Health Newsflash – a Quarterly Publication

New Drugs and Pipeline News Reviewed at the April to June 2009 DEC Meetings

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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.

Xeomin® (Clostridium Botulinum Neurotoxin Type A, intramuscular injection) is a new neuromuscular paralytic agent available from Merz Pharmaceuticals. It received NOC in March 2009 and is indicated for the symptomatic management of blepharospasm (twitching of the eyelids), cervical dystonia (abnormal muscle contractions causing movements of the neck) and post-stroke spasticity of the upper limb (stiff or rigid muscles of the arms after a stroke). Xeomin is very similar to Botox® as both contain essentially the same active ingredient but with a different formulation. Xeomin does not contain complexing proteins which are present in Botox, and the absence is postulated to decrease the formation of antibodies making it less prone to adverse events. In addition, complexing proteins are thought to be responsible for the resultant resistance which can occur when using neurotoxins at high doses and for extended periods of time. There are head-to-head clinical trials comparing Xeomin and Botox for the use in cervical dystonia and blepharospasm, and Xeomin was shown to be non-inferior to Botox. Although the dosage varies by indication, the period between each treatment session for all 3 indications is recommended to be at least 12 weeks as the effect of each treatment generally lasts 3-4 months. The price of Xeomin is approximately $330 per vial and is priced in line with Botox, with an estimated yearly cost of $1,320 – $5,280. Xeomin is expected to have a minimal impact to private payers and suggestions for management include prior authorization to ensure the product is only used for its approved indications.

Drug Name	Manufacturer	Route of Adminis-tration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Xeomin	Merz Pharmaceuticals	Intramus-cular Injection	• Blepharospasm • Cervical Dystonia • Post-stroke spasticity of upper limb	Botox	$330 per vial	Minimal	Prior Authorization

Simponi™ (Golimumab 50mg/0.5mL, subcutaneous injection) is a new biologic available from Centocor Inc. This is a human monoclonal antibody, tumor necrosis factor alpha inhibitor (TNFα inhibitor) that received Health Canada approval in April 2009. It has been approved for three indications: rheumatoid arthritis (pain, swelling, stiffness and loss of function in joints), psoriatic arthritis (inflammation of joints associated with skin disease characterized by circumscribed red patches covered with white scales), and ankylosing spondylitis (rheumatoid arthritis of the spine). For all three indications, Simponi is to be administered by subcutaneous injection at a dose of 50 mg on the same day each month. Trials suggest that clinical response is usually achieved within 14-16 weeks of treatment (i.e., after 4 doses).

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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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Other TNF inhibitors available on the Canadian market include Enbrel™ (etanercept), Humira™ (adalimumab), and Remicade™ (infliximab). These 3 agents are also approved to treat the same medical conditions as Simponi. Currently, no head-to-head clinical trials are available to determine comparative efficacy and safety. The cost of Simponi is not yet available but is expected to be priced similarly to its alternatives. Depending on the choice of biologic, indication and dosage, the annual cost of these biologics may range anywhere from $17,000 to $32,000. Due to the high cost of these biologics, Simponi is expected to have intermediate impact to private payers. However, strategies such as Prior Authorization can be used to ensure the product is reimbursed appropriately for its improved indications only.

Drug Name	Manufacturer	Route of Adminis-tration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Simponi	Centocor Inc	Subcutane-ous Injection	• Rheumatoid arthritis • Psoriatic arthritis • Ankylosing spondylitis	Enbrel Humira Remicade	Not available (but expected to be in line with compar-ators)	Intermediate	Prior Authorization

Omnitrope™ (somatropin [rDNA origin], subcutaneous injection) is the first subsequent entry biologic (SEB) approved for sale in Canada. It is marketed by Sandoz Canada Inc. and received NOC on April 20, 2009. Omnitrope is a recombinant human growth hormone indicated for the long-term treatment for children with growth failure due to an inadequate secretion of endogenous growth hormone, and long-term replacement therapy in adults with growth hormone deficiency due to an underlying hypothalamic or pituitary disease or who were growth deficient during childhood. Its approval has been based on comparative data to the reference product, Genotropin, which is approved but not marketed in Canada. Other growth hormones available in Canada include Humatrope®, Nutropin®, Saizen®, and Serostim®.

