Health Newsflash

A Quarterly Publication

New Drugs and Pipeline News Reviewed at the October to December 2015 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

Amitiza® (lubiprostone)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Capsule	02447363 – 24mcg	Takeda Canada Inc.	56:92.00 – Miscellaneous GI Drugs

Indication(s)

Amitiza is indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Dose

One 24 mcg capsule of Amitiza orally twice daily with food and water.

Therapeutic Alternatives

Constella, Resotran

Clinical Notes

Lubiprostone is a locally acting chloride channel activator that promotes the secretion of a chloride-rich intestinal fluid without altering electrolyte concentrations in the serum. By increasing intestinal fluid secretion, lubiprostone can facilitate passage of the stool and alleviate some symptoms associated with constipation.

Place in Therapy

Amitiza provides another treatment option for patients with chronic idiopathic constipation.

Comparative Pricing

Price not available

Impact/Plan Management Suggestions

Insufficient information

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Arnuity™ Ellipta® (fluticasone furoate)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Dry Powder Inhaler	02446561 – 100 µg/Blister 02446588 – 200 µg/Blister	GlasoSmithKline Inc.	52:08.08 – Corticosteroids

Indication(s)

Arnuity™ Ellipta® (fluticasone furoate) is indicated for the once-daily maintenance treatment of steroid-responsive bronchial asthma in patients aged 12 years and older.

Dose

The recommended dose is one inhalation of Arnuity™ Ellipta® 100 mcg or 200 mcg once-daily.

The highest recommended dose is one inhalation of Arnuity™ Ellipta® 200 mcg once-daily. The safety and efficacy of Arnuity™ Ellipta® when administered in excess of the recommended dose have not been established.

Therapeutic Alternatives

Flovent MDI/Diskus (fluticasone propionate); Alvesco MDI (ciclesonide, once-twice daily dosing); Asmanex Twisthaler (mometasone furoate); Pulmicort Turbuhaler (budesonide); Qvar MDI (beclomethasone dipropionate).

Clinical Notes

Arnuity Ellipta is an effective and safe agent for improving lung function, decreasing asthma symptoms, and reducing rescue medication use in patients with persistent asthma not controlled on prior therapy. Arnuity Ellipta and Flovent Diskus contain two chemically different forms of fluticasone both delivered via dry powder inhaler devices. In one pivotal trial, Arnuity Ellipta was found to be noninferior to Flovent Diskus for the improvement of trough FEV_1. As with other Ellipta devices, the maximum stability is six weeks after removal from foil tray.

Place in Therapy

Arnuity Ellipta appears to be a therapeutic alternative to other inhaled corticosteroids for the maintenance treatment of asthma.

Comparative Pricing

Drug	Estimated annual cost
Arnuity Ellipta	$480-$965
Flovent Diskus	$525-$900
Pulmicort Turbuhaler	$385-$700
Alvesco MDI	$575-$950

Impact/Plan Management Suggestions

Minimal impact. Cover similar to existing inhaled corticosteroids.

Basaglar™ (insulin glargine)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Subcutaneous injection	02444852 – 100unit/mL	Eli Lilly Canada Inc.	68:20.08 – Insulins

Indication(s)

Basaglar (insulin glargine (rDNA origin) injection) is a recombinant human insulin analogue indicated for once-daily subcutaneous administration in the treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Basaglar is also indicated in the treatment of pediatric patients (>6 years old) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Dose

As with all insulins, the dose is individualized based on each patient's glycemic response.

Therapeutic Alternatives

Lantus (insulin glargine); Levemir (insulin detemir); Toujeo (insulin glargine)

Clinical Notes

Basaglar [insulin glargine (rDNA origin)] injection is a recombinant human insulin analogue that is a long-acting, parenteral blood-glucose-lowering agent. Basaglar is produced by recombinant DNA technology utilizing a non-pathogenic laboratory strain of Escherichia coli (K12) as the production organism.

Insulin glargine differs from natural human insulin in that the amino acid asparagine at position 21 of the A-chain is replaced by glycine and two arginines are added to the C-terminus of the B-chain.

