



Health Newsflash - a Quarterly Publication

New Drugs and Pipeline News Reviewed at the April to June 2008 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.

New Drugs

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

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Relistor™ (20 mg/mL methylnaltrexone bromide) is a new mu-opioid receptor antagonist for subcutaneous (under the skin) injection available from Wyeth Canada. It is indicated for the treatment of opioid-induced constipation in patients with advanced illness, and who are receiving palliative care. Relistor should be used as an adjunct therapy to induce a prompt bowel movement, when response to laxatives has been insufficient. This is the first medication to be officially approved for this indication. The recommended dose (usually either 8 mg or 12 mg) is based on the patient's weight and is given as a subcutaneous injection every other day, as needed to relieve constipation.

Opioid medications work on receptors in the brain and spinal cord. Relistor does not cross into the brain or spinal cord; therefore, it does not interfere with the pain relieving effects of opioid medications. Relistor costs approximately \$280* per package. However, as this drug is indicated for palliative patients only after laxative use has failed, the impact on private payers is expected to be minimal.

Retisert® (0.59 mg fluocinolone acetonide) is a new device from Bausch & Lomb Inc. that is implanted into the back of the eye, providing consistent long-term delivery of fluocinolone acetonide, a corticosteroid. It is indicated for the treatment of chronic, non-infectious posterior uveitis (inflammation of the back portion of the eye). The drug is released at an initial rate of 0.6 mcg/day for the first month, decreasing to a steady release of 0.3-0.4 mcg/day; the implant is designed to last for 30 months. Unlike topical corticosteroids, Retisert is designed to deliver medication directly to where it is needed to control inflammation, and systemic absorption is negligible.

Uveitis is a rare medical condition affecting vision, but it is the third leading cause of preventable blindness in the developed world. Based on the year 2000 census, over 12 thousand Canadians are estimated to have the disorder. About four thousand new cases are diagnosed each year. Topical steroids are first-line agents in the treatment of uveitis. Other agents can be added depending on response, and these include non-steroidal anti-inflammatory drugs, immunomodulators, and biologic response modifiers (for very stubborn and aggressive inflammation). Retisert provides a more convenient alternative to the multiple daily administrations of topical corticosteroids required for uveitis. Pricing is currently not available; therefore, the impact on private plans remains unknown at this point and it will depend on how Retisert is used in clinical practice.

Vectibix® (100 mg/5 mL, 200 mg/10 mL, and 400 mg/20 mL panitumumab) is a new biological drug available from Amgen Inc. It is the first fully human recombinant monoclonal antibody that binds specifically to the human epidermal growth factor receptor (EGFR), which is expressed on a variety of tumor cells. Vectibix is indicated as a single agent for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. Only patients with tumors without gene mutations (as determined by a lab test) will benefit from therapy. The recommended dose

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Issue 4

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* All prices listed are Ontario prices.



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of Vectibix is 6mg/kg administered over 60 minutes as an IV infusion every 14 days. There are serious skin toxicities and severe infusion reactions associated with Vectibix.

Pricing is not currently available. Because of its adverse effect profile and the lack of clinical experience associated with it, Vectibix is most appropriately administered in a hospital setting. As such, it has been added to ESI Canada's Hospital Drug Program.

Volibris® (5 & 10 mg ambrisentan) is a new oral tablet from GlaxoSmithKline Inc. It is an endothelin-A (ETA) receptor antagonist indicated for the treatment of pulmonary arterial hypertension (PAH) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening. These patients have heart disease which causes slight limitation (class II) or marked limitation (class III) in physical activity; less than ordinary or ordinary activity may lead to fatigue, palpitation, shortness of breath, or chest pain. Volibris is to be started at 5 mg once daily and the dose may be increased to 10 mg once daily if the starting dose is tolerated.

Treatment with Volibris has been associated with dose-dependent liver injury and liver function tests should be measured prior to initiation and during treatment with Volibris. Also, Volibris is contraindicated in pregnant women because it may cause fetal harm. Because of the risks of liver injury and birth defects, the distribution of Volibris will be severely restricted. The drug will be used as an alternative to Thelin™, Tracleer® and Revatio®. Pricing is currently not available; however, due to the restricted distribution of Volibris, the impact on private plans should be minimal.

