



# Health Newsflash – a Quarterly Publication

## New Drugs and Pipeline News Reviewed at the January to March 2011 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

#### Nucynta CR (tapentadol HCl)

<u>Dosage Form</u>	<u>DIN &amp; Strength</u>	<u>Manufacturer</u>	<u>AHFS Class</u>
Oral tablet	02360373 – 50mg 02360381 – 100mg 02360403 – 150mg 02360411 – 200mg 02360438 – 250mg	Janssen Inc.	28:08.08 – opiate agonists

#### Indication(s)

For the management of moderate to moderately severe pain in adults who require continuous treatment for several days or more.

#### Dose

100mg to 250mg twice a day.

#### Therapeutic Alternatives

tramadol, codeine, morphine, oxycodone, hydromorphone, fentanyl

#### Clinical Notes

Tapentadol is a centrally acting synthetic pain reliever, whose exact known mechanism is not fully understood, but it is believed that tapentadol works in a similar fashion to tramadol (e.g., Zytram XL®, Raliva™) by interacting with two different pain pathways, opioid receptors and norepinephrine.

#### Place in Therapy

Tapentadol hydrochloride is indicated for the treatment of moderate to severe acute pain in adult patients who require continuous pain treatment for several days or longer. It would be used in a similar fashion to other long-acting pain medications such as Zytram XL®, Raliva™ or OxyContin®.

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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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## Comparative Pricing

	Nucynta CR	Zytram XL (Tramadol)	Ralivia (Tramadol)	Oxycontin 10mg-80mg
Estimated annual cost	\$1045 to \$2445	\$616 - \$1540	\$456 - \$1369	\$635 - \$3146
Estimated Monthly cost	\$90 to \$210	\$50 - \$130	\$40 - \$120	\$50 - \$260

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### Impact

Minimal impact – many other treatment options are currently available.

### Plan Management Suggestions

Tiered formulary

## Revolade (Eltrombopag)

Dosage Form	DIN & Strength	Manufacturer	AHFS Class
Tablet	02361825 – 25mg 02361833 – 50mg	GlaxoSmithKline	20:16.00 Hematopoietic agents

### Indication(s)

Used to treat immune (idiopathic) thrombocytopenic purpura (ITP) in adult patients who have not responded to therapy with corticosteroids, immunoglobulins, or spleen removal. Immune (idiopathic) thrombocytopenic purpura is a rare disease where the patient's immune system destroys blood platelets resulting in too few platelets in the blood.

### Dose

Initial dose: 50 mg orally once daily on an empty stomach; in patients of East Asian ancestry (Chinese, Japanese, Taiwanese, or Korean) or in patients with moderate to severe liver impairment, the starting dose is 25 mg orally once daily. Maintenance dose: after 2 weeks, increase dose by 25 mg daily to achieve and maintain a blood platelet count of 50 x 10<sup>9</sup>/L or more. Maximum dose: 75 mg/day.

### Therapeutic Alternatives

Nplate (romiplostim) Injection





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### Clinical Notes

Revolade is an oral tablet used to treat thrombocytopenia (low platelets in the blood) in patients with a blood disorder called chronic idiopathic thrombocytopenic purpura (ITP). ITP occurs when certain immune system cells produce antibodies against platelets. The antibodies attach to the platelets. The spleen destroys the platelets that carry the antibodies. Platelets help clot the blood, so a person with thrombocytopenia may have bleeding problems. Revolade works by stimulating the bone marrow to produce more platelets.

### Place in Therapy

Revolade is indicated for adult chronic ITP patients who have had their spleens removed (splenectomised) and have not responded (are refractory) to first-line treatments, such as corticosteroids and immunoglobulins. Revolade may also be considered as second-line treatment for adult non-splenectomised patients, where surgery is not possible. Revolade should only be used in those with low platelet level due to ITP not due to other causes.

### Comparative Pricing

	Revolade	Nplate
Estimated cost per week	\$460 - 1370	Based on 75kg adult: = \$885- 2650

### Impact/Plan Management Suggestions

High cost drug for rare condition may have high impact on certain private plans. Prior Authorization recommended to verify indication for use.