Subsequent Entry Biologics (SEBs) are also known as "biosimilars" in Europe or "follow-on biologics" in the US. SEBs are second versions of previously approved biologics but will not be declared as bioequivalent to its reference drug. SEBs will be approved using the new drug submission pathway, unlike generic drugs which are approved using the abbreviated new drug submission pathway. Due to the fact that SEBs are currently being developed outside of Canada using non-Canadian reference drugs, Health Canada will not make it mandatory for the reference biologic to have been approved and marketed in Canada. SEBs may be granted approval regardless of the approval status of its reference drug in Canada. In addition, SEBs will always require clinical trials before they are approved in Canada.

The cost of Omnitrope is not yet available; however, it is expected to be priced similar if not lower than other growth hormones. For example, the annual Humatrope® cost for treating growth hormone deficiency in a 35kg child is $27,600 and that for a 75kg adult is $17,400. Since the cost of this type of therapy has been relatively high, we anticipate Omnitrope would have an intermediate impact to private payers. ESI Canada will continue to follow the pricing structure, trend, as well as provincial/federal regulations on SEBs.

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Drug Name	Manufacturer	Route of Adminis-tration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Omnitrope	Sandoz Canada Inc	Subcutaneous Injection	Growth hormone deficiency in children and adults	Humatrope Nutropin Saizen Serostim	Not available (but expected to be on par or cheaper than competit-ors)	Intermediate	Prior Authorization

Tykerb™ (lapatinib 250mg oral tablet) is an anticancer drug available from GlaxoSmithKline, and received NOC in May 2009. Tykerb is to be used in combination with another oral anticancer drug, Xeloda™, for patients with hormone-sensitive metastatic breast cancer whose tumours over express Human Epidermal Receptor Type 2 (HER2 [ErbB2]) and who have progressed following prior therapies including taxanes, anthracyclines and Herceptin™. The recommended dose is 1250mg orally once daily until disease progression or unacceptable toxicity occurs. The other anticancer agent indicated specifically for metastatic breast cancer with over expression of HER2 is Herceptin™, which is a weekly intravenous injection. Tykerb provides advantages over Herceptin in terms of patient convenience and eliminates the burden on infusion clinics.

Breast cancer is the most common form of cancer for women in Canada. It is estimated that one in nine Canadian women will develop breast cancer in their lifetime. Approximately 25% of women with breast cancer will have over expression of the HER2 protein. Over expression of the HER2 receptors is associated with poor prognosis and reduced overall survival.

The cost of each Tykerb 250mg tablet is $24.79. Its estimated weekly cost of $868 is priced lower than the weekly cost of $970 for Herceptin (maintenance dose for 75kg adult). It is expected that Tykerb would have an intermediate impact to private payers.

Drug Name	Manufacturer	Route of Adminis-tration	Approved Indications	Alternative(s)	Cost	Anticipated Impact	Plan Management Suggestions
Tykerb	GlaxoSmithKline	Oral	Metastatic HER2 positive breast cancer	Herceptin	$24.79 per 250mg tablet	Intermediate	Monitor provincial coverage and possibly with Prior authorization

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Alberta – Rare Diseases Drug Program in Effect

On April 1, 2009 the Alberta Rare Diseases Drug Program came into effect. This new program, a first in Canada, helps citizens with extremely rare genetic disorders to pay for their prescription drugs, To be eligible for this program, an individual or family must have resided in Alberta for at least five years, have government sponsored drug coverage and their physician must have applied for coverage. Under the program, individuals will be required to pay premiums and make co-payments consistent with their government-sponsored drug coverage.