New Schedule

Plan B® (0.75 mg levonorgestrel) is an emergency contraceptive that is used for the prevention of pregnancy when taken within 72 hours following unprotected intercourse. The National Drug Scheduling Advisory Committee (NDSAC) has recommended levonorgestrel – when sold in concentrations of 1.5 mg per oral dosage unit, packaged and labeled for emergency contraception, in package sizes containing no more than 1.5 mg of levonorgestrel – to be listed as Schedule III, from Schedule II. If this specific labeling is not in place, levonorgestrel will continue to be under Schedule II. This means that Plan B can now be sold in the self-selection area of the pharmacy, and does not require pharmacist contact or intervention. Plans that currently cover Schedule II (behind the counter) medications will no longer cover Plan B if the manufacturer decides to only market the Schedule III package. The impact of this schedule change is expected to be minimal.

Authors: Mayce Al-Sukhni, RPh, BScPhm, Pharmacy Resident, ESI Canada;
Diana Mak, RPh, BScPhm, Clinical Specialist, ESI Canada

Editor: Becky Chin, BScPhm, Clinical Specialist, ESI Canada

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Policies and Legislation (PAL) Committee Update – 2nd Quarter 2008

Ontario – Proposed amendment to Ontario Regulation 201/96 under the *Ontario Drug Benefit Act*

Under the proposed amendment, the Executive Officer would no longer be required to pay a dispensing fee for the dispensing of a drug to an eligible person in a quantity that is sufficient for less than a 30-day course of treatment, **unless**:

- (a) the eligible person is a resident of a long-term care home; or
- (b) the prescriber has indicated on the prescription that a lower quantity is to be dispensed.

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It is our understanding that if a prescriber has directed that an ongoing prescription be dispensed more frequently than once monthly, the Executive Officer will pay such dispensing fee.

The 30-day consultation period during which the public could submit written comments on the proposed regulations ended on May 30, 2008.

The Impact: There could be an increase in coordination of benefit claims for fees not covered by ODB in situations where an eligible person has private insurance and is dispensed a drug in a quantity that is sufficient for less than a 30-day course of treatment and such a treatment was not indicated on the prescription by the prescriber or the eligible person is a resident of a long-term care home.

Source:

http://www.health.gov.on.ca/english/public/legislation/drugs/notice_proposed_reg_935_20080430.pdf

Quebec – Medication price indexation

On April 21, 2008, the annual price indexation of medications was published and 749 DINs saw their price increase between 1.21% and 1.82%, with an overall average increase of 1.3% in regards to the expenditure for these DINs in 2007. Based on the entire expenditure of medication for ESI Canada in 2007, the indexation represents a total increase of 0.62%.

On June 2, 2008, a second round of price modifications took place which makes new medications available, modifies the reimbursement conditions of certain medications, applies the lowest price method to certain medications, as well as a price indexation, in accordance with the Quebec Drug policy. In regards to the price modifications, from the close to 200 changes, only 45 of them are for medications included on the ESI Canada top 100 list. The modifications on these 45 DINs represent an overall average increase of 5.4% in comparison to the expenditure for such DINs in 2007. Based on the entire expenditure of medication for ESI Canada in 2007, the indexation equates a total increase of 0.3%.

The Impact: The impact of such an increase of the ingredient cost on private payers is unfortunately not directly measurable in Quebec as pharmacies are reimbursed under the U&C model. However, we can presume that it will be transferred to the U&C price reimbursed by private payers.

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Quebec – Generic prices at 60% and 54%

In regards to the 60% and 54% limits on generic prices in Quebec, the Conseil du médicament is presently examining all of the generic products registered in the List of Medications. The results will be given to the minister with the October update of the list.

We must keep in mind that Quebec has already benefited from an important reduction in generic ingredient cost as in February 2008, as 1253 of the 8900 DINs on the RAMQ price list saw their cost decrease by approximately 21% to 28%. This price decrease was due to the application of the 50% pricing rule on generic drugs included on the ODB price list as per Quebec's lowest price method.

The Impact: Private payers should experience a cost reduction; however, as it was the case with the February price decrease, we can presume that not all of the savings will be passed along to the customers via the U&C price charged by pharmacists.

