



Health Newsflash - a Quarterly Publication

New Drugs and Pipeline Drugs Reviewed at the October to December 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.

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New Drugs

Celsentri[†] (150 mg and 300 mg maraviroc) is a new oral tablet from Pfizer Canada. Celsentri is the first in a new class of antiretroviral agents—the CCR5 antagonists—to be approved in Canada. In combination with other agents, this drug is an option for treatment-experienced adult patients who are infected with CCR5-tropic HIV-1 and have evidence of resistance to multiple antiretroviral agents. Because it has various interactions with other medications, including antiretroviral agents, Celsentri's dose must be carefully adjusted and it can range from 150 mg to 600 mg taken twice daily, depending on what other medications the patient is taking. Celsentri is only effective at treating patients with CCR5-tropic HIV-1 and efficacy against other types of the virus has not been demonstrated; as such, a laboratory test called a *tropism assay* should be performed prior to treatment initiation to determine if Celsentri will be useful for a patient. Depending on the dose, the cost of Celsentri ranges from \$34.82/day to \$69.63/day. On average, this is more expensive than other antiretroviral agents. However, Celsentri is expected to have minimal impact because of the relatively specific group of patients for which it is indicated.

Cymbalta[†] (30 mg and 60 mg duloxetine) is a new medication from Eli Lilly Canada Inc. It is indicated for the symptomatic relief of major depressive disorder (MDD) and the management of nerve pain associated with diabetic peripheral neuropathy (DPN). Like Effexor[†], Cymbalta is a serotonin/norepinephrine reuptake inhibitor (SNRI). These agents are claimed to be at least as effective as tricyclic antidepressants but with lower toxicity, and with greater efficacy than selective serotonin reuptake inhibitors (SSRIs). For MDD, the recommended starting and target dose is 60 mg once daily; a lower starting dose of 30 mg may be considered for tolerability reasons. For DPN, the recommended starting and target dose is 60 mg once daily, with a possible dosing range of 30-120 mg/day. SNRIs are useful alternatives for patients with MDD who have responded poorly to or have experienced severe side effects with other agents (e.g. tricyclics or SSRIs). At present, Cymbalta is not recommended over Effexor—the only other currently available SNRI in Canada—for these patients. For the 1-year period Nov 2006 to Oct. 2007, the total ingredient cost for Effexor was approximately \$24 million, which ranked eighth in ESI Canada's book of business (BOB).

Invega[§] (3 mg, 6 mg, and 9 mg paliperidone) is a new antipsychotic oral tablet available from Janssen-Ortho Inc. It belongs to the class of agents known as the atypical antipsychotic drugs indicated for the treatment of both the negative (e.g. emotional flatness and withdrawal) and positive (e.g. hallucinations) symptoms of schizophrenia. Other atypical antipsychotic agents currently on the market include Risperdal^{**} (risperidone), Zyprexa^{††} (olanzapine), Seroquel^{‡‡} (quetiapine), and Clozaril^{§§} (clozapine). Invega is the major active metabolite of Risperdal, and its side effect profile is similar to that of the other drugs in the same class. The recommended starting and target dose of Invega is 6 mg once daily, with no dose titration required. However, a lower dose of 3 mg/day may be sufficient for some patients. The maximum daily dose is 12 mg. Invega is another option for patients suffering from schizophrenia.

* TM Celsentri is a trademark of Pfizer Products Inc. / Pfizer Canada Inc., licensee

† TM Cymbalta is a registered trademark of Eli Lilly and Company

‡ [®] Effexor is a registered trademark of Wyeth Canada

§ TM Invega is a registered trademark of Johnson & Johnson

** TM Risperdal is a registered trademark of Johnson & Johnson

†† TM Zyprexa is a registered trademark of Eli Lilly and Company

‡‡ TM Seroquel is a registered trademark of AstraZeneca UK Limited

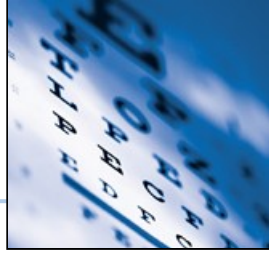
§§ TM Clozaril is a registered trademark of Novartis AG