The similarity between the subsequent entry biologic (SEB) product Basaglar and the reference product Lantus® (insulin glargine) was established in accordance with Health Canada's *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs).*

Comparability between Basaglar and the reference product has been established based on comparative chemistry and manufacturing studies, comparative non-clinical studies and comparative pharmacokinetic/pharmacodynamic (PK/PD) and clinical trials. Comparative PK/PD and clinical trials were carried out in healthy volunteers and in adult patients with Type 1 diabetes mellitus or Type 2 diabetes mellitus. The indication for pediatric Type 1 diabetes mellitus (age: >6 years old) has been granted on the basis of similarity, demonstrated between Basaglar and the reference product, in product quality, mechanism of action, disease pathophysiology, safety profile, dosage regimen and based on clinical experience with the reference products.

Place in Therapy

Basaglar is a long-acting insulin analog used to provide basal insulin to control blood glucose levels in insulin requiring individuals. It is the first SEB insulin to become available.

Pricing

Drug	Estimated annual cost*
Basaglar	$1,100
Lantus	$1,300
Toujeo	$1,250
Levemir	$1,500

*assuming daily dose of 55 Units

Impact/Plan Management Suggestions

Minimal impact – potential cost shift from the higher cost basal insulin analogs.

Entresto™ (valsartan/ sacubitril)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet	02446928 – 25.7/24.3mg 02446936 – 51.4/48.6mg 02446944 – 102.8/97.2mg	Novartis Pharmaceuticals Canada Inc.	24:32.92 – Renin-Angiotensin-Aldosterone System inhibitors, Misc.

Indication(s)

Entresto (sacubitril/valsartan) is indicated for the treatment of heart failure with reduced ejection fraction (HFrEF) in patients with New York Heart Association (NYHA) Class II or III heart failure, to reduce the incidence of cardiovascular death and heart failure hospitalisation.

Entresto should be administered in combination with other heart failure therapies (e.g., diuretics, beta-blockers, mineralocorticoid receptor antagonists), in place of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB).

Entresto should be initiated, and up-titration conducted, by a physician experienced with the treatment of heart failure. Entresto should normally be used in clinically stable patients whose baseline systolic blood pressure, serum potassium and renal function are at acceptable levels.

Dose

The usual recommended starting dose is one tablet of 48.6 mg sacubitril / 51.4 mg valsartan taken twice daily. The target dose is one tablet of 97.2 mg sacubitril / 102.8 mg valsartan taken twice daily.

A starting dose of one tablet of 24.3 mg sacubitril /25.7 mg valsartan taken twice daily should be considered in certain patients:

- Patients on less than guideline-recommended doses of ACEi or ARB prior to initiation of Entresto.
- Patients who have risk factors for hypotension, including patients ≥ 75 years old and patients with low systolic blood pressure.

Therapeutic Alternatives

ACEi: ramipril*; lisinopril*; Coversyl (perindopril); enalapril*; captopril*; Mavik (trandolapril);
ARBs: valsartan*; candesartan*; losartan*

*generics available

Clinical Notes

The active substances of Entresto are sacubitril and valsartan. The medicine works in two complementary ways: valsartan blocks the angiotensin II type-1 receptor, suppressing the harmful effects of angiotensin II on the cardiovascular system, while sacubitril blocks an enzyme known as neprilysin to enhance the protective neurohormonal systems of the heart.

The benefit with Entresto is its ability to reduce the risk of cardiovascular death or need for heart failure hospitalisations as compared to enalapril in patients with symptomatic chronic heart failure with reduced ejection fraction. The most common side effects are hypotension, hyperkalaemia and renal impairment. Angioedema occurs uncommonly.