Extremely rare genetic disorders are defined as being those occurring in fewer than one in 50,000 Canadians or fewer than 50 Albertans and include: Gaucher's disease; Fabry Disease; MPS-I(Hurler/Hurler Scheie); Hunter disease; and Pompe disease. The Alberta government is funding this program for ethical and compassionate reasons as the drug cost for such diseases can vary between $250,000 to $1 million per patient per year.

Impact

This new program could reduce costs for private payers.

Sources

http://alberta.ca/home/NewsFrame.cfm?ReleaseID=/acn/200903/25601486C5787-F1CD-3032-0AFB274337B5DA30.html
http://www.health.alberta.ca/documents/Pharma-Strategy-2008-rare-disease.pdf

Alberta – Legislative framework for phase one of *Alberta's Pharmaceutical Strategy*

On June 4, 2009, Bill 34, the *Drug Program Act*, received Royal Assent in the Alberta legislature and will come into force on a day to be fixed by proclamation, with exceptions. This Bill provides the legislative framework for the initiatives included in phase one of the Alberta Pharmaceutical Strategy (APS) announced in December 2008, which includes establishing a single, government-sponsored drug plan, improving the transparency of the drug approval process, introducing a drug coverage program to help Albertans with extremely rare diseases, adjusting premiums for drug coverage for Albertans under 65 years of age who are registered with government's non-group program and redesigning drug coverage for seniors to provide greater support for those with low incomes.

The Act would also create a process for Albertans who don't respond to standard drug therapy, provide citizens with more information about drug coverage decisions, and support drug review committee structures like the Expert Committee on Drug Evaluation and Therapeutics and a new public members' committee

Sources

http://alberta.ca/home/NewsFrame.cfm?ReleaseID=/acn/200904/25824F365C1A0-A6AB-A92C-FFD636C05E0E27E5.html
http://www.assembly.ab.ca/net/index.aspx?p=bills_status&selectbill=034

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Alberta – Lower Co-payments under Proposed Seniors' Drug Plan

The government of Alberta has revised its proposed seniors' drug plan so that, effective July 1, 2010:

i. A single senior with a taxable income of $12,000 or less and a senior family with a combined taxable income of $24,000 or less will receive free prescription drugs. ;
ii. A single senior with a taxable income of $12,001 to $24,000 and a senior family with a combined taxable income of $24,001 to $48,000 will pay 20 per cent of each prescription's cost up to a maximum of $15; and
iii. A single senior with a taxable income of $24,001 or more and a senior family with a combined taxable income of $48,001 or more will pay the co-payment plus a monthly premium based on their taxable income.

The plan is optional; seniors are not required to participate. A three-month waiting period will apply to seniors who choose to participate at a later date.

Impact

System changes are currently being worked on by ESI Canada for 2010. Since the new enhancements to the provincial plan are income based, the system changes will involve removal of the 30% copayment to a maximum of $25 per script, and all the claims for seniors are to be accepted. However, carriers will be responsible for establishing the eligibility of their members, based on the new thresholds and the fact that the program will become voluntary.

Source

Alberta Health and Wellness, "Government Improves Seniors' Drug Plan," April 23, 2009. (date accessed: April 23)

British Columbia – New Prescribing Powers for Naturopathic Physicians

The government of British Columbia has amended the *Naturopathic Physicians Regulation* in order to authorize naturopathic physicians who have successfully completed a certification course to prescribe medication as appropriate to their primary care practices. The standards, limits and conditions for prescribing will be established by the College of Naturopathic Physicians of B.C., based on recommendations from an inter-professional committee that includes medical doctors, pharmacists and a Ministry of Health Services representative. Furthermore, the College will have the capability to monitor its members' prescribing patterns. As of today, there are over 300 registered naturopathic physicians in B.C.

Impact

Carriers should verify the wording of the applicable insurance contracts to make sure certified naturopathic physicians are recognized prescribers.