### Byetta (exenatide)

<u>Dosage Form</u>	<u>DIN &amp; Strength</u>	<u>Manufacturer</u>	<u>AHFS Class</u>
Solution for injection – pre-filled pen	02361809 - 5mcg/dose 02351817 - 10mcg/dose	Eli Lilly Canada, Inc.	68:20.06 – Incretin mimetics

### Indication(s)

Exenatide is used in combination with metformin, or a sulfonylurea medication to treat type 2 diabetes.

### Dose

The initial dose is 5mcg twice daily, administered as a subcutaneous injection, within 60 minutes before the morning and evening meal (or before the two main meals of the day, at least 6 hours or more apart). Based on effectiveness of the drug, the dose can be increased to 10mcg twice daily after 1 month of use to further improve blood glucose control. Maximum dose is 10mcg twice daily.





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### Therapeutic Alternatives

Victoza (liraglutide)

### Clinical Notes

Exenatide is the second drug in Canada (after Victoza®) to become available in a class of medications called incretin mimetics. It works by stimulating the pancreas to secrete insulin when blood sugar levels are high. Insulin helps move sugar from the blood into other body tissues where it is used for energy. Exenatide also slows the emptying of the stomach and causes a decrease in appetite. Exenatide is not used to treat type 1 diabetes. Exenatide is not used instead of insulin to treat people with diabetes who need insulin.

### Place in Therapy

Exenatide is to be used in combination with metformin and/or a sulfonylurea medication when neither one nor both of these drugs are able to keep blood sugar levels under control.

### Comparative Pricing

	Byetta	Victoza
Estimated cost per day	Price not yet available	\$5.25 - \$7.75

### Impact

Intermediate Impact

### Plan Management Suggestions

Use of prior authorization recommended to ensure metformin or sulfonylurea have been attempted and to prevent off-label use (e.g., weight loss).

## Abstral (fentanyl citrate)

<u>Dosage Form</u>	<u>DIN &amp; Strength</u>	<u>Manufacturer</u>	<u>AHFS Class</u>
Sublingual Tablet	02364174 – 100mcg 02364182 – 200mcg 02364190 – 300 mcg 02364204 – 400 mcg 02364212 – 600 mcg 02364220 – 800mcg	Paladin Labs Inc.	28:08.08 - Opiate agonist

### Indication(s)

Fentanyl sublingual (under the tongue) tablets are used only to treat breakthrough cancer pain (sudden episodes of pain that occur despite round the clock treatment with pain medication) in cancer patients who are taking regularly scheduled doses of another narcotic (opiate) pain medication, and who are tolerant (used to the effects of the medication) to narcotic pain medications.

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### Dose

All patients should start treatment with the 100mcg dose and individually adjust the dose based on pain relieving effectiveness. If adequate pain relief is not experienced within 30 minutes of the first dose, a second dose of equal strength can be repeated. No more than two such doses should be given per breakthrough pain episode. Once the adequate pain relieving dose has been found, this dose should be used for further breakthrough pain episodes. Each breakthrough pain treatment should be separated by at least two hours and no more than four episodes should be treated every 24 hours.

### Therapeutic Alternatives

Onsolis (fentanyl buccal film)

Other immediate release opioid analgesics such as: hydrocodone (Hycodan); hydromorphone (Dilaudid); meperidine (Demerol); morphine sulfate (Statex); oxycodone (OxyIR, Supeudol).

### Clinical Notes

Abstral is a sublingual tablet formulation of fentanyl citrate that is dissolved under the tongue. Fentanyl is potent opioid pain medication with rapid onset of pain relief and short duration of action. Fentanyl is approximately 100-fold more potent than morphine as a pain reliever. Effects of fentanyl on central nervous system, respiratory and gastrointestinal function are typical of opioid pain medications and are considered to be effects common to that type of medication. Abstral should not be taken by patients who are not already tolerant to opioids because life-threatening reduction in breathing and death could result from any dose in patients not already taking opioid pain medications on a regular around-the-clock basis. For this reason, Abstral should not be used to treat pain other than chronic cancer pain; it should not be used for short-term pain such as pain from an injury or pain after a medical or dental procedure.

### Place in Therapy

Abstral should be used only to treat breakthrough cancer pain in cancer patients who are taking regularly scheduled doses of another narcotic (opiate) pain medication, and who are tolerant (used to the effects of the medication) to narcotic pain medications. It may provide more rapid pain relief than other fast acting pain medications.