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The total daily cost of Invega ranges from \$3.38 to \$10.12. This is comparable to the prices of the other atypical antipsychotic medications (ranging from \$2.42 to \$14.51 per day). However, it is considerably more expensive than generic risperidone (\$2.42-\$3.62 per day). Due to the lack of comparative efficacy data with other atypical antipsychotic agents and the significant cost difference between Invega and generic risperidone, the place of therapy of paliperidone in the treatment of schizophrenia is unclear.

Rasilez[™] (150 mg and 300 mg aliskiren) is a new oral tablet from Novartis Pharmaceuticals Canada Inc. It belongs to a class of antihypertensive agents called renin inhibitors. This is the first new therapy class for treating high blood pressure (BP) in about 10 years, and it has a different mechanism of action from other BP-lowering agents currently available on the market. Rasilez may be used as monotherapy or in combination with thiazide diuretics (e.g. hydrochlorothiazide), ACE inhibitors (e.g. Altace^{†††}), or dihydropyridine calcium channel blockers (e.g. Norvasc^{‡‡‡}). However, it will likely be reserved as add-on therapy to other agents, particularly for patients who do not have optimal blood pressure control with their current medications. The recommended starting dose of Rasilez is 150 mg once daily, and this can be increased to 300 mg daily in patients who require further BP control. The daily cost is \$1.20, as both Rasilez strengths have the same cost. Rasilez is priced comparably to other BP-lowering agents and is expected to have minimal impact on drug plans; however, it will be closely monitored once it reaches the Canadian market to determine its overall utilization and impact.

Zeldox^{\$\$\$} (20 mg, 40 mg, 60 mg, and 80 mg ziprasidone) is a new antipsychotic oral capsule from Pfizer Canada. Zeldox is similar to Invega (see above) in that it also belongs to the class of atypical antipsychotics. The usual starting dose for Zeldox is 40 mg taken twice daily with food; the maximum dose is 80 mg twice daily. Zeldox does not appear to offer any efficacy advantages over other atypical antipsychotics. Therefore, Zeldox likely will be used as another alternative for patients with schizophrenia, and the overall impact of the drug is expected to be minimal.

New Indications

The following drugs have had new indications for use approved. Impact is considered to be minimal unless otherwise noted.

Aclasta^{**}** (5 mg/100 mL zoledronic acid) is an intravenous drug from Novartis Pharmaceuticals Inc. which belongs to the class of drugs called the bisphosphonates, used to regulate bone metabolism. It is newly indicated for the treatment osteoporosis in postmenopausal women to reduce the incidence of hip, vertebral, and non-vertebral fractures. This is in addition to Aclasta's original indication for the treatment of Paget's disease of the bone in both men and women. Aclasta contains the same active ingredient that is found in Zometa^{††††} which has several indications in oncology. Osteoporosis is a disease that exacts a large economic burden with \$1.9 billion spent each year for its treatment and associated fractures. The yearly ingredient cost of Aclasta is \$645, which is higher than that of other bisphosphonates. Still, the impact on drug plans will depend on the acceptability of an IV infusion by patients and the availability of resources and facilities to administer the drug. For the 1-year period Nov 2006 to Oct. 2007, the total ingredient cost for bisphosphonates was ~\$12 million in ESI Canada's BOB.

