Health Newsflash – A Quarterly Publication

New Drugs and Pipeline News Reviewed at the January to March 2013 DEC Meetings

The Drug Evaluation Committee (DEC) of Express Scripts Canada conducts monthly reviews of all new drugs receiving their Notice of Compliance from Health Canada , to ascertain their place in therapy and their possible impact on the private payer sector. The prices quoted in this document are approximations for general information purposes only, and are not intended, nor should they be relied upon, for purposes of any actual claims adjudication or reimbursement. This publication, describing new drugs of significance, is provided to our 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

Bystolic (nebivolol hydrochloride)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet	02398990 – 2.5mg 02399008 – 5mg 02399016 – 10mg 02399024 – 20mg	Forest Laboratories Canada Inc.	24:24.00 – Beta-Adrenergic Blocking Agents

Indication(s)

Canadian Product Monograph not available; information from US Prescribing Information
Bystolic is a beta-adrenergic blocking agent indicated for the treatment of hypertension, to lower blood pressure. Bystolic may be used alone or in combination with other antihypertensive agents.

Dose

The dose of Bystolic must be individualized to the needs of the patient. The recommended dose is 5 to 40mg per day, as monotherapy or in combination with other agents.

Therapeutic Alternatives

Beta-blockers: carvedilol, bisoprolol

Clinical Notes

Bystolic (nebivolol) is a long-acting cardioselective beta-1 adrenoceptor antagonist without membrane stabilizing or intrinsic sympathomimetic activities. Beta-blockers antagonize the effects of sympathetic neurotransmitters by competing for beta-1 and beta-2 receptor binding sites. Beta-1 cardioselective agents (eg, atenolol, nebivolol) primarily block receptors located in cardiac tissue; however, cardioselectivity tends to diminish as the dose increases and beta-2 adrenoceptors are antagonized as well. The antihypertensive mechanism of beta-blockers is related to decreased cardiac output (negative inotropic and chronotropic effects), reduced adrenergic activity, and inhibition of renin release. Nebivolol has been shown to suppress plasma renin and aldosterone levels. Nebivolol also appears to possess nitric oxide-mediated vasodilatory properties. Carvedilol also has some vasodilatory properties but through a different mechanism. Nebivolol has demonstrated efficacy in lowering blood pressure in patients with mild to moderate hypertension.

Beta-blockers are not recommended as first-line treatment for hypertension as compared to other classes of drugs due to their modest effect on stroke and no significant reduction in mortality or coronary heart disease. A recent Cochrane review found that first-line beta-blockers for elevated blood pressure were not as good at decreasing mortality and morbidity as other classes of drugs: diuretics, calcium channel blockers, and renin angiotensin system inhibitors (e.g., ACE inhibitors, angiotensin receptor blockers).

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Place in Therapy

Bystolic is indicated for treatment of hypertension as monotherapy or in combination with other agents. CHEP guidelines consider beta-blockers to be an alternative to a diuretic as initial monotherapy in younger patients (< 60 years of age) without compelling indications for specific agents.

Comparative Pricing

	Bystolic	Apo-Bisoprolol	PMS-Carvedilol
Unit cost	Not available	5mg: $0.10 10mg: $0.15	3.125mg: $0.34 6.25mg: $0.34 12.5mg: $0.34 25mg: $0.34
Annual cost	Not available	$37-$55	$125

Impact/ Plan Management Suggestions

Insufficient information

Diacomit (stiripentol)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Capsule, Oral powder for suspension	02398958 – 250mg/capsule 02398966 – 500mg/capsule 02398974 – 250mg/packet 02398982 – 500mg/packet	Biocodex SA	28:12.92 – Miscellaneous Anticonvulsants

Indication(s)

Canadian Product Monograph not available; information from European Medicines Agency Summary of Product Characteristics
Diacomit is indicated for use in conjunction with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, also called Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate.

Dose

The dose of Diacomit is calculated on a mg/kg body weight basis. The daily dosage may be administered in 2 or 3 divided doses. The initiation of adjunctive therapy with Diacomit should be undertaken over 3 days using upwards dose escalation to reach the recommended dose of 50 mg/kg/day administered in conjunction with clobazam and valproate.

