



Health Newsflash - a Quarterly Publication

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

Optimizing the Value of Health Benefits

New Drugs

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

Tasigna™ (200 mg nilotinib hydrochloride monohydrate), by Novartis Pharmaceuticals Inc., is a new oral cancer drug that has received a conditional approval from Health Canada for the treatment of accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in adult patients resistant to, or intolerant of at least one prior therapy including imatinib (Gleevec™).

Chronic myeloid leukemia (CML) is a blood-bone marrow related cancer in which white blood cells do not mature and become too numerous. It is estimated that about 550 people in Canada have this specific type of cancer. Currently, the first line agent for the treatment of Ph+ CML is Gleevec™, also an oral medication. However, should resistance or intolerance leading to discontinuation develop, second line treatment options include dasatinib (Sprycel™) and now Tasigna™. At this moment, the only treatment that offers a possible cure is stem cell transplantation.

Tasigna™ should be dosed at 400 mg, twice daily, on an empty stomach. Currently, Tasigna™ is only available as a 200 mg capsule priced at \$45.63. The cost of one year's treatment is estimated to be \$66,600 per patient. This cost is comparable to Gleevec (\$42,000-82,000/year) and Sprycel (\$55,000-100,000/year). Tasigna™ may have a modest impact on drug costs; however, because the patient population is expected to be small, the overall impact should be minimal.

Xarelto™ (10 mg rivaroxaban) is a new oral anticoagulant (blood thinner) marketed by Bayer Inc. It is approved for the prevention of venous thromboembolic events (VTE) (blood clots) in patients who have undergone elective total hip replacement or total knee replacement surgery. The recommended starting dose for the prevention of VTE is 10 mg once daily. The duration of treatment depends on the type of surgery: 35 days post elective total hip replacement and 14 days post elective total knee replacement.

There were approximately 69,000 hospitalizations for hip and knee replacements in Canada between 2005 and 2006 and most of these patients would have received some kind of blood clot prevention post surgery. The majority (63%) were 65 years of age or older. Other agents utilized for this indication include warfarin, unfractionated heparin and low-molecular weight heparins (LMWH). Warfarin is given orally but requires frequent monitoring of the level of blood clotting in patients. Unfractionated heparin is only provided to patients in hospital. LMWH, such as enoxaparin (Lovenox™) or dalteparin (Fragmin™), requires daily injections under the skin. The only other recently approved oral anticoagulant not requiring strict monitoring is dabigatran (Pradax™).

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Xarelto™ 10 mg is priced at \$9.92 per tablet. The cost for a course of treatment for total knee or hip replacement surgery varies from \$140 to \$348 per patient. A course of treatment with Lovenox™ can fluctuate between \$170 and \$433 per patient while with Fragmin™ it can range from \$145 to \$365 per patient. Alternatively, treatment with Pradax™ can range from \$111 to \$285 per patient. Xarelto™ is priced within the range of alternative treatments. Since Xarelto™ will most likely be used in an older population, combined with the shifting of market share, this drug is expected to have minimal impact on private payers.

New Indication

Revlimid™ (5, 10, 15, 25 mg lenalidomide) is an oral cancer drug available from Celgene Canada. It has recently received a new indication for the treatment of multiple myeloma, in combination with dexamethasone, in patients who have received at least one prior therapy. Multiple myeloma is a rare, progressive and fatal blood cancer usually diagnosed between 63-70 years of age. Approximately 6,000 Canadians have multiple myeloma. Previously, Revlimid™ received a conditional NOC for the treatment of patients with myelodysplastic syndromes. More details about the previous approval can be found in Volume 10, Issue 3 of the *Health Newsflash*.

Therapy of multiple myeloma is generally reserved for patients with symptoms or imminent complications because there is no evidence that early treatment prolongs survival. The only treatment that may potentially cure the disease is stem cell transplantation. Unfortunately, this treatment modality is rarely used because of the associated toxicity. Other agents used to treat this type of cancer include melphalan (Alkeran™), bortezomib (Velcade™), thalidomide (Thalomid™) and other conventional chemotherapeutic agents. Generally, all of these agents have similar efficacy, with Revlimid™ having fewer side effects than Thalomid™. Over time, however, each agent can lose its efficacy and another will need to be tried.

