



Health Newsflash - a Quarterly Publication

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

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New Drugs

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

Catena[®] (150 mg idebenone) is the first approved drug worldwide for the treatment of Friedreich's Ataxia, and it is available from Santhera Pharmaceuticals. The drug is believed to increase the supply of energy to cells in the body. In addition, its antioxidant properties may protect cells which are damaged by the disease. In clinical studies, Catena showed clinically relevant improvements in activities of daily living scores as well as cardiac and neurological functions. The dose for Catena is 450 to 1350 mg/day for patients weighing 45 kg or under and 900 to 2250 mg/day for those over 45 kg.

Friedreich's Ataxia is a rare but severe genetic neuromuscular disorder that results in the degeneration of an individual's nerve and muscle tissue. Consequently, patients experience loss of muscle control, uncoordinated movements, muscle wasting, and thickening of heart walls, which frequently leads to a shortened life span. Average life expectancy is in the range of 35 to 50 years for patients with this disease. Friedreich's Ataxia affects approximately 300 to 600 patients in Canada.

The anticipated launch date for Catena is the end of October 2008. Each 150 mg Catena tablet costs \$19.15*. The annual cost per patient can range from about \$21,000 to \$105,000, depending on the dose and the patient's weight.

Pradax[™] (75 mg and 110 mg dabigatran) is a new oral anticoagulant available from Boehringer Ingelheim Canada Ltd. It acts by directly inhibiting thrombin, a key protein involved in clotting. Pradax is indicated for the prevention of venous thromboembolism (VTE) in adult patients who have undergone elective total hip or total knee replacement surgery. The recommended dose is 220 mg once daily. A lower dose of 150 mg once daily is recommended for certain populations (e.g. the elderly). Other drugs used for this indication include warfarin, unfractionated heparin, and low-molecular weight heparins (eg Lovenox). Warfarin, an oral drug, requires close and frequent monitoring to test the level of blood clotting in patients; the heparins are administered by injection under the skin. Several trials have demonstrated that Pradax is non-inferior to Lovenox, and with a similar safety profile.

Volume 10
Issue 5

Sept. 30,
2008

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** All ESI Canada Book of Business (BOB) data cited is for all of Canada, excluding Québec.



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Pradox is priced at \$4.40 per capsule (British Columbia pricing). The cost for a course of treatment for total knee or total hip surgeries is in the range of \$88 to \$308. A course of treatment for Lovenox can range from \$87 to \$433, depending on indication. For now, Pradox is expected to have minimal impact. However, ESI Canada will continue to monitor developments in this area, including pipeline medications with similar indications, and updates to clinical practice guidelines in the field of orthopaedic surgery and VTE prophylaxis and treatment.

Zeftera™ (500 mg/vial ceftobiprole medocartil for injection) is a new cephalosporin antibiotic available from Janssen-Ortho Inc. It is indicated for the treatment of complicated skin and skin structure infections, including non-limb threatening diabetic foot infections without concurrent osteomyelitis (bone infection), caused by certain bacteria. The recommended dose is 500 mg every 8 or 12 hours, for a total of 7 to 14 days. Zeftera is to be reconstituted and then further diluted prior to administration by intravenous infusion over a period of one or two hours.

Since patients with complicated skin and skin structure infections often require hospitalization, it is expected that Zeftera will mainly be used in a hospital setting. Thus, it is expected that Zeftera will have minimal impact to private payers.

Zostavax™ (varicella zoster virus vaccine) is a new vaccine available from Merck Frosst Canada Ltd. It is approved for the prevention of shingles (herpes zoster) in individuals 60 years of age and older. It is a powdered form of the Oka/Merck strain of live varicella-zoster virus that is attenuated, meaning it has been modified so that it can no longer cause disease. The vaccine uses essentially the same ingredients as VARIVAX®, a chickenpox vaccine by Merck, but has higher potency in order to induce a significant immune response to varicella-zoster virus in older adults.

Shingles is a reactivation of the virus that causes chickenpox; shingles starts with a painful skin rash and can lead to weeks, months or even years of severe, debilitating nerve pain. It is estimated that nearly one in three people will develop shingles in their lifetime, and up to one in two people who reach age 85 will develop the condition.

Zostavax is the first vaccine that is approved for the prevention of shingles. The manufacturer indicated that Zostavax should be available in 2009 from Canadian physicians and pharmacists. Although pricing information is unavailable, given the indication is for those 60 years of age or older, it is estimated that there will be minimal impact to private payers.

New Generics

Ratio-quetiapine (25 mg, 100 mg, 200 mg, and 300 mg quetiapine) is the first time generic for Seroquel® and it is available from ratiopharm. It is indicated for schizophrenia and bipolar disorder. Since ratiopharm received a Notice of Compliance for generic quetiapine in June 2008, eight other generic manufacturers have also received approval for quetiapine.

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Quetiapine dosing is usually initiated at 25-50 mg twice daily, and this is then titrated upward over the course of approximately one week. The usual maintenance dose is 300-600 mg/day given twice daily for schizophrenia and up to 800 mg/day for bipolar disorder.

In 2007, the total ingredient cost for Seroquel tablets was approximately \$11 million (about 0.5% of the ESI Canada BOB)**. Assuming a generic price equivalent to 63% of the brand price, and a 50% switch rate, the estimated annual savings would be approximately \$2 million.