Therapeutic Alternatives

Valproate, topiramate, levetiracetam, clobazam, the Ketogenic Diet

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Clinical Notes

Severe myoclonic epilepsy in infancy (SMEI, Dravet's Syndrome) is a rare disorder with an incidence ranging between 1 per 20,000 to 1 per 40,000 children, and affects males twice as often as females. It is by febrile or afebrile generalized tonic–clonic and often prolonged unilateral or generalized clonic seizures, occurring from the first year of life in an otherwise normal infant. Later on, myoclonus, absence, and partial seizures may appear. In its typical form, patients carry a high risk of mental retardation and behavioral disorders after age 2. Long-term follow-up of a series of patients suggests that seizures have a deleterious effect on cognitive development. Psychomotor development is retarded from the second year of life onwards, including development of ataxia, pyramidal signs and interictal myoclonus. Experience with this form of epilepsy shows it to be very resistant to most forms of currently available treatment and may even be worsened by some of them (e.g., vigabatrin, lamotrigine).

The source of anticonvulsant activity of stiripentol is not known, but it is purported to be due partly by direct anticonvulsant activity related to effects on GABA and also by potentiation of the efficacy of some other antiepileptics as the result of pharmacokinetic or pharmacodynamic interactions. In particular: a) stiripentol does not act as a GABA receptor agonist but instead it inhibits the synaptosomal uptake of radiolabelled GABA; b) the effect of stiripentol is based on an inhibition of cytochrome P-450 isoenzymes involved in the hepatic catabolism of other antiepileptic drugs (inhibition by stiripentol of several isoenzymes, in particular 3A4, 1A2 and 2C19). Stiripentol has been used in clinical trials in other forms of epilepsy such as Lennox-Gastaut syndrome, and in preliminary studies that included all forms of epileptic syndromes. Amongst all these types of epilepsy, subjects with SMEI appeared to have the best response in open studies. In a randomized, double-blind trial (n=41), stiripentol as add-on therapy to valproate and clobazam reduced clonic and tonic-clonic seizure frequency to a significantly greater extent than did add- on placebo in children with SMEI (mean age, 9.35 years). Overall, 15 of 21 children (71%) in the stiripentol group had at least a 50% reduction in seizure frequency (clonic or tonic-clonic) compared to 1 of 20 (5%) in the placebo group (p less than 0.0001). Nine patients in the stiripentol group became seizure-free compared to none in the control group (p=0.0013). Seizure frequency decreased 69% from baseline among stiripentol-treated children and increased 7% among controls; median number of seizures in 1 month was 5 and 14 in stiripentol- and placebo-treated children, respectively (p=0.0063).

Place in Therapy

Stiripentol has been proven to be useful when combined with valproate and clobazam in SMEI, a rare but highly deleterious and difficult to treat form of childhood epilepsy.

Comparative Pricing

	Diacomit	Topamax Sprinkle Capsules	Apo-Topiramate	Apo-Levetiracetam
Unit cost	Not available	15mg: $1.25 25mg: $1.30	25mg: $0.35 100mg: $0.60 200mg: $0.90	250mg: $1.15 500mg: $1.40 750mg: $2.00

Annual costs are indeterminate because doses are weight based and individualized.

Impact/Plan Management Suggestions

Insufficient information

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Adcetris (brentuximab vedotin)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet	02401347 – 50mg/vial	Seattle Genetics Inc.	10:00.00 – Antineoplastic agents

Indication(s)

Canadian Product Monograph not available; information from US Prescribing Information

Notice of Compliance with Conditions (NOC/c):
Adcetris (brentuximab vedotin) is indicated for the treatment of patients with:

- **Hodgkin lymphoma** (HL) after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates
- **Systemic anaplastic large cell lymphoma** (sALCL) after failure of at least one prior multi-agent chemotherapy regimen.

Dose

The recommended dose is 1.8 mg/kg administered only as an intravenous infusion over 30 minutes every 3 weeks. The dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg. Continue treatment until a maximum of 16 cycles, disease progression or unacceptable toxicity.

Therapeutic Alternatives

None for HL
For sALCL: salvage chemotherapy such as EPOCH (etoposide, vincristine, and doxorubicin), ESHAP (etoposide, cisplatin, cytarabine, prednisone), or ICE (ifosfamide, carboplatin, etoposide) [all of these deliver 25-30% remission rate at best which lasts < 1 year]

Clinical Notes

Approval for the indications noted above are based on response rate. Currently there are no data available demonstrating improvements in patient reported outcomes or survival with Adcetris.