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*** [™] Rasilez is a registered trademark of Novartis AG

††† [®] Altace is a registered trademark of Sanofi-Aventis Deutschland GmbH

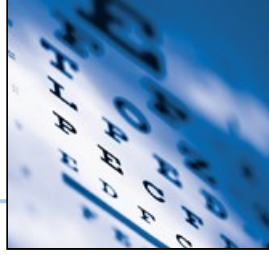
‡‡‡ [™] Norvasc is a trademark of Pfizer Products Inc. / Pfizer Canada Inc., licensee

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**** [™] Aclasta is a registered trademark of Novartis AG

†††† [™] Zometa is a registered trademark of Novartis AG





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Policies and Legislation (PAL) Update:

Newfoundland and Labrador – Enhanced Prescription Drug Program

On October 31st 2007, the Newfoundland and Labrador government implemented a new component to their provincial prescription drug program, the *Assurance Plan*. This new plan offers protection for individuals and families against the financial burden of eligible high drug costs (it may be from the cost of one extremely high cost drug or the combined cost of different drugs). Depending on their income level, individuals and families will be assured that their annual out-of-pocket for eligible drug costs will be capped at a percentage of their net family income, as outlined below.

Net annual income	Maximum percent of the net income paid for eligible drugs
\$0 - \$39,999	5%
\$40,000 up to \$74,999	7.5%
\$75,000 up \$149,999	10%

If the individuals and/or families have private insurance, they may still be eligible for the Newfoundland and Labrador Prescription Drug Program (NLPDP) but as was already the case with the three other components of the NLPDP, they are required to bill their private insurance first. .

Source: <http://www.health.gov.nl.ca/health/nlpdp/newoverview.htm> (Accessed on Dec. 17, 2007)

Newfoundland and Labrador – New regulation governing the maximum prices for drug products listed on the Newfoundland and Labrador Interchangeable Drug Products Formulary (NIDPF)

On December 21st 2007, Regulation 125/07, the *Interchangeability Drug Formulary Regulations, 2007* was published in the Newfoundland and Labrador Gazette. Regulation 125/07 namely specifies that the maximum price listed for a drug in the NIDPF shall not exceed the price listed for the same drug in the Ontario public drug program formulary, plus an inventory adjustment fee set by the Minister. In the event the guaranteed price submitted by a manufacturer exceeds the best available price policy, the minister may refuse to list the drug in the NIDPF, or remove the drug from the NIDPF.

The effective dates

- a) For the new categories additions to the NIDPF, as approved by the Minister of Health and Community Services in November 2007, the mandatory charging of the lowest price **came into effect on January 15, 2008.**
- b) As for products that are non-compliant with the *Pharmaceutical Services Act* and its *Regulations*, they may be delisted from the NIDPF. Affected products will be marked for deletion and cease to be legally interchangeable **on February 1, 2008** (and therefore also removed from the benefit list of the Newfoundland and Labrador Prescription Drug Program (NLPDP)).
- c) As for existing categories, due to significant price changes, the new pricing will not come into effect until **April 1, 2008**, although it was initially scheduled to come into effect February 1, 2008.

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All modification to the ESI Canada pricing databases will be completed by ESI Canada at the appropriate date. No action is required by customers.

Sources :

<http://www.health.gov.nl.ca/health/nlpdp/bulletin.htm> (Accessed on Jan. 02, 2008)

<http://www.gs.gov.nl.ca/gsoq/gazette/misc/wk/2007-12-21.pdf> (Accessed on Jan. 02, 2008)

Newfoundland and Labrador Prescription Drug Program, Bulletin No. 3, January 30, 2008

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Nova Scotia – New Family Pharmacare Program

Effective March 1, 2008, the province of Nova Scotia has established a Family Pharmacare Program to assist all permanent residents who hold a valid Nova Scotia health card. This program provides drug coverage for individuals or families who do not have access to drug coverage or are experiencing high drug costs which are not covered by their private insurance.

Eligible residents must enrol in the program, in which there are no yearly premiums, and for which the program's copayment and deductible have yearly maximums that are set depending on a family's size and annual income.