Due to Revlimid™'s structural similarity to thalidomide (a drug known to cause birth defects), Revlimid™ is only available through a controlled distribution program called RevAidSM. Only prescribers and pharmacists registered with the program are able to prescribe and dispense the product. Patients must also be registered with the program. For multiple myeloma patients, the recommended dose is 25 mg daily administered as a single capsule on Days 1-21 of a 28-day cycle which is repeated every 4 weeks. Revlimid™ 25 mg is priced at \$424.00 per capsule. The cost of treatment for multiple myeloma is estimated at up to \$106,000 per patient per year which is more expensive than current conventional therapies. Revlimid™ may have a modest impact on drug costs, but the patient population is expected to be small for both multiple myeloma and myelodysplastic syndromes.

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Policies and Legislation (PAL) Committee Update — 4th Quarter 2008

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

As a follow-up from the previous edition in which we detailed the new condition for the payment of dispensing fees under the Ontario Drug Benefit (ODB) program, it is our understanding that other than the exceptions noted under Section 21 of the regulations under the *Ontario Drug Benefit Act*, a dispenser (pharmacist) may not charge or accept payment of a person other than the Executive Officer. For example, under section 21, the dispenser is permitted to charge an ODB eligible person an amount equal to the amount otherwise payable by the Executive Officer if such person (a) elects to pay the amount and b) before the product is supplied, the person is advised that, subject to any co-payment, the product is available free of charge under the ODB program.

Ontario – Competitive agreements

As detailed in our last issue, in order to achieve better value and best use of resources for drug spend, the Ontario Government has introduced the Competitive agreements framework. On December 1, 2008, the Executive Officer announced that Merck Frost Canada Ltd. was the successful applicant for the *Enalapril Maleate Call for Application*. As such, effective January 8, 2009, Vasotec 2.5mg, 5mg, 10mg and 20mg tablets will be the only drug product listed on the Ontario Drug Benefit program Formulary for Enalapril Maleate. The current interchangeable products will retain their “Not a Benefit” for interchangeability purposes for non ODB recipients.

Impact:

As a result, for ODB eligible patients covered under a private insurance and taking Vasotec, COB rules will apply and the private plan is considered second payer for the copay. As previously mentioned, 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.

Private payers should not benefit at all from the price reduction on the competitive listing agreement as the previous Bill 102 50% generic rule created 2 tiered pricing.

http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/exec_office_20081201_2.pdf

Ontario – Coverage under the public drug program for six new drugs

On December 3, 2008, the province of Ontario announced it would cover six drugs under the Ontario Public Drug Programs. These drugs are Lantus (to lower blood glucose levels), Vectibix (for colorectal cancer patients), Rasilez (for hypertension), Orenzia (for rheumatoid arthritis), Enbrel (for psoriasis) and Raptiva (for psoriasis).

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Impact:

As these drugs will be covered under publicly funded plans for eligible Ontarians, private payers should see a decrease in cost for these drugs.

Source:

http://www.health.gov.on.ca/english/media/news_releases/archives/nr_08/dec/nr_20081203.html

Optimizing the Value of Health Benefits

British Columbia – Pharmacist adapting a prescription – New generic drugs pricing – Frequent-dispensing policy for pharmacy

Pharmacist adapting a prescription

Effective January 1, 2009, BC pharmacists will be permitted to adapt prescriptions, in accordance with the Professional Practice Policy #58 (PPP-58) entitled *Protocol for Medication Management (Adapting a Prescription)*. PPP-58 outlines that pharmacists may dispense a drug contrary to the terms of an existing prescription (changing, renewing or substituting a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescription drug and the pharmacists sequentially followed the seven fundamentals. In order to adapt a prescription, pharmacists must namely possess a minimum personal professional liability of \$2 million. Pharmacies will receive from PharmaCare, in addition to the normal dispensing fee, up to a maximum clinical services fee of:

- an amount equal to the PharmaCare accepted maximum fee (\$8.60) for a renewal or for changing a dose, formulation, regimen, and
- an amount equal to twice the PharmaCare accepted maximum dispensing fee for therapeutic substitution.