Brentuximab vedotin is a CD30-directed antibody-drug conjugate (ADC) consisting of three components: 1) the antibody cAC10, specific for human CD30, 2) the potent antimicrotubule agent monomethyl auristatin E (MMAE), and 3) a protease-cleavable linker that covalently attaches MMAE to cAC10. The biological activity of brentuximab vedotin results from a multi-step process. Binding of the ADC to CD30 on the cell surface initiates internalization of the ADC-CD30 complex, which then travels to the lysosomal compartment. Within the cell, MMAE, is released via proteolytic cleavage. Binding of MMAE to tubulin disrupts the microtubule network within the cell, induces cell cycle arrest, and results in apoptotic death of the CD30-expressing tumor cell.

Hodgkin lymphoma is a neoplasm of lymphoid tissue that is histopathologically defined by the presence of Hodgkin Reed-Sternberg cells in a background of inflammatory cells. The characteristic surface antigen expressed on Hodgkin Reed-Sternberg cells is CD30. The mean age of HL patients at diagnosis is 38 years with 90% of patients < 60 years. Approval for use in HL was based on positive response rates (complete and partial remission, CR/PR) in a Phase II single arm clinical trial. The overall response rate (ORR, CR+PR) was 73-75%.

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Systemic ALCL is a subtype of mature T- and NK-cell lymphomas characterized by the uniform expression of the cell surface antigen CD30. sALCL is a rare T-cell non-Hodgkin lymphoma. 40-60% of patients develop recurrent disease. Only 25-30% of patients achieve a second complete remission which then lasts < 1 year. Approval for use in sALCL was based on a single-arm Phase II clinical trial which demonstrated an ORR of 86%.

Several serious side effects have been associated with the use of this drug including: progressive multifocal leukoencephalopathy (PML), neutropenia, peripheral sensory neuropathy, infusion reactions and Stevens-Johnson syndrome. The most significant of these is peripheral neuropathy which occurred in 48% of all patients, 79% of these have persistent neuropathy. This appears to be linked to the overall cumulative exposure to the drug.

Place in Therapy

Adcetris would be an alternative to salvage therapy in patients who have relapsed on multiple prior therapies for both HL and sALCL.

Pricing

	Adcetris
Unit cost	Not available
Annual cost	Not available

Impact/Plan Management Suggestions

Insufficient information

Picato (ingenol mebutate)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Topical gel	02400987 – 0.015% 02400995 – 0.05%	Leo Pharma Inc.	84:92.00 – Miscellaneous Skin and Mucous Membrane Agents

Indication(s)

Picato (ingenol mebutate) gel is indicated for the topical treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.

Dose

Actinic keratosis on the face and scalp Picato® gel, 0.015% should be applied to the affected area once daily for 3 days. For the treatment of actinic keratosis on the trunk and extremities Picato® gel, 0.05% should be applied to the affected area once daily for 2 days.

Therapeutic Alternatives

Efudex (5-fluorouracil); Zyclara (imiquimod), Aldara (imiquimod)

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Clinical Notes

Actinic keratosis (AK) is a commonly occurring skin disease in fair-skinned people of advanced age that results from cumulative ultraviolet irradiation. AK is widely regarded as the initial clinical manifestation of a disease continuum in sun-damaged skin that may ultimately result in invasive squamous cell carcinoma. Ingenol mebutate is a diterpene ester extracted and purified from the plant Euphorbia peplus. The sap of this plant, also known as petty surge or radium weed, has a history of use as an alternative therapy for skin diseases. The efficacy of ingenol mebutate is thought to involve multiple mechanisms. While the exact mechanisms of action are currently uncertain, it is thought that initially at high concentrations, there is initial rapid and direct cell death; this is followed by a second phase involving a complex inflammatory response. This dual mechanism allows for clearance rates with 2-day or 3-day treatment regimens that are comparable to those achieved with other therapies that require longer treatment periods (e.g., 4-weeks with 5-fluorouracil; 2-3-weeks with imiquimod).

Treatment regimens for other AK therapies:

- **Aldara 3.75% Cream**: Apply (maximum of 1 full packet) twice a week for 16 weeks. Rest periods are permitted as required due to local skin irritation.
- **Zyclara 5% Cream**: Apply (up to a maximum of 2 packets) once daily for 2 weeks, followed by a 2-week no-treatment period, followed by another 2-week treatment period. (total 6 weeks)
- **Efudex 5% Cream**: Apply twice daily until full response (erosion, ulceration, necrosis stage) has occurred [response sequence: erythema, vesiculation, erosion, ulceration, necrosis, and epithelisation], usually two to four weeks. Complete healing may take up to two months following cessation of therapy.

