





Express Scripts Canada 2011 Drug Trend Report

INTRODUCTION

For years, experts have issued warnings about the need to control the spiraling cost of prescription drugs for Canadians. The country's health-care system is facing a crisis when it comes to ensuring Canadians have broad access to affordable prescription medications.

Benefits-plan sponsors that provide health benefits to their employees have been hit even harder by these soaring costs. As only some of the drug reforms introduced by the provinces apply to the private sector, plan sponsors may be more vulnerable to cost increases, and they lack the leverage and the tools to manage costs. And while generic pricing reforms have provided some short-term cost relief, the wave of specialty medications in the drug pipeline will cause costs related to the delivery of the prescription drug benefit to soar once again.

In today's economy, plan sponsors are becoming increasingly conscious of the need to get the greatest possible value for every dollar they spend on the prescription drug benefit. And given current trends with respect to rising costs to maintain health-benefits programs, changes to the way Canadians access affordable prescription drugs are inevitable and necessary.

Plan-sponsor drug plans are vital to Canadians and must be preserved. They provide coverage to millions of people who need it, and they provide companies with a way to attract and retain employees. The sad fact is that while drug-benefit coverage is becoming unaffordable for plan sponsors, there is a huge amount of money being wasted within their drug plans. For example, most plan sponsors have generic fill rates in the low 50% range; this indicates that patients far too often are taking a brand-name drug when a lowercost, clinically or therapeutically equivalent generic is available. This is only one of several proof points of waste within drug plans, and evidence that plan sponsors have been unable to influence two key drivers of waste – the behaviour of plan members and the workings of the prescription-drug supply chain that will be explored throughout this report.

John Herbert
Director, Pharmacy & Clinical Services

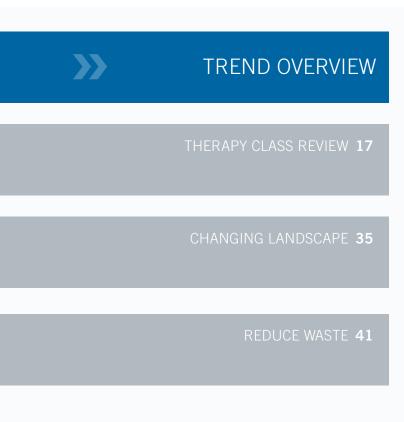
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Contents



1



Trend Overview

By nearly every measure, private payers in Canada face a pharmacy landscape that is becoming increasingly complex. This complexity is being driven, in large part, by the ongoing and future provincial drug reforms across Canada, and the opposing strategies undertaken by various stakeholders.

Being in the midst of the brand patent cliff and the generic price reductions, private payers have financially benefited from these changes, as reflected by the overall flat drug trend. However, this near-zero growth trend will not last long.

With the rapid growth in both the availability and utilization of high-cost specialty drugs, plan sponsors must react quickly. They must reduce pharmacy-related waste now to keep their plans manageable, affordable and sustainable once the trend again picks up — and it's inevitable that it will — in the near future.

TREND FOR 2011 DRUG SPEND STAYS FLAT

- Increasing utilization offset by decreases in cost per script
- Changing landscape will impact future drug spend

WASTE IN DRUG SPEND EXCESSIVE

- Waste = Spending more without improving health outcomes
- Private plans are wasting more than \$5 billion in drug spend per year

CHANGES NEEDED TO MEMBER BEHAVIOUR

To reduce waste, innovative solutions are required to encourage optimal plan-member behaviour

TREND - ONE WORD, TWO APPROACHES...

Express Scripts Canada's drug-trend analysis is based on a retrospective methodology and, therefore, will differ from an insurance carrier's health-plan premium increase, which is based on a prospective methodology. The Express Scripts Canada retrospective methodology also includes a drug plan's specific claims experience, change in proportion of eligible members with a claim, demographic changes, anticipated changes in the future mix of drugs, the erosion of member portion, a risk component, and other health-plan claims experience.

As a result, Express Scripts Canada's trend factor will typically be lower than an insurance carrier's predicted average increase of an extended health care (EHC) plan, of which prescription drugs are only one component.

TERMINOLOGY USED IN THIS REPORT

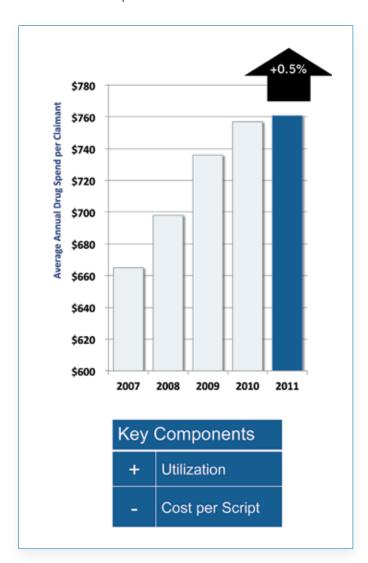
- Drug Trend: Historical increase in cost
 allowable per claimant over the previous year
- Cost Allowable: Amount payable before plan-member contribution
- Claimant: Each unique person who submits a
 prescription claim, including all dependents
 eligible for coverage under a plan member's
 health-benefits plan
- Script: prescription or claim

DRUG SPEND 2011

On a national basis, the average annual drug spend per claimant increased by 0.5% in 2011 to \$761, just \$4 more per claimant than in 2010. This trend is considerably lower than the increases in spend seen during the past decade. The flat trend for the calendar year ended December 31, 2011 is a reflection of the increases in utilization, which have been offset by the decreases in cost per prescription, which will be explored throughout this report.