### Comparative Pricing

	Abstral 200mcg	Onsolis 200mcg	Oxycodone 10mg	Hycodan 5mg	Hydromorphone 4mg	Statex 25mg
Estimated daily cost (based on four episodes per day)	Price not available	\$9.50**	\$1.25	\$4.00	\$1.00	\$1.00

\*\* price must be confirmed from manufacturer/distributor





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### Impact

Insufficient information – Pricing not available

### Plan Management Suggestions

To be determined based on pricing

### Rapaflo (silodosin)

<b>Dosage form</b> Capsule	<b>DIN &amp; Strength</b> 02361663 – 4mg 02361671 – 8mg	<b>Manufacturer</b> Watson Laboratories Inc.	<b>AHFS Class</b> 12:16.04 - Alpha adrenergic blocking agent
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### Indication(s)

Rapaflo is used in men to treat the symptoms of an enlarged prostate (benign prostatic hyperplasia; BPH), which include difficulty urinating (hesitation, dribbling, weak stream, and incomplete bladder emptying), painful urination, and urinary frequency and urgency.

### Dose

The recommended dose of Rapaflo® is 8 mg orally once daily with a meal. In patients with moderately reduced kidney function, the dose should be reduced to 4 mg once daily with a meal.

### Therapeutic Alternatives

terazosin (Hytrin and generics); doxazosin (Cardura and generics); tamsulosin (Flomax and generics); alfuzosin (Xatral and generics).

### Clinical Notes

Silodosin is in a class of medications called alpha-blockers. It relieves the symptoms of BPH by relaxing the muscles of the bladder and prostate. Silodosin controls the symptoms of BPH but does not cure it. Common side effects are similar to other drugs in this class (listed as therapeutic alternatives): orgasm with little or no semen (fluid) (called retrograde ejaculation), diarrhea, dizziness, and low blood pressure.

### Place in Therapy

Alpha-blockers such as Rapaflo usually provide prompt relief of symptoms of BPH. Rapaflo has properties and actions most similar to tamsulosin. It joins the four other alpha-blockers already on the market for BPH without appearing to demonstrate any significant therapeutic advantage over them.

### Comparative Pricing

	Rapaflo	Tamsulosin	Alfuzosin	Doxazosin	Terazosin
Estimated daily cost of treatment	Price not available	\$0.50	\$0.75	\$1.00	\$1.00





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### Impact

Low impact – many other alternatives available.

### Plan Management Suggestions

To be determined based on pricing.

### NEW DRUG COMBINATION

#### Vimovo (naproxen and esomeprazole)

<u>Dosage Form</u>	<u>DIN &amp; Strength</u>	<u>Manufacturer</u>	<u>AHFS Class</u>
Modified Release Tablet	02361701 – 375mg/20mg 02361728 – 500mg/20mg	AstraZeneca Canada, Inc.	28:08.04 – Non-steroidal anti-inflammatory drug (NSAID)

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### Indication(s)

Vimovo (naproxen/esomeprazole) is used to relieve pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints), rheumatoid arthritis, juvenile arthritis, and ankylosing spondylitis.

### Dose

The recommended daily dose of either strength is one tablet twice daily.

### Therapeutic Alternatives

Arthrotec (diclofenac/misoprostol); individual agents: naproxen (or other NSAID) + esomeprazole (or other Proton Pump Inhibitor [PPI]).

### Clinical Notes

Vimovo is a modified release oral tablet containing two ingredients: a pain medication called naproxen, and a medication to protect the stomach called esomeprazole. Naproxen is used to relieve pain, tenderness, swelling, and stiffness caused by osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. Naproxen is in a class of medications called nonsteroidal anti-inflammatory drugs (NSAIDs) that works by stopping the body's production of a substance that causes pain, fever, and inflammation.

Esomeprazole works by decreasing acid production in the stomach, thereby decreasing the chance that people who are taking NSAIDs will develop ulcers (sores in the lining of the stomach or intestine).