Significant adverse local skin reactions are common with all therapies which frequently lead to non-adherence to treatment (early cessation) and subsequent suboptimal therapeutic outcomes. Since the treatment course for Picato is much shorter than for the other alternative therapies, it is likely that treatment would have been fully completed prior to the need to discontinue the treatment due to adverse skin reactions.

Place in Therapy

Picato is an alternative treatment for AK that provides equivalent efficacy to existing treatments (when used for their full treatment courses) with shorter treatment courses required. This will improve adherence to treatment compared to therapeutic alternatives.

Comparative Pricing

	Picato	Efudex	Zyclara	Aldara
Unit cost (per package)	$405	$35	$310	$375
Maximum cost of one course of treatment	$405	Undetermined	$620	$750

Impact/Plan Management Suggestions

Minimal impact. Picato offers a lower cost alternative to existing therapies with the potential for improved treatment adherence and outcomes.

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Myrbetriq (mirabegron)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet, Extended-release	02402874 – 25mg 02402882 – 50mg	Astellas Pharma Canada Inc.	86:12.00 – Genitourinary smooth muscle relaxants

Indication(s)

Canadian Product Monograph not available; information from US Prescribing Information
Myrbetriq is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Dose

The recommended dose of Myrbetriq is 25 to 50 mg once. Myrbetriq 25 mg is effective within 8 weeks.

Therapeutic Alternatives

Anticholinergic drugs: oxybutynin [immediate release, extended release]; Detrol/LA (tolterodine); Enablex (darifenacin); Toviaz (fesoterodine); Vesicare (solifenacin); Trosec (trospium)

Clinical Notes

Mirabegron, a beta-3 adrenergic receptor agonist, activates beta-3 adrenergic receptors in the bladder resulting in relaxation of the detrusor smooth muscle during the urine storage phase, thus increasing bladder capacity. At usual doses, mirabegron is believed to display selectivity for the beta-3 adrenergic receptor subtype compared to its affinity for the beta-1 and -2 adrenoceptor subtypes.

Mirabegron was approved by the US Food and Drug Administration in June 2012 for the treatment of overactive bladder, on the basis of three randomized trials that demonstrated reduced urinary frequency and wetting episodes for patients assigned to medication compared to placebo. The most common side effects observed in the trials were increased blood pressure, nasopharyngitis, urinary tract infection, constipation, fatigue, tachycardia, and abdominal pain. Mirabegron is not recommended for use in those with severe uncontrolled high blood pressure. Evidence of cytochrome P450 (CYP) 2D6 inhibition in clinical trials highlighted a concern for pharmacokinetic interaction with other drugs that are CYP2D6 substrates (eg, metoprolol). Further trials are ongoing to evaluate long-term efficacy, safety, and tolerability.

Place in Therapy

Myrbetriq represents a new drug with a novel mechanism of action which provides an alternative therapy for OAB. It may be particularly useful for those patients who are unable to tolerate anticholinergic drugs. There is a different set of adverse effects associated with drug compared to anticholinergics. There are no data available comparing mirabegron with other OAB treatments.

Comparative Pricing

	Myrbetriq	Apo-Oxybutynin	Detrol-LA
Unit cost	Not available	5mg: $0.10	2mg: $2.01 4mg: $2.05
Annual cost	Not available	$150	$735-$750

Impact/Plan Management Suggestions

Insufficient information

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NEW INDICATION

Soliris (eculizumab)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Intravenous injection	02322285 – 300mg/30ml vial	Alexion Pharma Canada	92:32.00 – Complement inhibitors

Indication(s)

New indication: Treatment of patients with atypical hemolytic uremic syndrome (aHUS) to reduce complement-mediated thrombotic microangiopathy (TMA). For adults and adolescents aged 13-17 weighing more than 40kg, marketing authorization without conditions has been issued.

For children less than 13 years of age and/or weighing less than 40kg, marketing authorization with conditions has been issued for aHUS. [NOC/c] Soliris is not indicated for the treatment of patients with Shiga toxin-producing E. coli related hemolytic uremic syndrome (STEC-HUS).