The Nova Scotia Family Pharmacare Program is the payer of last resort and therefore, the private insurance will be required to be the first to pay any claim with any portion unpaid for by the private insurance sent to Family Pharmacare for coverage. In a bulletin recently sent by CLHIA*****, the Nova Scotia government identified the following situations where an individual with private insurance may be able to make a claim through the Family Pharmacare program:

1. drug costs are extremely high and as a result co-payments to private insurance exceed the family deductible; and/or
2. drug costs greatly exceed a maximum allowable annual claim to private insurance; and/or
3. drug costs not covered by private insurance due to excluded benefits at the time of enrolment.

A citizen is not eligible to the Nova Scotia Family Pharmacare Program if he is receiving drug coverage through:

1. the Nova Scotia Seniors' Pharmacare Program
2. the Nova Scotia Diabetes Assistance Program
3. under 65-Long Term Care Pharmacare Plan
4. any Department of Community Services Pharmacare Benefits

Action required: In order to ensure ESI Canada system compliance with this change, each carrier requires a COB Rule definition for the province of Nova Scotia. This will avoid the rejection of eligible claims for Nova Scotia residents that are age 65 or older. Carriers that do not currently have a COB Rule definition for Nova Scotia are recommended to select a value of either "1" or "C" for this province, whichever better resembles their reimbursement policy on Coordination of Benefits (i.e. do they apply plan details or not).

Source: http://www.gov.ns.ca/health/pharmacare/info_ns/family_pharmacare/family_pharmacare.asp (Accessed on Dec. 17, 2007)



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Nova Scotia – Dental Hygienist granted expanded powers

On December 11, 2007, Bill 24, *An Act Respecting Dental Hygienists*, was passed on third reading in the Nova Scotia legislature and received the Royal Assent two days later. The Bill namely authorizes dental hygienists in Nova Scotia to practice independent of dentists and perform teeth scaling and root planning, including curetting of surrounding tissue, if they have completed additional training and, if none of the contra-indications prescribed in the regulations to performing the procedure are present.

An Act Respecting Dental Hygienists will come into force on a date to be fixed by proclamation.

Source:

http://www.gov.ns.ca/legislature/legc/bills/60th_2nd/1st_read/b024.htm (Accessed on Dec. 17, 2007)

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Nunavut – Proposed act to give Midwives prescribing authority

Bill 20, the *Midwifery Profession Act*, has gone through the second reading in the Nunavut legislature on November 6, 2007. The purpose of the Bill is to set out the scope of practice of registered midwives and establish eligibility requirements for registration. Provisions are also in place for the professional development, investigation and discipline of registrants. In addition, the Bill amends section 2 of the *Pharmacy Act* to provide that nothing in that Act shall be deemed to prohibit or prevent a registered midwife from supplying a patient with such medicines as the patient may require.

This Bill provides for the regulation of the midwifery profession. This Bill sets out the scope of practice of registered midwives and the eligibility requirements for registration. Midwives are also granted the right to prescribe and administer drugs and substances authorized in the regulations and order, prescribe and fit medical equipment and devices authorized in the regulations.

A Midwifery Registration Committee is established to decide on applications for registration and renewal of registration, advise the Minister on matters of midwifery policy and legislation and promote continuing competence and professional development of registered midwives. The Committee may also recommend standards of practice and standards of competence, and may appoint practice auditors to conduct reviews of the practice of registered midwives.

This Bill establishes the Board of Inquiry and sets out the procedure to be followed when a notification is given or issued that an act or omission of a registered midwife may constitute unprofessional conduct.

The *Midwifery Profession Act*, 62. or any provision of the Act comes into force on a day or days to be fixed by order of the Commissioner.

Source :

http://www.assembly.nu.ca/english/bills/4th_bill20.pdf (Accessed on Dec. 17, 2007)

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Ontario – Dental Hygienist practice in Ontario

In spring 2007 the *Dental Hygienist Act* 1991 was amended to allow Ontario's dental hygienists to self initiate and perform, subject to the terms, conditions and limitations imposed on his or her certificate of registration, the scaling teeth and root planning including curetting surrounding tissue, as well as orthodontic and restorative procedures.