New generic drugs pricing and Frequent-dispensing policy for pharmacy

On December 12, 2008, the Province of BC and the BC Pharmacy Association (BCPhA) announced that they have reached an agreement that will make changes to PharmaCare prices for new generic drugs and will introduce a frequent-dispensing policy for pharmacy.

The Interim policy for pricing and reimbursement is effective since January 1, 2009 and as such, new generics coming to the market will not exceed 50% of the brand price. However, it is important to note that the list price for the new generic will not be set at 50% of the brand but rather that the reimbursement by BC PharmaCare will not be more than 50% of the brand price. The cost reduction factor will be specific to each new generic drug and is the difference between: (1) the manufacturer's list price for the new generic drug; and (2) 50% of the brand name manufacturer's list price for the equivalent brand name drug. Each month, PharmaCare will calculate the total payment reduction for each pharmacy by multiplying the drug-specific reduction factors by the total ingredient costs paid by PharmaCare to each pharmacy for each new generic drug.

Impact: Although, BCPhA has committed that there will be no additional fees or charges to BC residents, private payers may end up picking up the difference in the cost of these drugs and what PharmaCare is reimbursing for them.

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Effective February 1, 2009, a new dispensing policy will be implemented in order to restrict the practice of charging dispensing fees to individuals for each drug they receive on a daily or weekly basis (i.e., methadone). Currently, there is very little detail on the announcement, other than this new approach to payment for frequently dispensed drugs is expected to save PharmaCare \$20 million and that patients will not experience any difference in the way they receive their prescriptions.

Impact: The possible impacts cannot be evaluated at this time as we do not have enough information on this new dispensing policy.

Sources:

http://www2.news.gov.bc.ca/news_releases_2005-2009/2008HSERV0117-001892.htm

http://www.bcpharmacists.org/about_us/key_initiatives/index/articles29.php

<http://www.health.gov.bc.ca/pharme/newsletter/08-012news.pdf>

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Ontario – Drugs that can be prescribed by Chiropractors and Podiatrists

Ontario Regulation 338/08 made under the *Chiroprody Act*, was published in the October 11, 2008 issue of the Ontario Gazette. The regulation allows a chiroprody or podiatry class member holding a general or academic class certificate of registration to prescribe the drugs enumerated in such regulation, as long as the member complies with the standards of practice.

Source:

<http://www.gov.on.ca/GOPSP/en/graphics/256351.pdf>

British Columbia – Insulin Pumps coverage for Children aged 18 or younger

Since November 17, 2008, BC PharmaCare covers the cost of insulin pumps for children aged 18 or younger with Type 1 diabetes or other forms of diabetes requiring insulin, who are covered under Fair PharmaCare or PharmaCare Plan C and whose diabetes physician confirms that they meet the medical criteria. The program will cover 100% of the cost of one of the approved insulin pumps every five years, subject to the rules of the appropriate PharmaCare plan. As for the supplies for insulin pumps, they are already covered for both children and adults.

Source:

<http://www.health.gov.bc.ca/pharme/medsup.html>

New-Brunswick – Pharmacist Granted prescription rights

In the November 26, 2008 edition of the New Brunswick Royal Gazette, the province's pharmacists were granted prescribing rights as Section 2 of New Brunswick Regulation 84-170, made under the *Prescription Drug Payment Act*, was amended by adding "pharmacist," in the definition of "prescriber". The definition also includes legally qualified medical practitioners, nurse practitioners, optometrists and dentists.

Source:

<http://www.gnb.ca/0062/acts/BBR-2008/2008-140.pdf>

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Northwest Territories – Pharmacist Prescribing Rights

In accordance with the *Pharmacy Act*, the *Continued Care Prescriptions Regulations* was published in the November issue of the Northwest Territories Gazette, and allows pharmacists, under certain conditions, to prescribe a defined quantity of a drug for the continued care of a patient. When doing so, a pharmacist shall not issue more than one continued care prescription for each original prescription, notify the prescribing practitioner of the continued care prescription within 24 hours and maintain a record of the continued care prescription, including a reference to the identifying number of the original prescription.