Sources

http://www.health.gov.bc.ca/leg/pdfs/BC_Reg_156_2009.pdf
http://www2.news.gov.bc.ca/news_releases_2005-2009/2009HSERV0045-000871.htm

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British Columbia – Frequent dispensing policy for pharmacy

In our last edition, we informed you that effective February 1, 2009, a new dispensing policy was implemented in order to restrict the practice of charging dispensing fees to individuals for each drug they receive on a daily or weekly basis. At the time, the possible impacts could not be evaluated as we did not possess enough information on this new dispensing policy.

We now know that under its new policy, PharmaCare will cover one dispensing fee when a single fill is provided for (i) the total quantity the prescriber specified on the written prescription, or (ii) no less than the maximum days supply allowed under PharmaCare policy. However, PharmaCare will limit the number of dispensing fees covered when (i) a prescriber orders daily dispensing, or (ii) a prescriber or pharmacist initiates more frequent dispensing.

The policy also enumerates when pharmacies are permitted to charge patients directly for dispensing fees above the maximum number of fees allowed under the policy. If a patient is below the Fair PharmaCare deductible, Pharmacies are permitted to charge patients directly for dispensing fees above the maximum number of fees allowed under the policy (as PharmaCare will cover only the number of fees specified in the Frequency of Dispensing Policy and only the number of fees covered by PharmaCare will accumulate toward the Fair PharmaCare deductible).

Impact

Private payers may have to pay for dispensing fees submitted which are beyond the maximum number set by PharmaCare as nothing in the policy restricts patients from purchasing smaller quantities and paying the additional dispensing fees. It also allows pharmacies to charge patients the difference between their usual and customary dispensing fee and the maximum allowable dispensing fee covered by PharmaCare (presently at $8.60).

Source

http://www.health.gov.bc.ca/pharme/newsletter/09-002news.pdf

British Columbia – Optometrists given prescribing and dispensing rights

In March 2009, the Optometrists Regulation came into force in British Columbia. The regulation enhances the scope of practice of optometrists by giving optometrists that have successfully completed a certification course, the authority to prescribe, dispense and administer topical prescription. The regulation also obligates the optometrists to notify a patient's medical doctor of any medications prescribed or administered.

Impact

Carriers should verify the wording of the applicable insurance contracts to make sure certified optometrists are recognized prescribers.

Sources

http://www2.news.gov.bc.ca/news_releases_2005-2009/2009HSERV0014-000237.htm
http://www.bclaws.ca/Recon/document/freeside/--%20h%20--/health%20professions%20act%20%20rsbc%201996%20%20c.%20183/05_regulations/27_33_2009.xml

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Manitoba – Proposed Legislation Addresses Interchangeable Drug Products

On June 11, 2009, Bill 18, the *Regulated Health Professions Act*, received the Royal Assent in the Manitoba legislature and will come into force on a day to be fixed by proclamation. Sections 214 to 217 of this proposed Bill address Interchangeable Pharmaceutical Products. The general principle states that no dispenser shall, in dispensing a drug pursuant to a prescription, substitute one drug for another, or one brand of drug for another, without the consent of the practitioner. However, if a prescription directs the dispensing of a specific interchangeable product, the Bill indicated that the dispenser must dispense either the interchangeable product that is prescribed or another interchangeable product, at a cost that is not more than the sum of: (i) the cost for the lowest priced interchangeable product prescribed in the formulary and (ii) the maximum additional amount prescribed in the regulations.

Impact

Until the legislation is finalized, the final impacts cannot be identified. However, as drafted today, the Act would not change any current practices if put into effect. Private payers may benefit from any pricing the public puts into place for interchangeable products; as part of this therapeutic substitution will not be allowed.