Dose

The recommended dosage regimen in aHUS is as follows:
For patients 18 years of age and older, Soliris therapy consists of:

- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter

For patients less than 18 years of age, administer Soliris based upon body weight as described in the Product Monograph.
NB: dose for aHUS is higher than for paroxysmal nocturnal hemobloginuria (PNH).

Soliris is administered by intravenous infusion over 35 minutes by gravity feed or an infusion pump. The drug should be administered immediately after mixing.

Therapeutic Alternatives

None besides supportive care including hemodialysis, kidney transplantation (+/- liver transplantation), plasma therapy (plasma infusion, plasma exchange)

Clinical Notes

In aHUS, a genetic mutation causes impairment in the regulation of complement activity leading to uncontrolled complement activation, resulting in platelet activation, endothelial cell damage and TMA, subsequently leading to progressive systemic end-organ damage, and mortality. Eculizumab inhibits this process by specific blockade of terminal complement.

Eculizumab is a high affinity monoclonal antibody that specifically binds the complement protein C5 and thereby inhibits the chronic terminal complement activity, thereby blocking complement mediated intravascular hemolysis and subsequent morbidities in PNH patients as well as blocking complement mediated TMA and subsequent organ damage in aHUS.

aHUS is considered to be an ultra-rare disease with a prevalence rate of 2 to 3 per million children. Because the complement mediated activity is on-going, eculizumab treatment will have to be continued for a patient's lifetime.

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Place in Therapy

Soliris is the only medical treatment for aHUS that has demonstrated efficacy in preventing or even reversing end organ damage in patients with this rare disease.

Pricing

		Soliris
Unit cost		$6,742/30ml vial (10mg/ml)
Annual cost	aHUS	Year 1: $728,136 Subsequent years: $701,168
	PNH	Year 1: $539,360 Subsequent years: $525,876

Impact/Plan Management Suggestions

Soliris is a very high cost drug indicated for use in two rare diseases, paroxysmal nocturnal hemoglobinuria and now, atypical hemolytic uremic syndrome. While utilization of this drug for aHUS is expected to be very low (less than 60 individuals across Canada), it can have a very high impact on plans that may be required to cover this. In July 2011, Canadian provincial premiers in the Council of the Federation agreed to pool their resources to purchase Soliris as a group for provision to citizens thorough public drug coverage, which could impact about 90 individuals with PNH in Canada. In Ontario, this drug was added to the Exceptional Access Program for use in PNH in September 2011.

FIRST TIME GENERICS

First-Time Generic Drugs (Notices of Compliance from Dec 6, 2012 to Mar 5, 2013)

Generic Name	Reference Drug (Brand)	Rank by ingredient cost in 2012	Manufacturer	Route of Administration	Approved Indications
Fluvastatin sodium	Lescol	506	Teva Canada Incorporated	Oral	High blood cholesterol
Darunavir ethanolate	Prezista	218	Patriot, a division of Janssen Inc.	Oral	Treatment of HIV infection
Zoledronic acid	Zometa Concentrate	274	Sandoz Canada Incorporated	Intravenous injection	Tumour-induced hypercalcemia and bone metastases of solid tumours, and osteolytic lesions of multiple myeloma
Pilocarpine HCl	Salagen	609	Sterimax Inc	Oral	Treatment of xerostomia (dry mouth) and xerophthalmia (dry eyes) due to Sjögren's syndrome or radiotherapy for cancer of the head and neck
Tetrabenazine	Nitoman	561	Pharmascience Inc	Oral	Treatment of hyperkinetic movement disorders such as Huntington's chorea, hemiballismus, senile chorea, tic and Gilles de la Tourette's syndrome and tardive dyskinesia

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PRODUCT LINE-EXTENSIONS

Product Line-Extension (Notices of Compliance from Dec 6, 2012 to Mar 5, 2013)

