



# Health Newsflash – a Quarterly Publication

## New Drugs and Pipeline News Reviewed at the January to March 2010 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

#### Adcirca (tadalafil)

Dosage Form	DIN & Strength	Manufacturer	AHFS Class
Oral tablet	02338327 – 20mg	Eli Lilly Canada Inc.	24:12.12- Phosphodiesterase inhibitors

#### Indication(s)

For the treatment of idiopathic (“primary”) pulmonary arterial hypertension (PAH) or PAH associated with connective tissue disease, congenital heart disease or anorexigen use in people with WHO functional class II or III who have not responded to conventional therapy.

Pulmonary arterial hypertension (PAH) is an increase in pressure (due to blockage or improper blood flow) in the pulmonary artery, the artery that carries blood from the heart to the lungs to pick up oxygen. PAH is a rare disease, with an estimated prevalence of 30-50 cases per million. PAH is an incurable disease, with survival between 3 to 5 years depending on disease severity. Disease progression may lead to angina, heart failure, and death.

#### Dose

Adcirca is taken 40mg once daily. It is not recommended to divide the dose over the course of the day.

#### Therapeutic Alternatives

Endothelin Receptor Antagonists – Thelin (sitaxsentan), Volibris (ambrisentan), Tracleer (bosentan)  
Prostacyclins – Remodulin (treprostinil), Flolan (epoprostenol)  
Phosphodiesterase type 5 (PDE5) Inhibitors – Revatio (sildenafil)

#### Clinical Notes & Place in Therapy

Tadalafil is an inhibitor of the enzyme PDE5 preventing its function to break down nitric oxide. Nitric oxide is made naturally and allows for the dilation of blood vessels thereby increasing blood flow.

Tadalafil is used in patients with PAH class II or III and is used to improve exercise ability. It's oral formulation and once daily administration provides much convenience over other treatment options (IV endothelin receptor antagonists and IV prostacyclins).

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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

	Adcirca (tadalafil) 20mg	Revatio (sildenafil) 20mg (Rank 570)	Tracleer (bosentan) 125mg (Rank 207)
Approximate Cost per Patient per Year	\$9500/year	\$12,000/year	\$49,000/year

### Impact

Intermediate impact

### Plan Management Suggestions

Prior Authorization

## Afinitor (everolimus)

Dosage Form	DIN & Strength	Manufacturer	AHFS Class
Oral tablet	02339501 – 5mg 02339528 – 10mg	Novartis	10:00.00 Antineoplastic

### Indication

For patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy such as Sutent (sunitinib) or Nexavar (sorafenib).

### Dose

10mg orally once daily. Treatment is continued until disease progression or unacceptable toxicity.

### Therapeutic Alternatives

- Sorafenib (Nexavar) – 400mg orally twice daily.
- Sunitinib (Sutent) – 50mg orally daily for 28 days every 42 days
- Temsirolimus (Torisel) – 25mg IV infused once weekly

### Clinical Notes & Place in Therapy

Renal Cell Carcinoma is a very aggressive form of cancer. Approval of Afinitor is based on progression-free survival - individuals whose disease remains stable and does not worsen. In a randomized, double-blind, placebo-controlled, multicenter Phase III study, Afinitor had a median progression-free survival of 4.9 months vs. 1.9 months with placebo. There are limited treatment options for kidney cancer. According to Cancer Care Ontario, interferon alfa, Nexavar and Sutent are all considered as core standard therapy. Afinitor is used as a second or later line of treatment in Canada.





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## Comparative Pricing

	Afinitor (everolimus) 10mg	Sutent (sunitinib) 50mg	Nexavar (sorafenib) 200mg	Torisel 25mg I.V
Approximate Cost Per Patient Per Year	\$71,000**	\$66,000	\$69,500	\$68,500

\*\* Duration of survival (4.9 months) should be taken into consideration for anticipated therapy cost

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## Impact

Minimal to Intermediate Impact

## Plan Management Suggestions

Prior Authorization or list Afinitor similar to other oral antineoplastic agents for treating kidney cancer.

## Targin (oxycodone/naloxone)

Dosage Form	DIN & Strength	Manufacturer	AHFS Class
Oral tablet	02339609 - 10mg/5mg 02339617 - 20mg/10mg 02339625 - 40mg/20mg	Purdue Pharma	28:08.08 - Opioid agonist

## Indication

No official listing for Canadian Indication(s). Targin® is a combination of a strong opioid receptor agonist, oxycodone, and a locally acting opioid receptor antagonist, naloxone. The oxycodone provides pain relief while naloxone prevents opioid-induced constipation.

