

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Lucentis™ (10 mg/mL ranibizumab injection; Novartis Pharmaceuticals) is a new vascular endothelial growth factor A (VEGF-A) inhibitor indicated for the treatment of wet age-related macular degeneration (wet-AMD). Wet-AMD is a degenerative disorder of the central area of the retina (image forming region of eye). The disease is characterized by the growth of abnormal blood vessels, allowing blood and fluid to leak into and around the retina, eventually leading to loss of vision. Lucentis is given as an intravitreal injection (eye injection) at a dose of 0.5 mg. Treatment is initiated with a loading phase of 1 injection/month for 3 consecutive months; dosing can then be every 1 or 3 months. The frequency of dosing during the maintenance phase is dependent on the extent of disease progression. Approximately 280 000 Canadians over the age of 50 have wet-AMD. Current treatment options for wet-AMD include photo-dynamic therapy with Visudyne™ (verteporfin), and anti-VEGF therapy with Macugen™ (pegaptanib sodium). Recent clinical trials suggest Lucentis is the first drug to improve vision in patients with wet-AMD. Lucentis clinical trials show better outcomes compared to Macugen clinical trials, although there are no direct comparative studies. Depending on the dosing regimen, the yearly cost per patient for Lucentis ranges from \$9450 to \$18 900 compared to \$9450 for Macugen. The impact on private drug plans will depend on how Lucentis is used in clinical practice although its cost could be higher than Macugen.

Emend™ (80 & 125 mg aprepitant oral capsules) and **Emend™-Tri-Pack** (1x80 mg plus 2x125 mg aprepitant oral capsules; Merck Frosst Canada Ltd.) is the first drug of its class - a P neurokinin 1 (NK₁) receptor antagonist. It is used to prevent nausea and vomiting in patients receiving chemotherapy and is usually given with other anti-nausea drugs such as corticosteroids and Zofran® (ondansetron, a 5-HT₃ receptor antagonist). For patients receiving highly emetogenic (high-risk for nausea and vomiting) chemotherapy, Emend is given on Days 1 to 3 of chemotherapy. Triple therapy consisting of Emend, dexamethasone and Zofran was found to be better than dexamethasone + Zofran for these patients. Because Emend offers an advantage to patients and is the first in a new class of drugs, it is expected that it may be more costly than existing agents. However, price is unknown at this time; therefore, the impact on private plans remains unknown at this point.

New Strengths

Cialis® (2.5 & 5 mg tadalafil oral tablets; Lilly ICOS LLC) is now available in 2 new strengths for the treatment of erectile dysfunction. Currently, the 10 mg and 20 mg strengths of Cialis are dosed on an "as needed" basis and taken prior to anticipated sexual activity. With the new lower strengths, continuous, once-daily dosing of Cialis may be a new dosing strategy. The pricing for these new strengths is not currently available.

New Brand

Seasonale® (0.15 mg levonorgestrel/0.03 mg ethinyl estradiol oral tablets; Duramed Pharmaceuticals, a subsidiary of Barr) is a new brand of oral contraceptive. It is the first extended-cycle oral contraceptive available on the market. One active tablet is taken for 84 consecutive days, followed by 7 days on which a placebo tablet (no hormones) is taken. The patient then begins the next cycle without interruption. The price of Seasonale is expected to be roughly equal to a 3-month supply of other oral contraceptives and is, therefore, expected to have a minimal impact.

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New Indication

Humira[®] (40 mg/0.8 mL adalimumab injection; Abbott Laboratories Ltd.) received a new indication for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. Humira is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Remicade[®] (infliximab), also a biological response modifier and would thus be considered the treatment of last resort. Humira is also indicated for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. The recommended dose for the treatment of Crohn's disease is 160 mg on Day 1, 80 mg on Day 15, then a maintenance dose of 40 mg administered every other week by subcutaneous (under the skin) injection. The yearly cost per patient for the maintenance dose is approximately \$18 000. This new indication is expected to have a minimal impact on private plans.

Sativex[®] (27 mg/mL delta-9-tetrahydrocannabinol (THC)/ 25 mg/mL cannabidiol buccal spray; Bayer Inc.) has a new indication (conditional Notice of Compliance (NOC)) as adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain. Sativex was first available in April 2005 with a conditional NOC for the treatment of neuropathic pain in patients with multiple sclerosis. The daily cost is approximately \$13 to \$21 for 5 to 8 sprays. Sativex provides an alternative for patients. The buccal spray (to be directed below the tongue or towards the inside of the cheeks) and ease of administration may be advantages for patients with difficulties in swallowing. The new indication is expected to have a minimal impact.

