



## Health Newsflash - a Quarterly Publication

New Drugs and Pipeline News Reviewed at the July to September 2009 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, 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.

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### New Drugs

The following new drugs are expected to have minimal impact to private payer plans unless otherwise specified.

Abilify™ (Aripiprazole 2, 5, 10, 15, 20, 30mg; Oral Tablet) is a second generation antipsychotic made by Bristol-Myers Squibb Canada™. In July 2009, it was approved for treatment of schizophrenia and related psychotic disorders as well as the treatment of manic or mixed episodes in Bipolar disorder. For treatment of patients with Bipolar disorder, Abilify™ is used for acute treatment of manic or mixed episodes, and can be used alone as monotherapy or in conjunction with other medications such as lithium or divalproex. Other second generation antipsychotics that would be therapeutic alternatives to Abilify™ include Zyprexa™ (olanzapine), Seroquel™ (quetiapine) Risperidal™ (risperidone), Zeldox™ (ziprasidone). Abilify™ is associated with lower rates of adverse effects than the older first generation antipsychotics (ex: haloperidol and perphenazine); and studies show that it is as efficacious as other second generation anti-psychotics.

The recommended starting dosage is between 10 to 15mg orally once daily; maintenance dosing is based on a patient's clinical response and ranges between 10 to 30mg/day. The maximum dose of Abilify™ should not exceed 30mg/day. The cost of Abilify™ is not yet available, but it is expected to be priced in line with other second generation antipsychotics. Without current pricing available, it is difficult to anticipate the impact of Abilify™ on private payers.

Drug Name	Manufacturer	Route of Administration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Abilify™	Bristol-Myers Squibb Canada	Oral Tablet	Schizophrenia and Bipolar Disorder	Quetiapine (Seroquel) Olanzapine (Zyprexa) Risperidone (Risperidal) Ziprasidone (Zeldox)	Not Available (expected to be in line with alternatives)	Insufficient information	Pending further information

Cimzia™ (Certolizumab pegol 200mg/mL Subcutaneous) is a new biologic response modifier made by UCB Canada Incorporated. It is a recombinant, human antibody that acts as a Tumor Necrosis Factor Alpha inhibitor (TNF-α inhibitor). Cimzia™ received approval from Health Canada in August 2009 and is indicated to be used either alone or in combination with methotrexate to reduce the signs and symptoms of moderately to severely active Rheumatoid Arthritis (RA) in adult patients. Cimzia™ is to be administered just under the skin subcutaneously, starting with two 200mg injections at Week 0, 2, 4, after which maintenance dose is 200mg every other week. An alternative maintenance dosing schedule is 400mg every 4 weeks.

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All prices listed are Ontario prices, unless otherwise indicated.  
All ESI Canada Book of Business (BOB) data cited is for all of Canada, excluding Québec.



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According to trials provided by the manufacturer, some patients report symptom improvement within 1 to 2 weeks of initiating therapy, and significant improvements after 4 weeks of treatment. Maximum response rate was achieved after 12 weeks of therapy. Other TNF $\alpha$  inhibitors available on the Canadian market include Enbrel™ (etanercept), Humira™ (adalimumab), Remicade™ (infliximab) and Simponi™ (Golimumab). All four of these medications are also approved to treat RA. Currently, there is no head-to-head clinical trial available to determine the comparative efficacy and safety between Cimzia™ and any of the anti-TNF $\alpha$  agents. Cimzia™ requires less frequent dosing than Enbrel™ and Humira™ and is expected to have enhanced penetration into the joints thereby reducing inflammation at the site, rather than an overall systemic reduction in inflammation. Cimzia™ costs \$664.51 for each pre-filled syringe containing 1mL (=200mg), and is priced closely to similar medications within the anti-TNF $\alpha$  class. Cimzia™ has received a FDA (US) Box warning for increased risk of lymphoma and other cancers associated with the use of these drugs in children and adolescents. This box warning has been applied to all drugs in this class including Remicade™, Enbrel™, Humira™, and Simponi™. The annual cost of a patient on Cimzia™ would range between \$17,000 and \$25,000. Due to the high annual cost of this medication, Cimzia™ is expected to have intermediate impact to private payers. However, strategies such as Prior Authorization can be used to ensure the drug is reimbursed for the appropriate patient for the appropriate indication only.

Drug Name	Manufacturer	Route of Administration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Cimzia™	UCB Canada Incorporated	Subcutaneous Injection	Rheumatoid Arthritis	Etanercept (Enbrel) Adalimumab (Humira) Infliximab (Remicade) Golimumab (Simponi)	\$1329.02 for 2 pre-filled syringes for a 28-day supply	Intermediate	Prior Authorization

Multaq™ (Dronedaron 400mg Oral Tablet) is a new Class III anti-arrhythmic and the first new anti-arrhythmic to be produced in almost 20 years. In August 2009, Multaq™ received approval for the treatment of patients with atrial fibrillation. Arrhythmias are irregular heart rhythms that can be caused by a variety of different problems. Atrial fibrillation is the most common form of arrhythmia and is a potentially life-threatening condition. Patients with atrial fibrillation are at an increased risk for strokes or heart attacks. The risk of mortality is increased by two-fold, and the risk of stroke is increased by up to five-fold. It is estimated in Canada there are 43,000 hospitalizations each year due to atrial fibrillation. In a large study it was found that when compared to placebo, Multaq™ 400mg given twice daily would reduce the risk of hospitalization or death from cardiovascular causes related to atrial fibrillation by up to 24% and greatly reduced hospitalization of patients with atrial fibrillation.