Source:

http://www.justice.gov.nt.ca/pdf/Legislation/Gazette/2008_11_2.pdf

<http://www.justice.gov.nt.ca/PDF/ACTS/Pharmacy.pdf>

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Alberta – Alberta Pharmaceutical Strategy

On December 8, 2008, the Government of Alberta announced a new pharmaceutical strategy intended to make drug coverage more accessible, affordable, efficient and therapeutically effective by improving the management, funding and purchasing processes for prescription drugs paid for fully or partially by the Government of Alberta. It is also designed to bring greater clarity and consistency to the operation of government sponsored drug benefit programs and improve the efficiency and effectiveness of program governance and management. The key changes announced under phase one of the strategy include:

Alberta Rare Disease Drug Program (effective date April 1, 2009)

This program will cover catastrophic drug costs for Albertans with extremely rare diseases (a genetic disorder that occurs in less than one in 50,000 Canadians or fewer than 50 Albertans). In order to be eligible for the program, an individual or family must reside in Alberta for five years and have coverage in the public plan. A panel of specialists in genetic disorders will be established to provide advice about the drugs covered, treatment guidelines and criteria for coverage. Eligible individuals will be required to pay premiums and make co-payments consistent with their government-sponsored drug coverage. The above mentioned panel will also make decisions on individual patient coverage and monitor patient response to therapy.

Impact: For eligible patients who have both private and public plans, the catastrophic drug claims would now be covered by the public plan. Therefore, there may be less cost to private drug plans.

Adjustment of non-group coverage premiums (beginning July 2009)

Beginning in July 2009, the premiums for non-group coverage will be increased, over two years, to reflect current market rates (comparable to those of employer and private plans). For an individual, monthly premiums will increase from \$20.50 to \$41 and then to \$63.50. As for a family, they will increase from \$41 to \$82 and then to \$118.

Impact: Due to premium increases, an individual (non-senior) could decide to drop out from the provincial program and get coverage from a private plan.

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Improving drug coverage for seniors (effective January 1, 2010)

Drug coverage for seniors will be redesigned, increasing support to those in need. Low-income seniors will not pay for drug coverage (single seniors with an annual income of less than \$21,325 and senior families with a household annual income of less than \$42,650). Other seniors will pay a deductible based on their income, up to a maximum of \$7,500. The co-payment of up to \$25 per prescription will no longer be required when the new plan becomes effective.

Impact: Carriers will need to manage eligibility as it is income based. As for the financial impacts, they are difficult to assess as the model will change from a co-payment model to a deductible model, which could be submitted to private payers.

Establishing a single, government-sponsored drug plan

As of today, five ministries provide drug coverage to Albertans. A single, government-sponsored drug plan using a common drug list will be established in order to provide greater consistency and clarity. No effective dates have been given.

Impact: The impact cannot be evaluated as it will depend on the changes made to the formulary drug listing.

Creating a more timely and transparent drug review process

This objective is to be achieved by establishing a new committee consisting of public members (to provide societal and ethical perspectives), adopting guidelines for drug coverage decisions, improving drug review procedures, simplifying the special authorization process and introducing a process for independent consideration. As for the Expert Committee on Drug Evaluation and Therapeutics, they will continue to make recommendations (based on clinical and therapeutic value and on economic considerations) to the department and Minister for addition to the Alberta Drug Benefit List. These changes will be introduced after the legislative framework to support the Alberta Pharmaceutical Strategy is approved and implemented. The target timeline for listing generic drugs is 30 days. Since brand name drugs are required to be reviewed nationally through the Common Drug Review process, the target timeline for brand name drugs is 120 days. As for products that require societal and ethical input, it is 150 days.

Impact: If a drug is added to the provincial formulary earlier than it would have before the implementation, there could be potential savings for private payers.

As for phase two of the strategy, it will examine how to attain a more cost-effective drug purchasing (including the possibility of developing common Western Canadian drug purchasing and procurement processes) and by exploring an expanded role for pharmacists (possibility of moving to a different type of incentive and reimbursement model that rewards pharmacies and pharmacists for increased involvement in patient care and appropriate drug therapy).

Impact: Impact of the above 2 strategies included in phase 2 are unknown at this time until further information becomes available.