Entresto was granted accelerated review by Health Canada. The efficacy of this drug was demonstrated in the landmark PARADIGM-HF trial which was reported last year. The trial was stopped early due to the pre-specified termination point being attained with significant efficacy levels for active treatment being demonstrated. There was a relative risk reduction of 20% for cardiovascular death and risk for hospitalization for heart failure (primary outcome) [absolute risk reduction (ARR) of 4.7%; Number Needed to Treat (NNT) = 21 for 2.25 years to prevent one death or hospitalization (primary event) and 32 to prevent one death from cardiovascular causes]. There was also a relative risk reduction of 16% for death from any cause [ARR = 2.8%; NNT= 36].

These benefits came at the cost of increased risk of symptomatic low blood pressure including reductions in systolic blood pressure < 90mmHg.

These results were so significant that the Canadian Cardiovascular Society (CCS) decided to recommend use of Entresto in its guideline update written at the end of 2014 before the drug become available in Canada.

It is estimated that approximately 400,000 people in Canada live with heart failure. Less than 20% of these have a left ventricular ejection fraction less than 40%.

Place in Therapy

While the ultimate place in therapy for this drug has not yet been established, CCS recommends its use in patients with mild to moderate heart failure with a reduced ejection fraction < 40% and an elevated natriuretic peptide level or hospitalization for heart failure in the last year, similar to the population studied in the PARADIGM-HF trial.

Pricing

Drug	Estimated annual cost
Entresto	$2,650
Teva-Enalapril	$190-235†
Mylan-Valsartan	$220†

† doses used for heart failure

Impact/Plan Management Suggestions

Minimal impact – average utilization, relatively low annual drug cost.

Opdivo™ (nivolumab)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Intravenous injection	02446626 – 40mg/vial 02446634 – 100mg/vial	Bristol-Myers Squibb Canada	10:00.00 – Antineoplastic agents

Indication(s)

Opdivo (nivolumab) is indicated for the treatment of unresectable or metastatic BRAF V600 wild-type melanoma in previously untreated adults.

Dose

The recommended dose of Opdivo (nivolumab) is 3 mg/kg administered intravenously over 60 minutes every 2 weeks. Continue treatment as long as clinical benefit is observed or until treatment is no longer tolerated by the patient.

Dose escalation or reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability.

Therapeutic Alternatives

Keytruda (pembrolizumab); Yervoy (ipilimumab)

Clinical Notes

In Canada, it is estimated that in 2015, 6,800 Canadians will be diagnosed with melanoma, 1,150 Canadians will die from melanoma, 3,700 men will be diagnosed with melanoma and 730 will die from it, and 3,100 women will be diagnosed with melanoma and 420 will die from it.

The outcome of melanoma depends on the stage at presentation. Approximately 85% of patients with melanoma present with localised disease, 10% with regional disease and 5% with distant metastatic disease. The 5-year survival rates in patients who present with localised disease and primary tumours 1.0mm or less in thickness are very good, with more than 90% of patients surviving. The 5-year survival rates decrease as the tumour spreads: for tumours of more than 1.0mm in thickness, survival rates range from 50% to 90%, with regional node involvement survival rates are around 50%, for within stage III (regional metastatic melanoma) 5-year survival rates range between 20-70%, depending on primary nodal involvement. For distant metastatic melanoma, the 5-year survival is less than 10%.

The co-inhibitory receptor programmed cell death – 1 (PD-1) protein is a key regulator of T cell activity that belongs to the same immunoglobulin superfamily which includes the co-stimulatory receptor CD28 and the co-inhibitory receptor CTLA-4. Opdivo (nivolumab) is a human immunoglobulin G4 (IgG4) monoclonal antibody (HuMAb), which binds to the PD-1 receptor and blocks its interaction with PD-1 ligand-1 (PD-L1) and PD-1 ligand-2 (PD-L2). The PD-1 receptor is a negative regulator of T cell activity that has been shown to be involved in the control of T cell immune responses. Engagement of PD-1 with the ligands PD-L1 and PD-L2, which are expressed in antigen presenting cells and may be expressed by tumours or other cells in the tumour microenvironment, results in inhibition of T cell proliferation and cytokine secretion. Nivolumab potentiates T cell responses, including anti-tumour responses, through blockade of PD-1 binding to PD-L1 and PD-L2 ligands.