Section 5 of the *Dental Hygienist Act* 1991 adds that a hygienist may perform such procedures on his own initiative, if none of the contraindications prescribed in the regulations to performing the procedure are present, and if the hygienist ceases the procedure if any of the prescribed contraindications to continuing the procedure are present (or if the procedure is ordered by a member of the Royal College of Dental Surgeons of Ontario). Such contraindications have been established in the regulations and namely include (i.e. cardiac condition, an unstable medical or oral health condition, active chemotherapy or radiation therapy, any blood disorders, a medical or oral health condition with which the Dental Hygienist is unfamiliar or that could affect the appropriateness, efficacy or safety of the procedure, etc.).

Source:

http://www.e-laws.gov.on.ca/html/regis/english/elaws_regs_940218_e.htm (Accessed on Dec. 17th 2007)

Ontario - Reporting of professional allowances

Ontario's Ministry of Health and Long-term Care has released the reporting framework for professional allowances under *The Transparent Drug System for Patients Act, 2006*. As such, Ontario pharmacies will be required to provide the Executive Officer with the:

- *amount of all professional allowances received by the pharmacy/pharmacist from manufacturers. This includes allowances paid for drugs purchased for public and private prescriptions; and*
- *total amount of all professional allowance monies expended by pharmacy. This includes monies expended for private and public services. This amount must be reported at the individual store level e.g., independent pharmacies, or at the head office/chain level; and*
- *certification by two senior officers of the company or the manufacturer's auditors that :*
 - a. *the professional allowance monies were not expended on any of the prohibited uses as described in the Code of Conduct under the heading 'Use of Professional Allowances'; and*
 - b. *the professional allowance monies were expended for the purposes of direct patient care*

The first report had to be submitted no later than November 20, 2007 (for the period of July 1 to September 30, 2007). The second report must be submitted no later than February 29, 2008 (for the period of October 1 to December 31, 2007). Thereafter, reports must be submitted within two months after the last day of the reporting period. Pharmaceutical manufacturers will be required to submit information detailing the amount of professional allowances that are provided to each pharmacy or head office.

Source:

http://www.health.gov.on.ca/english/public/legislation/drugs/reporting_framework.html (Accessed on Dec. 17, 2007)

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Quebec - Wholesaler's Profit Margin

In our November 9, 2007, communication regarding the legislative changes following the Quebec Drug Policy, we indicated that the Quebec government had proposed a modification to the maximum profit margin governing the wholesalers of medications in Quebec, bringing it from 9% to 6%.

On January 16, 2008, the *Regulation modifying the Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications* was published in Part 2 of the Gazette Officielle du Québec and, in accordance with its section 3, shall come into force on January 31, 2008, the fifteenth day following its publication.

Saskatchewan - Midwives granted prescribing authority

Saskatchewan adopted *The Drug Schedules Amendment Regulations, 2007*, which entitles midwives to certain prescribing powers. As such, a midwife who is entitled to practice midwifery, pursuant to *The Midwifery Act*, may prescribe any drugs listed in Schedule I, II or III that is intended for the purpose of providing midwifery care. These prescribing rights are subject to *The Midwifery Act*, *The Midwifery Regulations*, the bylaws of the Saskatchewan College of Midwives, the terms and conditions of the Midwife's license and the *Controlled Drugs and Substance Act* of Canada.

This regulation comes into force on the day on which section 23 of the *The Midwifery Act* comes into force. At such date, audit procedures will be modified accordingly.

Sources:

The Drug Schedules Amendment Regulations, 2007 (page 539):

<http://www.qp.gov.sk.ca/documents/gazette/part2/2007/G2200738.pdf> (Accessed on Dec. 17, 2007)

The Drug Schedule Regulations, 1997:

<http://www.qp.gov.sk.ca/documents/English/Regulations/Regulations/P9-1R2.pdf> (Accessed on Dec.17, 2007)

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