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Sources:

Strategy:

<http://www.health.alberta.ca/documents/Pharmaceutical-Strategy-2008.pdf>

Facts Sheets:

<http://www.health.alberta.ca/documents/Pharma-Strategy-2008-seniors.pdf>

<http://www.health.alberta.ca/documents/Pharma-Strategy-2008-non-group.pdf>

<http://www.health.alberta.ca/documents/Pharma-Strategy-2008-rare-disease.pdf>

<http://www.health.alberta.ca/documents/Pharma-Strategy-2008-drug-approval.pdf>

Press Release:

<http://www.alberta.ca/acn/200812/2491217DCBC7C-9A4A-1671-473ED30594C1ECFF.html>

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New Brunswick – The *Modernization of Benefits and Obligations Act* received Royal Assent

On December 19, 2008, Bill 6, the *Modernization of Benefits and Obligations Act*, received Royal Assent in the New Brunswick legislature. This Act had passed 3rd reading on December 3, 2008. It amends many New Brunswick Acts in order to grant same sex common-law partners the same benefits as opposite sex common-law partners. The *Prescription Drug Payment Act* and the *Prescription Drug Regulations* have namely been amended accordingly.

Impact

Private payers need to validate that the plans they offer are in accordance with the *Modernization of Benefits and Obligations Act*.

Source:

<http://www.gnb.ca/0062/acts/BBA-2008/Chap-45.pdf>

British Columbia – The Health Professions Act

On December 12, 2008, the Ministry of Health Services of British Columbia announced that over the next seven months, the professions of pharmacy, dentistry, chiropractic, medicine, and optometry will transition under the *Health Professions Act* in order to provide a consistent approach to health profession regulation in B.C. These changes are aimed at improving the quality and efficiency of the regulation of health professions by insuring accountability and transparency and support high-quality, patient-focused care.

On March 1, 2009, the College of Chiropractors of British Columbia and the new College of Optometrists of British Columbia will be the first two self-regulating professional colleges to move under the Health Professions Act. On April 1, 2009, the College of Pharmacists of British Columbia will transition, followed by the College of Dental Surgeons of British Columbia (April 3, 2009) and the College of Physicians and Surgeons of British Columbia (on June 1, 2009).

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Impact

As of the date of this bulletin, we cannot evaluate the full scope of the transition of the pharmacy profession to the *Health Professions Act* as the new *Pharmacists Regulation* and the proposed bylaws for the College under the *Health Professions Act* and the *Pharmacy Operations and Drug Scheduling Act* have yet to be published.

Sources:

http://www2.news.gov.bc.ca/news_releases_2005-2009/2008HSERV0116-001891.pdf
<http://www.health.gov.bc.ca/leg/regulatoryreform.html>

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Prince Edward Island – Diabetes Control Program

On November 17, 2008, the Prince Edward Island government introduced the Diabetes Control Program, in order to provide limited coverage of blood glucose testing strips to patients that are eligible for PEI Medicare, diagnosed with Type I or Type II diabetes, have used insulin within the past 90 days, and are not be eligible for coverage of blood glucose testing strips through any other provincial or federal programs. The coverage of the blood glucose testing strips is limited to a quantity of 100 per 30 day period and for each purchase, eligible patients are required to pay a \$11 co-pay.

In a letter addressed to CLHIA, the Prince Edward Island government indicated that they expect that all private insurers in the province will:

- Continue to provide coverage of blood glucose testing strips for beneficiaries that will not qualify for this coverage,
- Continue to provide coverage of blood glucose testing strips in excess of the 100 strips per month maximum under the program,
- Provide beneficiaries with full or partial reimbursement of the \$11 per purchase co-pay where this is currently allowed by the beneficiary's plan,
- Continue to provide coverage of other diabetes supplies where this is currently allowed by the beneficiary's plan.

In their Health Issue Update, CLHIA indicated they would inform the Prince Edward Island government that coverage offered through extended health plans are arrangements requested by plan sponsors and therefore that insurers are not in a position to guarantee extended health plan will maintain the same coverage that currently exists in the province.

Impact: At this time, the impact of these changes to insurers is unclear. It will depend on contract wording as to whether test strips are already covered under individual plans. In PEI, private plans are considered first payer for drug benefits.

Source:

Prince Edward Island – Diabetes Control Program Introduced, effective November 14, 2008, Canadian Life and Health Insurance Association (CLHIA), Health Issue Update, November 13, 2008.

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