Place in Therapy

Opdivo's place in therapy will develop as new clinical trial data becomes available regarding sequencing of therapy and the optimal patient subgroups for whom treatment is most efficacious; however, based on currently approved indications, this drug is recommended as first-line therapy for advanced (unresectable, metastatic) melanoma.

Comparative Pricing

Drug	Estimated monthly/per cycle cost	Estimated annual cost
Opdivo	$9,500*	$123,000
Keytruda	$6,600*	$113,000
Yervoy	$24,400	$98,000†

*weight-based dosing assumes 70kg body weight; † maximum duration of 4 cycles of therapy.

Impact/Plan Management Suggestions

Based on information from the manufacturer, a combination of public coverage and a "robust compassionate program" will minimize impact to private payers.

Technivie™ (ombitasvir/paritaprevir/ritonavir)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet	02447711 – 12.5/75/50mg	AbbVie Corp.	08:18.40 – HCV Antivirals

Indication(s)

Technivie™ (ombitasvir/paritaprevir/ritonavir) tablets with ribavirin is indicated for the treatment of adults with genotype 4 chronic hepatitis C virus infection without cirrhosis who are either treatment naïve or previously treated with peginterferon and ribavirin.

Dose

The recommended oral dose of Technivie™ is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets taken once daily (in the morning) with food without regard to fat or calorie content. Technivie™ tablets should be used in combination with ribavirin (RBV)—available as Moderiba™ for patients enrolled in the AbbVie Patient Support Program.

Therapeutic Alternatives

See *Table 1*.

Clinical Notes

Technivie™ is an all-oral interferon-free regimen for the treatment of genotype 4 (GT4) hepatitis C virus (HCV) infection without cirrhosis. Of the six main genotypes of HCV, GT4 is one of the least prevalent genotype in Canada representing <1% of all HCV infections.

The fixed-dose combination therapy in Technivie combined with ribavirin for 12-weeks showed an SVR-12 rate of 100% in both treatment-naïve and treatment-experienced patients without cirrhosis with genotype-4 CHC in the PEARL-1 study. The safety profile of this regimen was similar to that seen in patients taking Holkira Pak for genotype 1 CHC.

Place in Therapy

Technivie (plus Moderiba) will become the most cost effective treatment for genotype 4 CHC.

Comparative Pricing

Table 1. **Interferon-free treatments of chronic hepatitis C genotype 4 infection (from CASL guidelines)**

Regimen	Treatment duration	Dosage	SVR-12*	Estimated total treatment cost
Technivie™ + Moderiba™†	12 weeks	2 qd + bid	100%	$59,000
Harvoni™ (off-label)◊	12 weeks	1 qd	95%	$71,000
Sovaldi® + Ibavyr™‡	24 weeks	1 qd + bid	89-95%	$123,000-$124,000

CASL: Canadian Association for the Study of the Liver; SVR-12: Sustained Viral Response after 12-weeks of treatment completion—a proxy for virologic cure.
*from clinical trials supporting each regimen; therefore, not necessarily comparable.
†Moderiba™ available at no cost to patients using Technivie™ and enrolled in the AbbVie Patient Support Program.
◊Not approved by Health Canada but recommended in CASL guidelines.
‡Ibavyr weight-based dosing: 1,000mg/day < 75kg; 1,200mg/day ≥ 75kg.
Highlighted rows are the preferred treatments in the CASL guidelines.

Impact/Plan Management Suggestions

High impact. Manage with Prior Authorization to ensure appropriate utilization.