## Dose

To be taken twice daily. The maximum daily dose is limited to 40 mg of oxycodone and 20 mg of naloxone.

## Therapeutic Alternatives

Opioid analgesics - codeine, morphine, oxycodone, hydrocodone

## Clinical Notes

Targin is a combination of a strong opioid receptor agonist, oxycodone, and a locally acting opioid receptor antagonist, naloxone. The oxycodone provides the analgesic effect in the central nervous system while the naloxone, exerts its effect only in the gut preventing the onset of opioid-induced constipation.





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### Place in Therapy

All Opioids can cause constipation; Targin would be an effective alternative for patients where treatments for opioid induced constipation such as Senokot and stool softeners are inadequate.

### Impact

Insufficient information - difficult to assess impact without pricing information.

### Plan Management Suggestions

Tiered formulary listing is likely appropriate.

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## Vidaza (azacitidine)

<u>Dosage Form</u>	<u>DIN &amp; Strength</u>	<u>Manufacturer</u>	<u>AHFS Class</u>
Powder for Injection	02336707 – 100mg/vial	Celgene	10:00.00 Antineoplastics

### Indications

1. Adults with Myelodysplastic Syndrome (MDS), intermediate-2 and high-risk according to the International Prognostic Scoring System (IPSS) who are not eligible for stem cell transplant
2. Adults with Acute Myeloid Leukemia (AML), with 20-30% blasts and multi-lineage dysplasia, according to the WHO classification who are not eligible for stem cell transplant

MDS is the pre-cursor condition of AML, and both are characterized by an abnormal clone of immature blood cells in the bone marrow.

### Dose

75 mg/m<sup>2</sup> of body surface area by subcutaneous injection daily for 7 days, followed by rest period of 21 days (28 days per cycle). Continued as long as the patient still benefits or intolerable to toxicity occurs. Recommend to continue a minimum of 6 cycles.

### Therapeutic Alternative

- Chemotherapy – very individualized. Acute Leukemia is treated with aggressive chemotherapy and patients require intensive supportive treatment; such patients should be managed by a specialist hematologic oncology unit. The most common remission induction therapy is cytarabine + daunorubicin, followed by a consolidation therapy containing high dose cytarabine.
- Stem cell transplant
- Supportive drug therapies





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### Clinical Notes & Place in Therapy

Vidaza was accepted for Rapid Review by The Ontario Ministry of Health Joint Oncology Drug Review (JODR) based on its clinical data. There is an estimated 1000 – 1500 cases per year in Canada. Median age at diagnosis is 76 years old. There are limited effective treatment options for these conditions and the key treatment is stem cell transplant. If patient is ineligible for transplant, therapy has been supportive care only. Vidaza provides a pharmacologic treatment option for this specific population.

Vidaza (azacitidine) 100mg/vial	
Recommended Dose	75 mg/m <sup>2</sup> daily for 7 days (28 day cycle)
Approx Cost Per Cycle	\$8,792/28 day cycle (using BSA of 1.8 m <sup>2</sup> )

### Impact

Intermediate impact – though incidence is low, annual cost is relatively high.

### Plan Management Suggestions

Prior Authorization

### First-Time Generic Drugs (Notice of Compliance From Nov 23, 2009-Feb 19, 2010)

Generic Name	Reference Drug (Brand)	Rank by ingredient cost in 2008	Manufacturer	Route of Administration	Approved Indications
sibutramine	Meridia	142	Apotex Novopharm	Oral tablet	Weight management
naratriptan	Amerge	180	Novopharm Sandoz	Oral tablet	Migraines
dorzolamide	Trusopt	651	Sandoz	Eye drop	Elevated intraocular pressure (ocular hypertension or open-angle glaucoma)
methylphenidate – ER-C	Concerta	18	Novopharm	Oral tablet	Attention Deficit Hyperactivity Disorder
*diclofenac/misoprostol	Arthrotec	78	Genmed (a division of Pfizer)	Oral tablet	Rheumatoid arthritis and osteoarthritis
*eletriptan	Relpax	218	Genmed (a division of Pfizer)	Oral tablet	Migraines
*quinapril-HCTZ	Accuretic	237	Genmed (a division of Pfizer)	Oral tablet	Hypertension
risedronate	Actonel	38	Novopharm	Oral tablet	Osteoporosis and Paget's Disease
finasteride	Proscar	146	Sandoz	Oral tablet	Benign prostatic hyperplasia