Authors: Mayce Al-Sukhni, RPh, BScPhm, Pharmacy Resident, ESI Canada

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

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Policies and Legislation (PAL) Committee Update — 3rd Quarter 2008

Ontario - Condition for Payment of Dispensing Fees under the Ontario Drug Benefit (ODB) Program

Effective August 1, 2008, there is a new condition for the payment of dispensing fees under the Ontario Drug Benefit (ODB) program. As a general rule, the dispenser should supply at one time, to an eligible person, the lesser of (a) the maximum quantity of a listed drug product for which ODB is required to pay under subsections (1) to (6) of section 18 of Regulation 201/96; or (b) the entire quantity of the listed drug product specified in the prescription to be dispensed at one time.

The dispenser can determine that the quantity supplied should be less than the one required if in his professional opinion, (i) the eligible person is incapable of managing his or her medication as a result of physical, cognitive or sensory impairment, and (ii) if the eligible person (or the person presenting the prescription) agrees that the quantity supplied should be less than the said amount required. In such a case, the dispenser must make a written record of the reasons for his professional opinion and obtain in writing the agreement of the eligible person (or of the person presenting the prescription). In these instances, ODB will not pay more than two dispensing fees for the supply of a listed drug product in a calendar month even if the prescription specifies intervals such that the listed drug product is to be dispensed in more than two intervals in the calendar month.

Therefore, for subsequent claims submitted in excess of the monthly dispensing fee limit, dispensers would only receive payment for the drug benefit price plus any applicable mark-up.

This amendment should not impact private drug plans as long as the dispenser cannot charge the eligible person the dispensing fee in excess of the monthly fee limit of two. Based on the information to date, it does not appear that the dispenser can pass on these additional charges to the eligible member however; ESI Canada will continue to investigate in order to confirm this interpretation of the change.

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Sources:

Ontario Regulation 264/08, Ontario Gazette, August 16, 2008, Volume 141-33

<http://www.gov.on.ca/GOPSP/en/graphics/251427.pdf>

http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/dispensing_fees_faq.pdf

http://www.health.gov.on.ca/english/providers/program/drugs/odbf/odbf_conditions_for_payment.html

Ontario - Competitive agreements

In order to achieve better value and best use of resources for drug spend, the Ontario Government has introduced the Competitive agreements framework. Competitive agreements will be issued for a small number of high volume off-patent drugs for which multiple generic alternatives exist. Two drugs will be selected and awarded two year contracts under the ODB program. Due to Quebec's lowest cost rule, the actual price in the ODB Formulary will be published at the 50% price rate and the volume discounts obtained by the Government will not be disclosed and will be reinvested in the Ontario Public drug Program.

Once the Competitive agreements are in place, the selected drugs will then be the only ones covered and reimbursed under the ODB program. As for the other drugs that used to be covered, their status will be switched to "not a benefit" on the Formulary but they will still retain their interchangeability status.

The four drug products (molecules) that will be part of the first wave are:

- Enalapril Maleate (2.5mg TAB, 5mg TAB, 10mg TAB and 20mg TAB) to treat high blood pressure
- Metformin (500mg TAB) to treat high blood sugar in patients with type 2 diabetes
- Gabapentin (100mg CAP, 300mg CAP, 400mg CAP) to treat seizures associated with epilepsy

Competitive agreements should not impact private drug plans as long as dispensers are obligated to dispense one of the selected drugs to the ODB eligible recipients and cannot switch to one of the other drugs that are now listed as a "not a benefit" on the Formulary.

Sources:

http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/exec_office_20080716.pdf

http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/stakeholder_briefing.pdf

Quebec - Privately Funded Treatments Provided in a Specialized Medical Centre

Effective January 5, 2009, the Quebec Minister of Health and Social Services has determined that, in addition to surgeries that may be provided in a specialized medical centre, specialized medical treatments such as liposuction; lipoinjection, interruption of pregnancy, breast surgeries, cosmetic surgery, abdominal lipectomy, rhytidectomy (facelift), orthopedic surgeries, upper respiratory tract surgeries, vascular and lymphatic surgeries, digestive system surgery, gynecological surgeries, nervous system surgeries, eye and ear surgeries, transsexual surgeries; cutaneous surgeries; and breast biopsies may also be provided in a specialized medical centres in Quebec.

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This legislative amendment could have an impact on private carriers as preoperative and postoperative services often include drug therapy treatments. Historically, these procedures and the associated drugs were administered only in a hospital setting, and thus covered by the provincial government. Following this new regulation, private carriers could be faced with claims from members for these drugs as the drugs administered in these specialized medical centres would not be covered by the provincial government,. Depending on the wording of the applicable insurance contract, some carriers could be compelled to cover these drugs.

Source:

http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/S_4_2/S4_2R7_2_A.HTM

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New Brunswick – Midwives prescribing powers

New Brunswick adopted *Midwifery Act*, which entitles midwives to certain prescribing powers. As such, a midwife who is entitled to practice midwifery, pursuant to *The Midwifery Act*, may prescribe and administer drugs in accordance with the regulations. The Act or any provision of such Act comes into force on the day or days to be fixed by proclamation.

Source:

<http://www.gnb.ca/0062/acts/BBA-2008/Chap-M-11-5.pdf>

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