Trulicity™ (dulaglutide)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Subcutaneous injection	02448572 – 0.75mg/0.5ml Prefilled Syringe 02448580 – 1.5mg/0.5ml Prefilled Syringe **02448599 – 0.75mg/0.5ml Single-Use Pen** **02448602 – 1.5mg/0.5ml Single-Use Pen**	Eli Lilly Canada Inc.	68:20.06 – Incretin mimetics

Bold DINs are the forms expected to be marketed by the manufacturer

Indication(s)

Trulicity is indicated for the once-weekly treatment of adult patients with Type 2 diabetes mellitus to improve glycemic control, in combination with:

- diet and exercise in patients for whom metformin is inappropriate due to contraindication or intolerance.
- metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control.
- metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.
- prandial insulin with metformin, when diet and exercise plus basal or basal-bolus insulin therapy (up to two injections of basal or basal plus prandial insulin per day) with or without oral antihyperglycemic medications, do not achieve adequate glycemic control.

Trulicity has not been studied in combination with basal (long acting) insulin.

Dose

The recommended initial dose of Trulicity is 0.75 mg once weekly. The dose may be increased to 1.5 mg once weekly for additional glycemic control. The maximum recommended dose is 1.5 mg once weekly.

Therapeutic Alternatives

Victoza (liraglutide);
Byetta (exenatide);
Eperzan (albiglutide)

Clinical Notes

Trulicity (dulaglutide) is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist to be used as an adjunct to diet and exercise in the treatment of patients with Type 2 diabetes mellitus. Trulicity can be used alone or in combination with other antidiabetic drugs. Similar to other GLP-1 receptor agonists, dulaglutide improves pancreatic beta-cell glucose-dependent insulin release, decreases alpha-cell glucagon release, and slows gastric emptying.

In clinical studies in patients with Type 2 diabetes, once-weekly subcutaneous dulaglutide 0.75 or 1.5 mg reduced both fasting and postprandial serum glucose concentrations and postprandial serum glucose incremental area under the concentration-time curve (AUC) and increased first-and second-phase insulin secretion more than placebo.

Compared with baseline, continued administration of dulaglutide increased fasting insulin and C-peptide concentrations and reduced fasting glucagon concentrations.

Trulicity was compared with other GLP-1 receptor agonists in two different head-to-head trials. One trial showed that both 0.75 mg and 1.5 mg once weekly of dulaglutide demonstrated superior HbA1c lowering compared to exenatide (Byetta®) 10 mcg twice daily after 26-weeks (greater reduction in HbA1c of -0.52% for 1.5 mg once weekly and -0.39% for 0.75 mg once weekly). Another trial compared dulaglutide 1.5 mg once weekly with liraglutide (Victoza®) 1.8 mg once daily and found dulaglutide to be non-inferior to liraglutide in terms of blood glucose lowering; however, liraglutide lowered bodyweight more than dulaglutide.

There is no direct comparative data between Trulicity and the other once weekly GLP-1 receptor agonist approved in Canada, Eperzan (albiglutide).

Trulicity will be available as single-use pen devices. Pre-filled syringes are not expected to be marketed in Canada.

Place in Therapy

Trulicity is a once weekly administered GLP-1 receptor agonist which shows comparable blood glucose lowering in terms of HbA1c with liraglutide (Victoza®). It is the second once weekly GLP-1 RA to be approved in Canada, after Eperzan (albiglutide).

Comparative Pricing

Drug	Estimated annual cost
Trulicity	$2,700
Victoza	$2,100-$3,200
Byetta	$1,800

Impact/Plan Management Suggestions

Minimal impact – potential cost-shift from Victoza.

FIRST TIME GENERICS

First Time Generic Drugs (Notices of Compliance (NOCs) from August 19, 2015 to November 25, 2015)

Generic Name	Reference Drug (Brand)	Rank by ingredient cost in 2014	Manufacturer	Route of Administration	Approved Indications/ Comments
mixed salts amphetamine	Adderall XL	81	Actavis Pharma Co.	Oral	Attention Deficit Hyperactivity Disorder (ADHD)
tadalafil	Adcirca	654	Apotex Inc.	Oral	Pulmonary Arterial Hypertension (PAH)
bivalirudin	Angiomax	—	Fresenius Kabi Canada Ltd.	Intravenous	Anticoagulant for cardiovascular surgery.
cinacalcet	Sensipar	422	Mylan Pharmaceuticals ULC	Oral	Hypercalcemia
aliskiren	Rasilez	525	Sandoz Canada Inc.	Oral	Hypertension
17β-estradiol	Estrace	72	Lupin Pharma Canada Ltd.	Oral	Estrogen replacement