Sources

Bill 18, the *Regulated Health Professions Act*, http://web2.gov.mb.ca/bills/39-3/pdf/b018.pdf
Status of Bills in Manitoba http://www.gov.mb.ca/legislature/bills/billstatus.pdf

Newfoundland and Labrador – Expanded Pharmacist Powers to Dispense Prescriptions by Out-of-province Prescribers

On May 28, 2009, Bill 12, *An Act to Amend the Pharmacy Act*, received Royal Assent in the Newfoundland and Labrador General Assembly. The legislation expands the definition of the term "prescription" in order to allow a pharmacist to dispense a drug pursuant to a prescription authorized by a prescriber licensed to practice in a province or territory of Canada other than Newfoundland and Labrador, if he has taken reasonable steps to ensure that (i) the prescriber is licensed and practises in Canada; and (ii) the prescriber belongs to a class of persons who, if licensed in Newfoundland and Labrador, would be entitled by law to prescribe that drug in the province.

Impact

This legislation should have minimal impact on third party payers, as there should be no significant increase in the number of claims in the province. However, carriers should review the wording of the insurance policies to make sure the definition of "prescription" includes all types of prescriptions deemed legal in the province.

Sources

http://www.assembly.nl.ca/business/bills/Bill0912.htm
http://www.assembly.nl.ca/business/bills/ga46session2.htm

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Nova Scotia – Lowering of the Co-Payment in the *Seniors' Pharmacare Program*

Since April 1, Nova Scotians aged 65 and older pay less when purchasing a prescription drug at the pharmacy as the copayment has been lowered from 33 to 30 per cent. The maximum annual copayment and the maximum annual premium remain unchanged.

Impact

Private payers will not benefit from the change as seniors are not eligible for the Seniors' Pharmacare Program if they have coverage under a private plan.

Source

http://www.gov.ns.ca/news/details.asp?id=20090122003

Ontario – New prescribing rights for various health care professionals and remote dispensing

On May 25, 2009, the Ontario legislature carried the second reading of Bill 179, the *Regulated Health Professions Statute Law Amendment Act, 2009*. If passed, the legislation amends various statutes which would change the rules for administering, prescribing, dispensing, compounding, selling and using drugs in practice for chiropodists and podiatrists, dental hygienists, dentists, midwives, nurse practitioners, pharmacists, physiotherapists and respiratory therapists.

In addition, the *Drug and Pharmacies Regulation Act,* and the *Ontario Drug Benefit Act* are amended in order to allow the dispensing of prescription drug products under the supervision of a licensed pharmacist, but without the pharmacist being physically present at the dispensing location (“remote dispensing”). Currently, Pharmacies cannot legally provide remote dispensing services in Ontario. Under the proposed amendments, the Executive Officer will have total discretion to determine which pharmacies, remote pharmacies or physicians should receive the ODB Program billing privileges. The amendments also allow the possibility of differing mark-ups and dispensing fees to different classes of pharmacies based on the type of dispensing model in place.

Impacts

For now, no changes are required. However, impacts are hard to evaluate at this time as the Bill has yet to become legislation and can still be modified.

Sources

http://www.ontla.on.ca/web/bills/bills_detail.do?locale=en&BillID=2189&detailPage=bills_detail_the_bill
http://www.health.gov.on.ca/english/public/legislation/regulated/regulated_health_professions.html
http://www.health.gov.on.ca/english/public/legislation/regulated/compendium_regulated_health.pdf

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Quebec – Drug Price Increase
The Minister of Health and Social Services made price changes to the list of medications. As of April 20, 2009, 1014 products had a price increase by a maximum ranging between 2.36% or 3.54%. The increases respect the criterias outlined in the Politique du Médicament.

Impact
The impact of these ingredient cost increases on private payers is 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.

Source
http://www.cdm.gouv.qc.ca/site/aid=186.phtml

Quebec – **Public Prescription Drug Insurance Plan changes**
Effective July 1, 2009, the Public Prescription Drug Insurance Plan in Quebec will introduce rate changes, including moving the coinsurance up one percent to 32% and the annual out of pocket to $954.

Impact
There is minimal anticipated impact for groups in Quebec since most of these plans already exceed the minimums.

Source:
Gazette Officielle du Québec, 20 juin 2009, 141e année, no 24

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