Source:

<http://www.cdm.gouv.qc.ca/site/download.php?f=0404591f1d4cf4a9559d707e99a9b983>

Quebec – Maximum Price Payable

Among the means set forth to establish a fair and reasonable price for the products included on the *List of Medications*, the *Politique du médicament* (Drug Policy) allows the Minister to establish a maximum price payable (MPP). The MPP is meant to be an exception intended to limit the financial responsibility of the Public Prescription Drug Insurance Plan.

Since the price difference between the guaranteed selling price (GSP) submitted by the manufacturer and the MPP will be assumed by the insured person, it will not enter into the calculation of their maximum monthly contribution. By Order-in-Council (328-2008) dated April 9, 2008, it was ordered that section 10 of the *Act to amend the Act respecting prescription drug insurance and other legislative provisions* (2005, c.40) come into force on April 21, 2008. This section stipulates that:

If an eligible person with a prescription chooses a medication that costs more than the maximum amount covered by the basic plan or if a prescribed medication costs more than that maximum amount, the difference between that maximum amount and the price paid is to be borne by the person, is not included in the contribution to be paid by the person, and does not count toward the person's maximum contribution.

It should be noted that there will be exceptions for insured persons who have a limited ability to pay and that private prescription drug insurance plans may not benefit from the MPP.

In its communiqué issued on May 14, 2008, the Conseil du médicament had already specified that the MPP would first be applied on the *List of Medications* published on June 2, 2008 and that it would affect 37 products (24 already included on the list for which the price increase exceeded the maximum rate applicable for 2008 and 13 new generic products).

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Sources:

May 14, 2008 communiqué from the Conseil du Médicament

<http://www.cdm.gouv.qc.ca/site/download.php?f=0404591f1d4cf4a9559d707e99a9b983>

Loi modifiant la Loi sur l'assurance médicaments et d'autres dispositions législatives (2005, c.40)

<http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2005C40F.PDF>

An Act to amend the Act respecting prescription drug insurance and other legislative provisions (2005, c.40)

<http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2005C40A.PDF>

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Quebec – Midwives granted prescribing authority

On April 9, 2008, two Draft Regulations made under the Midwifery Act were published in the *Gazette officielle du Québec*.

The first one, the *Règlement sur les médicaments qu'une sage-femme peut prescrire ou administrer dans l'exercice de sa profession* addresses a list of medications that a Midwife can prescribe or administer and determines the conditions under which she can do so. Exhibit I of the Regulation contains the 51 substances intended for a mother and Exhibit II contains the 13 intended for a child.

The second one, the *Règlement sur les examens et analyses qu'une sage-femme peut prescrire, effectuer ou interpréter dans l'exercice de sa profession* addresses a list of exams and analyses a midwife can prescribe, do or interpret and determines the conditions under which she can do so.

In accordance with the general regulation adoption procedure in Quebec, interested parties have 45 days from publication to forward their comments to the Minister. Upon expiry of this delay, the government can publish both Regulations, which, in accordance with their respective section 2, shall come into force on the fifteenth day following its publication in the *Gazette officielle du Québec*.

Sources: *Gazette officielle du Québec*, April 9, 2008, 140th year, no. 15.

New Brunswick – Pharmacist granted prescribing authority

Bill 60, *An Act to Amend the Pharmacy Act* passed the First Reading on May 20, 2008. The Bill amends the *Pharmacy Act* in order to allow legally qualified pharmacists to prescribe drugs and treatments that are designated in the regulations. The circumstances under which a licensed pharmacist may do so will be regulated by the New Brunswick Pharmaceutical Society, as per section 4 of the *Pharmacy Act*.

An Act to Amend the Pharmacy Act is scheduled to come into force on October 30, 2008.

Sources:

<http://www1.gnb.ca/legis/bill/print-e.asp?legi=56&num=2&page=4>

<http://www.gnb.ca/legis/bill/FILE/56/2/Bill-60-e.htm>

<http://www.gnb.ca/legis/bill/pdf/56/2/Bill-60.pdf>

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Prince Edward Island- Pharmacist granted prescribing authority

Bill 10, *An Act to Amend the Pharmacy Act* received Royal Assent on May 22, 2008. The Bill amends the *Pharmacy Act* in order to allow licensed pharmacists the right to give prescriptions as per the conditions and restrictions established by the Prince Edward Island Pharmacy Board. The amendments also specify that a certified clerk and registered student may not prescribe drugs. This Act comes into force on a date that may be fixed by proclamation of the Lieutenant Governor in Council.