New Schedule

Apo[®]-Famotidine (20 mg famotidine oral tablet; Apotex Inc.) and **Apo[®]-Ranitidine** (150 mg ranitidine oral tablet; Apotex Inc.) are both histamine₂ receptor antagonists and are indicated to treat conditions where a controlled reduction of gastric secretion is required. Only the new DINs for the Apotex brand of famotidine 20 mg and ranitidine 150 mg tablets are classified as over the counter products (i.e. do not require prescription). Currently, famotidine 10 mg is non-prescription requiring while 20 and 40mg are prescription requiring. Similarly, ranitidine 75 mg is non-prescription requiring while 150 and 300 mg are prescription requiring. The impact of this scheduling change is expected to be minimal.

Pipeline News

This section highlights newsworthy drugs that are expected to come to market in the near future and that are anticipated to be highly utilized, or priced at a premium in Canada.

Ontario Government Launches HPV Immunization Program

The Ontario Government recently announced the launch of the Gardasil[®] vaccination program intended to reach as many as 84 000 young women in Grade 8 across Ontario starting this fall. Gardasil is a vaccine that immunizes against Human Papilloma Virus (HPV), the leading cause of cervical cancer. Cervical cancer is the second most common cancer for women aged 20 to 44, after breast cancer. Every year in Ontario, about 500 women are diagnosed with cervical cancer and 140 die from the disease. Gardasil is given in 3 doses

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over 6 months. This vaccination program will be administered by public health officials in schools and is voluntary. The federal government, which announced \$300 million for a national vaccine program earlier this year, will fund the \$39 million/year program the first 3 years. In June, Nova Scotia announced its vaccination program for Grade 7 girls and PEI has said it plans to vaccinate Grade 6 girls.

<http://www.thestar.com/News/Ontario/article/242383>; Office of the Premier news release on August 2, 2007)

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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

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

Policies and Legislation (PAL) Update:

1. Amendments to the Ontario *Drug and Pharmacy Regulation Act* (Bill 171)

On June 4, 2007, the Government of Ontario granted Royal assent to the amendments introduced by Bill 171, the *Health Systems Improvement Act, 2007*, which, in particular, amends the *Drug and Pharmacy Regulation Act*.

One of the amendments allows pharmacists in the Province of Ontario to dispense a drug pursuant to a prescription issued by a person licensed to practice in a province or territory of Canada other than Ontario if, in the professional judgment of the pharmacist, the patient requires the drug. The amendments also allow pharmacists to dispense renewals.

Before the amendments, pharmacists could only dispense a drug pursuant to a written order signed by a physician or dentist licensed to practice in a province or territory of Canada other than Ontario, if in the professional judgment of the pharmacist the patient required the drug immediately. Moreover, the prescription could not be renewed.

Below are the old and new versions of section 158 of the *Drug and Pharmacy Regulation Act*.





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Before the amendments:

Prescription by doctor out of Ontario

158. A pharmacist may dispense a drug pursuant to a written order signed by a physician or dentist licensed to practice in a province in Canada other than Ontario, if in the professional judgment of the pharmacist the patient requires the drug immediately, but such order shall not be refilled.

After the amendments:

Prescription by doctor out of Ontario

158. A pharmacist may dispense a drug pursuant to a prescription authorized by a prescriber licensed to practice in a province or territory of Canada other than Ontario if, in the professional judgment of the pharmacist, the patient requires the drug.

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ESI Canada recently made changes to its audit procedures to reflect this new reality in Ontario.

2. GST applicable on professional fees in the near future?

The Canadian Association of Chain Drug Stores has been advised by the Canada Revenue Agency that the Department of Finance is currently studying the applicability of the GST on professional fees for dispensing of prescription drugs. An interpretation of the Excise Tax Act is expected from the federal government within the next few weeks. We will keep you informed of the developments.

Quick Notes:

Traditional Chinese Medicine in Ontario

Specific sections of the Traditional Chinese Medicine Act of 2006 are now law in Ontario. As such, a College of Traditional Chinese Medicine Practitioners and Acupuncturists will be established in Ontario. Since Traditional Chinese Medicine therapies includes namely acupuncture, therefore, its performance will now be restricted to: (i) members of the new College, (ii) members of certain other regulated health professions, and (iii) if acupuncture is performed as part of an addiction treatment program and the person performs the acupuncture within a health facility.

For more info on the subject:

http://www.health.gov.on.ca/english/public/legislation/bill_50/hu_tcm.html

http://www.health.gov.on.ca/french/public/legislationf/bill_50f/hu_tcmf.html

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