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NEW DRUGS AND PRODUCT LINE EXTENSIONS

New Drugs and Product Line Extensions (Notices of Compliance (NOCs) from August 19, 2015 to November 25, 2015)

Band name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Pergoveris	follitropin/ lutropin alfa	EMD Serono	Subcutaneous injection	New drug combination	For treatment of infertility.
Vectibix	panitumumab	Amgen Canada	Intravenous injection	New indication	Previously untreated patients with non-mutated (wild-type) RAS metastatic colorectal carcinoma in combination with FOLFOX.
Fluzone High Dose	trivalent influenza vaccine	Sanofi Pasteur	Intramuscular injection	New strength	Contains four-times the amount of antigen of regular Fluzone vaccine. Specifically indicated for adults 65 years and older.
Glucophage	metformin	Sanofi Aventis Canada	Tablet	New strength	1,000 mg tablet strength
TactuPump Plus	adapalene/ benzoyl peroxide	Galderma Canada	Topical gel	New strength	Three-times the concentration adapalene compared to regular TactuPump (same amount of benzoyl peroxide).
Abilify Maintena	aripiprazole	Otsuka Pharmaceutical	Intramuscular injection	New indication, New format (delivery system)	Indication expanded to include acute episodes of schizophrenia. New delivery system is dual-chamber pre-filled syringes.
Evotaz	atazanavir/ cobicistat	Bristol-Myers Squibb	Tablet	New drug combination	Two existing therapies combined on a single tablet: protease inhibitor (atazanavir, Reyataz) and pharmacokinetic enhancer (cobicistat, Tybost).
Zevtera	ceftobiprole medocaril	Basilea Pharmaceutica	Intravenous injection	New drug	New generation broad-spectrum cephalosporin to be used for hospital-acquired pneumonia or community-acquired pneumonia.
Avastin	bevacizumab	Hoffmann La Roche	Intravenous injection	New indication	For use in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin in patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Revestive	teduglutide	NPS Pharma	Subcutaneous injection	New drug	GLP-2 receptor agonist for treatment of adults with short bowel syndrome.
Qnasl	beclomethasone dipropionate	Teva Canada Limited	Nasal spray	New brand, New formulation	Waterless formulation for once daily administration for allergic rhinitis.

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NEW DRUGS AND PRODUCT LINE EXTENSIONS (continued)

New Drugs and Product Line Extensions (Notices of Compliance (NOCs) from August 19, 2015 to November 25, 2015)

Band name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Zerbaxa	ceftolozane/ tazobactam	Merck Canada Inc.	Intravenous injection	New drug combination	For complicated intra-abdominal and urinary tract infections (including pyelonephritis) caused by susceptible organisms.
Obizur	antihemophilic factor (recombinant) procine sequence	Baxalta Canada Corp.	Intravenous injection	New drug	For treatment of bleeding episodes in patients with Acquired Hemophilia A.
Xgeva	denosumab	Amgen Canada Inc.	Subcutaneous injection	New indication	For the treatment of hypercalcemia of malignancy that is refractory to intravenous bisphosphonate.
Somavert	pegvisomant	Pfizer Canada Inc.	Subcutaneous injection	New strengths	25 mg and 30 mg strengths
Humira	adalimumab	AbbVie Corp.	Subcutaneous injection	New indication	Extension of indication for polyarticular juvenile idiopathic arthritis of minimum age from 4 years to 2 years of age.
Niastase RT	eptacog alfa	Novo Nordisk Canada Inc.	Intravenous injection	New indication	In adult patients with acquired hemophilia, for treatment of bleeding episodes and prevention of bleeding for those undergoing surgery.
Jakavi	ruxolitinib	AbbVie Corp.	Tablet	New indication	For control of hematocrit in adult patients with polycythemia vera resistant to or intolerant of a cytoprotective agent.

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