Other drug treatments for atrial fibrillation include beta blockers (ex: metoprolol, atenolol), digoxin, calcium channel blockers (verapamil, diltiazem) and antiarrhythmics (ex: sotalol, amiodarone, and flecainide and propafenone). Preliminary data from a recently completed clinical trial seems to indicate that Multaq™ may not be as effective as amiodarone another Class III anti-arrhythmic. The major advantage of Multaq™ is its favorable safety profile when compared to amiodarone, which is notorious for its toxicities involving the thyroid, lungs, and other organ systems. The most common adverse effects of Multaq™ are diarrhea, nausea, abdominal pain, vomiting, and weakness. The cost of Multaq™ is not yet available and without current pricing it is difficult to anticipate the impact of Multaq™ on private payers.





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Multaq™	Sanofi Aventis Canada Inc.	Tablet	Atrial Fibrillation	Metoprolol, Atenolol, Digoxin, Verapamil, Diltiazem, Sotalol, Amiodarone, Flecainide Propafenone	Not Available	Insufficient	Pending further information

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### First Time Generic Drugs

**Apo-Lansoprazole™** (Lansoprazole 15, 30mg delayed release oral capsule) is a proton pump inhibitor (PPI) and the first time generic of the brand, Prevacid™. Apo-Lansoprazole™ is produced by Apotex™ and became available to the market in June 2009. Apo-Lansoprazole™ is indicated in the treatment of conditions where a reduction of gastric acid secretion is required such as: duodenal ulcers, gastric ulcers, reflux esophagitis including patients with Barrett's esophagus, healing/prevention of NSAID-associated gastric ulcers, symptomatic gastroesophageal reflux disease (GERD), and pathological hypersecretory conditions including Zollinger-Ellison Syndrome. Depending on the indication and the severity of the disease, the dosage can range from 15mg to 60mg orally once daily.

There are many different Proton Pump Inhibitors (PPIs) available on the Canadian market, including Nexium™ (esomeprazole), Losec™ (omeprazole), Pantoloc™ and Tecta (pantoprazole), Pariet™ (rabeprazole), and Prevacid™ (lansoprazole). Currently, Nexium™ is the only agent for which the patent has not yet expired and a generic product is not yet available. Either strength of Apo-Lansoprazole™ costs \$1.50/cap, which is approximately 71% of the price of the brand Prevacid™ (\$2.11/cap). Given all PPIs are of similar efficacy, when comparing the price of generic lansoprazole to other genericized PPIs (e.g. generic omeprazole 20mg \$1.10/tab, generic rabeprazole 20mg \$0.91/tab), generic lansoprazole may not be as cost-effective as other available options. Generic lansoprazole is expected to have a minimum impact to private payers.

Drug Name	Manufacturer	Route of Administration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Apo - Lansoprazole™	Apotex Inc.	Oral Capsule	For the reduction of gastric acid and its relative gastrointestinal diseases	Rabeprazole (Pariet) Omeprazole (Losec) Esomeprazole (Nexium) Pantoprazole (Pantaloc, Tecta)	\$1.50/capsule for both strengths	Minimal	Tiered formulary





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**Amlodipine** (Amlodipine Besylate 5,10mg oral tablet) – the first time generic of the calcium channel blocker, Norvasc™ became available to the market in July 2009. Amlodipine is indicated for hypertension and chronic stable angina. For both indications the dosage ranges between 5 to 10mg orally once daily. There are other calcium channel blockers available as brands and generics, including diltiazem, verapamil, nifedipine and felodipine.

Norvasc™ is highly prescribed in Canada and has been in the top 10 drugs prescribed in 2007 and 2008. There are already many generic companies manufacturing generic amlodipine and the generics are priced at ~50% of the brand, therefore, the estimated cost savings is significant. In the period from July 2008 to June 2009, the total cost of all Norvasc™ claims was approximately ~\$35 million. If only half of the patients were switched from brand name Norvasc™ to a generic, there would be a savings of ~\$ 8.75 Million. Generic amlodipine is already considered to be interchangeable with Norvasc™ in Ontario. Due to the high utilization of Norvasc™ and because the generics are priced at ~50% of the brand, generic amlodipine will lead to a high cost savings and have a high impact to private payers

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Drug Name	Manufacturer	Route of Administration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Generic Amlodipine	Many generic companies e.g. Ratiopharm, Novopharm .	Oral Tablet	Hypertension and stable angina	Diltiazem (Tiazac), Verapamil, Nifedipine (Adalat XL) Felodipine (Plendil and Renedil)	5mg : \$0.73/tablet 10mg: \$0.99/tablet	High	Tiered Formulary

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