### Place in Therapy

Vimovo is effective in relieving the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, as well as reducing the risk of developing gastric ulcer in patients at risk of NSAID-associated gastric ulcer, particularly those with a history of NSAID induced gastric ulcer; however, it has not been tested for longer than 6 months. If the total daily required dose of esomeprazole is less than 40 milligrams daily, a different product should be used.





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### Comparative Pricing

	Vimovo 375/20	Naproxen 375mg + Nexium 40mg	Naproxen 375mg + Rabeprazole 20mg	Vimovo 500/20	Naproxen 500mg + Nexium 40mg	Naproxen 500mg + Rabeprazole 20mg
Estimated daily cost	\$2.10	\$2.72	\$1.17	\$2.10	\$3.11	\$1.57

### Impact

Minimal impact – other less expensive options available

### Plan Management Suggestions

Tiered formulary

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### Zenhale (mometasone furoate and formoterol fumarate)

Dosage Form	DIN & Strength	Manufacturer	AHFS Class
MDI – metered dose inhaler	02361744 - 50mcg/5mcg 02361752 - 100mcg/5mcg 02361760 - 200mcg/5mcg	Merck Canada Inc.	12:12:08 – Beta-aderenergic agonists

### Indication(s)

Zenhale (mometasone furoate and formoterol fumarate) is indicated for the maintenance treatment of asthma, in adults and children 12 years of age and older, whose asthma cannot be adequately controlled on other asthma controller medications.

### Dose

Zenhale should be administered as two inhalations twice daily (for all strengths).

### Therapeutic Alternatives

Advair, Symbicort

### Clinical Notes

The mometasone furoate is an inhaled corticosteroid (ICS) that acts to reduce the inflammatory process of asthma. It works by decreasing swelling and irritation in the airways to allow for easier breathing. Formoterol fumarate is a selective, long-acting, beta<sub>2</sub>-adrenergic receptor agonist (LABA) that works by relaxing and opening air passages in the lungs, making it easier to breathe.

### Place in Therapy

The Canadian Thoracic Society Asthma Management Continuum 2010 Consensus Summary states that when a low dose of ICS in adults or moderate dose of ICS in children six years of age and over together with other measures are insufficient to control asthma symptoms, then a combination inhaler containing both an ICS and a LABA is the preferred treatment option.







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### Impact

Minimal Impact

### Comparative Pricing

	Zenhale MDI	Advair Diskus	Advair MDI	Symbicort
Estimated cost per day	\$2.35 - \$3.70	\$1.35 - \$4.70	\$3.25 - \$4.70	\$1 - \$5.50

### Plan Management Suggestions

Product is priced in line with other therapeutic alternatives.

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### FIRST TIME GENERICS

#### First-Time Generic Drugs (Notice of Compliance from Nov 23, 2010 – Mar 2, 2011)

Generic Name	Reference Drug (Brand)	Rank by ingredient cost in 2010	Manufacturer	Route of Administration	Approved Indications
Exemestane	Aromasin	388	Genmed, a division of Pfizer Inc.	Oral	Adjuvant treatment of estrogen receptor-positive breast cancer in post-menopausal women
Pregabalin	Lyrica	14	Genmed, a division of Pfizer Inc.	Oral	Management of neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, and spinal cord injury; and pain due to fibromyalgia
Rosiglitazone/ Metformin	Avandamet	154	Pharmascience Inc	Oral	Type 2 diabetes mellitus
Docetaxel for Injection	Taxotere	1137	Hospira Healthcare Corporation.	Intravenous injection	Cancer (various types)
Amlodipine/ atorvastatin	Caduet	149	Genmed, a division of Pfizer Inc.	Oral	High blood pressure and high blood cholesterol

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## Policies and Legislation (PAL) Committee Update – 2011 Quarter 1

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### Ontario – Drug and Pharmacies Regulations Act

Ontario Regulation 58/11 has been passed in Ontario. The major changes involve the regulation of remote dispensing, opening the door to automated pharmacy systems, as well as the authority for a pharmacist to extend, under certain conditions, prescription refills. The Regulation also includes terms and conditions around pharmacy bookkeeping, accreditation of pharmacies, condition of sale for the different drug schedules, pharmacy advertising and conflict of interests.