Sources:

<http://www.assembly.pe.ca/bills/onebill.php?session=2&generalassembly=63&number=10>

http://www.assembly.pe.ca/bills/pdf_first/63/2/bill-10.pdf

Manitoba – Optometrists granted prescribing authority

Bill 11, the *Optometry Amendment Act* received Royal Assent on June 12, 2008. The Bill amends the *Optometry Act* in order to allow eligible optometrists to prescribe or administer drugs designated in the regulations, remove superficial foreign bodies from the human eye or its adnexa and order and receive reports of screening and diagnostic tests designated in the regulations. In order to prescribe or administer a drug, an optometrist will be required to hold an optometric drug licence issued under the Act and the prescribed drug must be designated in the regulations. The Act will come into force on a day to be fixed by proclamation.

Sources:

<http://web2.gov.mb.ca/bills/sess/b011e.php> (English)

<http://web2.gov.mb.ca/bills/sess/pdf/b011.pdf> (français)

<http://www.gov.mb.ca/legislature/bills/billstatus.pdf>

Prince Edward Island- Optometrist granted prescribing authority

Bill 30, *An Act to Amend the Optometry Act* received Royal Assent on May 22, 2008. The Bill amends the *Optometry Act* in order to allow licensed optometrists that hold an authorization from the Minister under the *Pharmacy Act* the right to prescribe and administer any authorized drug (other than the ones administered topically for examination, investigation or diagnosis of disease, injury, or other abnormal conditions of the visual system). Section 4 of the Bill provides for the establishment and operation of a Therapeutic Drug Prescription Committee that will compile and provide a list of therapeutic drugs that licensed optometrists may be qualified to prescribe. This Act comes into force on a date that may be fixed by proclamation of the Lieutenant Governor in Council.

Sources:

<http://www.assembly.pe.ca/bills/onebill.php?session=2&generalassembly=63&number=30>

http://www.assembly.pe.ca/bills/pdf_first/63/2/bill-30.pdf

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Manitoba – Dental Hygienist Act proclaimed into force

On April 15, 2008, the *Dental Hygienist Act* (whole Act except section 71) was proclaimed into force in Manitoba. From now on, only a person who is registered as a dental hygienist under the Act can represent, expressly or implicitly, that he is a dental hygienist or is entitled to engage in the practice of dental hygiene as a dental hygienist; or use any sign, display, title or advertisement implying that he or she is a dental hygienist.

The Dental hygienists who meet the qualifications set out by legislation and regulations will now be able to provide services without a dentist's supervision in the community including personal-care homes, community programs or other settings approved by a patient's dentist.

Under the Act, The College of Dental Hygienists of Manitoba is established as a body corporate and must carry out its activities and govern its members in a manner that serves and protects the public interest. As of April 15, 2008, 558 dental hygienists had registered with the college.

Sources:

<http://news.gov.mb.ca/news/index.html?archive=2008-04-01&item=3519>
<http://web2.gov.mb.ca/laws/statutes/2005/c05105ei.php>
<http://web2.gov.mb.ca/laws/statutes/2005/c05105f.php>

Federal – Medical expense tax credit (METC)

In our last communication, we had indicated that the Federal Government announced in its budget that it would modify the *Income Tax Act* in order to exclude medications, preparations and other items available without a prescription from the Canada medical-expense tax credit. We had then suggested that carriers make no amendments or modifications to their drug plans at that time while we continue to monitor the issue.

This would still describe our understanding of the situation even though Bill C-50, the *Budget Implementation Act, 2008* received Royal Assent on June 18, 2008. The Explanatory notes published by the Department of Finance and describing the amendments, clause by clause lead us to believe no changes will be required to drug plans but there are still no final guarantees on the position that Canada Revenue Agency will adopt.

ESI Canada will continue to monitor this issue and will communicate updates with any new developments.

Sources:

<http://www.parl.gc.ca/legisinfo/index.asp?Language=E&Chamber=N&StartList=A&EndList=Z&Session=15&Type=0&Scope=l&query=5413&List=stat>
http://www.fin.gc.ca/drlreg/BIAApr08_1e.html#P1Amendments
<http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=3598008&file=4>

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