Brand name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Isentress	Raltegravir potassium	Merck Canada Inc.	Tablet, Chewable tablet	New indication, New strength	Expanded indication to pediatric patients 2 years of age and older; new strengths: chewable tablets 25mg, 100mg.
SMOFlipid	Soybean oil/ medium-chain triglycerides/fish oil/ olive oil	Fresenius Kabi Canada, a division of Calea Ltd.	Intravenous injection	New drug combination	New fat emulsion containing essential fatty acids and omega-3 fatty acids for parenteral nutrition
Nocdurna	Desmopressin acetate	Ferring Inc.	Orally disintegrating tablet	New brand, New strength	25µg strength for management of nocturia in women.
Rasilamlo	Aliskiren fumarate/ Amlodipine besylate	Novartis Pharmaceuticals Canada Inc.	Tablet	New drug combination	Fixed dose combination of a direct renin inhibitor with a calcium channel blocker for treatment of high blood pressure.
Pliaglis	Lidocaine/ Tetracaine	Galderma Canada Inc.	Topical cream	New drug combination	Topical local anesthetic for superficial dermatological procedures.
Silenor	Doxepin hydrochloride	Paladin Labs Inc.	Tablet	New brand, New strength, New indication	For treatment of insomnia characterized by frequent nocturnal awakening and/or early morning awakening
Nutropin AQ Nuspin	Somatropin	Hoffmann La Roche Limited	Subcutaneous injection	New strengths	2.5mg/ml (5mg/2ml injection device); 10mg/ml (20mg/2ml)
Erbitux	Cetuximab	Imclone LLC	Intravenous injection	New indication	For first-line treatment of EGFR-expressing K-ras metastatic colorectal carcinoma in combination with FOLFIRI regimen
Proquad	Combined measles, mumps, rubella, varicella live attenuated vaccine	Merck Canada Inc.	Subcutaneous injection	New drug combination	Quadravalent vaccine – equivalent to combination of MMR-II + Varivax-III – in a single vaccine; also available as Priorix-Tetra
BeneFIX	Coagulation Factor IX (recombinant)	Pfizer Canada Inc.	Intravenous injection	New indication	For routine prophylaxis of bleeding episodes in patients with hemophilia B. Supplied through Canadian Blood Services
Afinitor	Everolimus	Novartis Pharmaceuticals Canada Inc.	Tablet	New indications	(1) Hormone receptor-positive, HER-2-negative advanced breast cancer in combination with exemestane (2) Renal angiomyolipoma associated with tuberous scleorosis complex

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Brand name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Pentasa	Mesalazine (5-ASA, mesalamine)	Ferring Inc.	Extended-release tablet	New strength	1g
Cefazolin for Injection, USP	Cefazolin sodium	Pharmaceutical Partners of Canada, Inc.	Intravenous injection	New strength	100g/package; for hospital pharmacy admixture service use
Gamunex	Immune globulin (human)	Grifols Therapeutics Inc.	Intravenous/ subcutaneous injection	New indication	Guillain-Barré Syndrome; supplied through Canadian Blood Services
Genotropin Goquick/ Miniquick	Somatropin	Pfizer Canada Inc.	Subcutaneous injection	New strength, New presentations, New indications for children	Goquick pen: 5mg, 5.3mg, 12mg Miniquick syringes: 0.2mg, 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg For treatment of children with growth failure due to growth hormone deficiency, Prader-Willi syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature.
Arepanrix H5N1	Adjuvanted H5N1 (avian) monovalent influenza vaccine	ID Biomedical Corporation of Quebec	Intramuscular injection	New brand	H5N1 (avian) influenza vaccine for use in pandemic vaccination program
Lysteda	Tranexamic acid	Ferring Inc.	Tablet	New brand, New strength	650mg; for treatment of cyclic heavy menstrual bleeding.
Dovobet Gel	Calcipotriol monohydrate/ betamethasone dipropionate	Leo Pharma Inc.	Topical Gel	New indication	Gel now also indicated for use on body as well as scalp.
DuoTrav Q	Travoprost/timolol	Alcon Canada Inc.	Ophthalmic solution	New brand, New formulation	Change in preservative system from benzalkonium chloride to one using polyquaternium-1 (POLYQUAD). Other active ingredients in same strength.
Lumigan PF	Bimatoprost	Allergan Inc.	Ophthalmic solution	New brand, New formulation	Change to a preservative-free product from one using a benzalkonium chloride preservative system. Active ingredient increased to older (original) formulation strength, 0.03%.
Orencia	Abatacept	Bristol Myers Squibb Canada	Subcutaneous injection	New dosage form	New subcutaneous injection dosage form indicated only for rheumatoid arthritis in adults
Nimenrix	Meningococcal polysaccharide antigen groups A/C/ Y/W-135 conjugated to tetanus toxoid	GlaxoSmithKline Inc.	Intramuscular injection	New drug combination	New quadravalent meningococcal conjugate vaccine conjugated to tetanus toxoid. Similar to Menactra which is conjugated to diphtheria toxoid and has slightly lower amount of antigen (4µg compared to 5µg for Nimenrix)

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