Regarding prescriptions refills, these can be authorized by a pharmacist without a further prescription from a prescriber. In order for a pharmacist to do so, he/she must reasonably believe that:

1. reasonable efforts to contact the prescriber have been made and were unsuccessful;
2. the prescriber of the prescription to be refilled, if available, would have authorized the refill;
3. the patient for whom the drug is to be refilled has been prescribed the drug for a chronic or long term condition; and
4. the patient for whom the drug is to be refilled has a stable history with that drug.

If these four conditions are met, the total amount of the drug dispensed pursuant to the refill shall not exceed the amount of the drug previously dispensed by the pharmacy or a three months supply, whichever is less.

The following administrative conditions must also be met for the refill to be authorized:

1. A unique prescription identification number must be assigned to the refill prescription.
2. The assigned prescription identification number and the name of the original prescriber must be in the pharmacy's patient record.
3. The fact that the refill has been made with the authorization of a pharmacist and the name of that pharmacist must be recorded on the pharmacy's patient record.
4. Within seven days of the refill prescription, the pharmacy must send to the prescriber and, if known to the pharmacy and different from the prescriber, to the patient's primary health care provider, a report that includes (i) notice that a refill of the prescription was made on the authorization of a pharmacist; and (ii) the date, drug and quantity of drug dispensed by virtue of that refill.

Please note that pharmacist refills are not possible if the prescription is for a narcotic drug, a verbal prescription narcotic or a controlled drug.

#### Impact:

Private plans will now see claims being filled and submitted by remote dispensing locations using an automated dispensing system to dispense directly to members. Impact of such a change on plan sponsors will depend on the dispensing fees and mark-up charged by such pharmacies for their services, versus traditional model pharmacies where these scripts were previously filled.

As for the new rights regarding pharmacy initiated refills, this will extend by a maximum of 3 months the duration of the original scripts. As above, the conditions are very limitative and every effort should be made to contact the prescribing physician. The ability for pharmacists to extend maintenance scripts is to help ensure patients do not go without their medications. Often, today, pharmacists will loan patients tablets until a new script is written – this legislation gives them legal authority to fill 90 days.

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Source:

[http://www.e-laws.gov.on.ca/html/reg/english/elaws\\_regs\\_110058\\_e.htm](http://www.e-laws.gov.on.ca/html/reg/english/elaws_regs_110058_e.htm)

#### Quebec – Wholesaler maximum margin

On February 28, 2011, the Institut national d'excellence en santé et en services sociaux (INESSS) announced they had proposed a modification to the *Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized* in order to increase the maximum margin from 6% to 6.25%, as of April 1, 2011 and from 6.25% to 6.50% as of April 1, 2012. As for the limited maximum mark-up amount on certain drugs, it would be increased to \$37.50 (from \$24). As such, price criteria for the maximum to be applied would be increased from a minimum of \$400 to 600\$. If accepted, the application of these new margins would be effective with the new list on April 20, 2011.

Impact:

The increased acquisition cost for pharmacies could translate in an increase of a pharmacies' usual and price, thus an increased cost for plan sponsors.

Sources:

<http://www.cdm.gouv.qc.ca/site/download.php?f=dfc20bb5fc64a98bdd8f785c3c8fb674> (French only)

[http://www.ramq.gouv.qc.ca/fr/publications/documents/acces\\_info/reglement\\_conditions\\_reconnaissance.pdf](http://www.ramq.gouv.qc.ca/fr/publications/documents/acces_info/reglement_conditions_reconnaissance.pdf)  
(French only)

#### Saskatchewan – Pharmacist Prescribing Authority

Regulatory amendments have been made in Saskatchewan, in order to authorize pharmacists to provide services such as extending refills on existing prescriptions and provide emergency supplies of prescribed medications. In the near future, Saskatchewan pharmacist will be able to prescribe certain medications for minor ailments (if the pharmacist believes a minor condition can be better treated with a prescription rather than an OTC medicine).

Sources:

<http://www.gov.sk.ca/news?newsId=8fdd32e2-a63b-43a1-b480-5b54be396516>

<http://www.mypharmacistknows.com/site/>

#### Ontario – Private-label generic drugs

On February 3, 2011, an Ontario Court ruled that legislation banning pharmacies from substituting a brand name drug for their own private-label generic drug could not be enforced. Since then, the Ontario Government has appealed the decision.

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