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Generic Name	Reference Drug (Brand)	Rank by ingredient cost in 2008	Manufacturer	Route of Administration	Approved Indications
metformin-ER	Glumetza	19 (for all metformin)	Apotex	Oral tablet	Type 2 Diabetes
ramipril-HCTZ	Allace-HCTZ	233	Pharmascience	Oral tablet	Hypertension
dorzolamide/timolol	Cosopt	279	Sandoz	Eye drop	Elevated intraocular pressure (ocular hypertension or open-angle glaucoma)

\*Note – The first time generics of Arthrotec, Accuretic, and Relpax are all filed by GenMed, a division of Pfizer. Despite the Notice of Compliance approvals, it is not expected that these products will be available on the market anytime soon. Generics of Viagra (GD-sildenafil) and Celebrex (GD-celecoxib) have received NOC approvals since 2007, however, the patents of both brands have not yet expired and the generics are still not available on the market.

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### Policies and Legislation (PAL) Committee Update – 2010 Quarter 1

#### **Québec – Drug Cost Increase for 2010 - Update**

In our previous edition, we had indicated that the 2010 increase for formulary drugs would not exceed 0.48%. However, since then, Alberta announced that the maximum price increase in Alberta would be 0.3% for 2010. As the Alberta price increase is now lower than the one in Quebec, the Conseil du Médicament has informed manufacturers that had already submitted their price increase request that they will need to correct their requests for 2010.

Source:

<http://www.cdm.gouv.qc.ca/site/download.php?f=2709518c0e43be11be07ee5b322315e4> (French only)

#### **Alberta – Second phase of Alberta’s Pharmaceutical Strategy - Update**

As we had previously reported in our last edition, the Alberta Government indicated they would “significantly” reduce the price of existing generic drugs (generic drugs already included on the Alberta Drug Benefit List as of October 1, 2009) at the beginning of April 2010. On January 28, 2010, the Alberta Government announced that on April 1, 2010, the price of currently available or existing generic drugs will be reduced from 75% to 56% of the price of comparable brand name drugs.

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#### Impact:

The reductions in generic prices will reduce costs for private plans in Alberta as these prices apply to "all Albertans". These price reductions might also reduce costs for private plans in Quebec where the lowest price rule applies, however, Quebec is already following the Ontario Public Drug Program's 50% pricing for generics that are on the Ontario formulary. In addition, the impact of the ingredient cost decrease on private payers is not directly measurable in Quebec as pharmacies are reimbursed under the U&C model.

#### Source:

<http://alberta.ca/home/NewsFrame.cfm?ReleaseID=/acn/201001/277267697CCF8-C8B8-B2D6-D4419AFAE7D72E85.html>

#### Optimizing the Value of Health Benefits

#### Nova Scotia – Pharmacist prescribing rights

Recent changes in regulations made under the Pharmacy Act have introduced prescribing powers of pharmacists. Pharmacists now can:

- refill, extend or adapt prescriptions, and prescribe certain drugs, using his or her judgment (when making any change to a prescription, the pharmacist must notify the person who prescribed it);
- continue prescriptions for more than 30 days if appropriate
- provide certain medications to patients when their doctor is not available;
- change prescriptions to avoid delays dispensing them to patients; and
- prescribe drugs typically sold from behind the counter or from the area right in front of the pharmacist.

This new legislation also allows the College of Pharmacists to develop, in consultation with other colleges, standards of practice which would allow pharmacists to prescribe drugs to treat some conditions (including drugs presently prescribed only by doctors, dentists or nurse practitioners).

#### Impact:

We do not anticipate impacts on private plans.

#### Sources:

<http://www.gov.ns.ca/just/regulations/regs/pharmdrugrx.htm>

<http://www.gov.ns.ca/news/details.asp?id=20100127001>

#### Canada – Transition provisions / *Natural Health Products Regulations*

The 6-year transition period included in the *Natural Health Products Regulations* (SOR/2003-196) ended on December 31, 2009 and therefore, any DINs issued before January 1, 2004 for natural health products should have been replaced by a natural product number (NPN). After an NPN is issued for a product that once had a DIN, the older label stock (bearing the DIN) may still be used and found on the labels of NHPs on the market for a period of 6-12 months. Natural health products introduced after January 1, 2004 already have an NPN.

For a list of included and excluded natural health product substances please refer to Schedule 1 and 2 of the *Natural Health Products Regulations* (SOR/2003-196).

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## Policies and Legislation (PAL) Committee Update – 2010 Quarter 1



**Impact:**

Carriers need to make sure their drug plans include the up to date NPN's. ESI Canada has a process in place to share the newly listed NPNs at our monthly Validation committee meetings.

**Source:**

<http://www.canlii.org/en/ca/laws/regu/sor-2003-196/latest/sor-2003-196.html>

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