FIGURE 1 2011 National Drug Trend

Spend Flat After Years of Growth

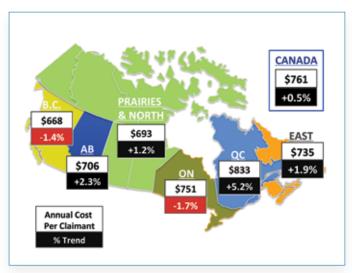


COST PER CLAIMANT BY REGION

In Ontario, for example, the impact of these price reforms was primarily responsible for the downward trend of 1.7% to \$751 in 2011; this compares with \$764 in the preceding year. Similarly, in British Columbia, generic price reforms caused a 1.4% decrease in spend per claimant to \$668 in 2011, compared with \$678 in 2010. Conversely, while Quebec implemented generic price reforms in 2011, the province continued to have an upward trend in spend, and recorded another high upward trend in Canada of 5.2%, or \$833 per claimant. This compares with a trend of 5.6%, or \$792 per claimant in the previous year.

FIGURE 2 Drug Trend by Region

Quebec Tops in Regional Spend



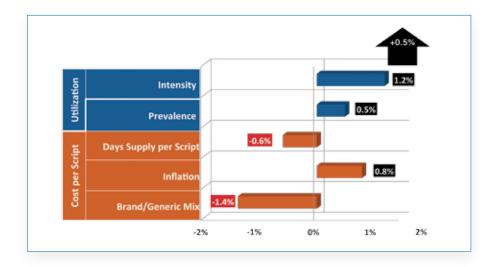
Drug trend varied by region in 2011, primarily due to differences in generic price reforms

COMPONENTS OF DRUG TREND

The national drug trend of +0.5% is comprised of two main components – Utilization and Cost per Script (Prescription). The accompanying chart demonstrates how each of these components contributed to the overall drug trend in 2011.

FIGURE 3 | Components of Drug Trend

Utilization and Cost per Script

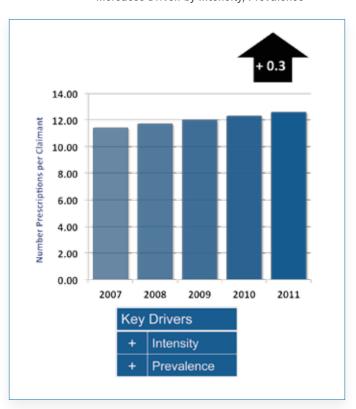


UTILIZATION

Utilization increased by 0.3 prescriptions per claimant in 2011, which brought the national average to 12.6 prescriptions per claimant per year. This is consistent with the increases in utilization seen over the past 10 years. The two key components that continue to drive the growth in utilization are increased intensity (more prescriptions per patient) and increased prevalence (greater percentage of eligible members with a claim). Among the contributing factors to the increase in intensity are that more drugs are now available for new or conventional medical conditions, more prescriptions are being filled for generic drugs due to improved affordability, and a decrease in the average days of supply per prescription. Intensity and prevalence continue to be driven by an aging Canadian population (utilization increases can be directly correlated to the aging process).

FIGURE 4 | Utilization on the Rise

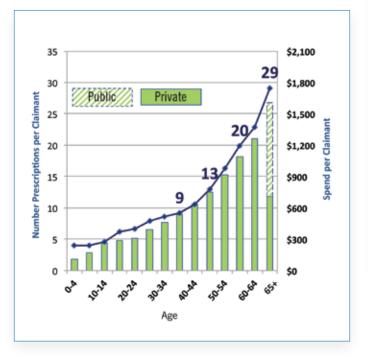
Increases Driven by Intensity, Prevalence



Utilization Increases with Age

Utilization increases as we get older, which results in a higher drug spend per claimant. As Canadian baby-boomers age, increased use generates higher overall costs. However, private plans, in general, experience a decrease in spend when their plan members move from the 60-64 age group to the over-65 segment. This does not imply drug spend for the older population has decreased; rather, the change can, in large part, be attributed to the fact that the provinical drug program becomes the first payer for seniors in several regions. For example, the Ontario Drug Program is currently the first payer for drugs on formulary for seniors. If the public payers across Canada continue to be the first payer for patients 65 and older, the spend per claimant by the private payers would be projected to reach about \$1,600. This would result in an increase in premiums for plan sponsors that cover seniors.

FIGURE 5 Utilization Increases with Age
Aging Population Drives Growth

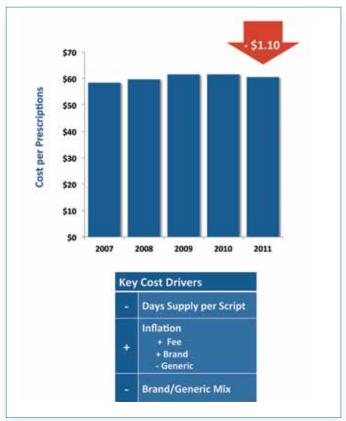


COST PER PRESCRIPTION

For the calendar year ended December 31, 2011, the cost per prescription decreased \$1 to \$60.45, 1.8% lower than for the preceding year. This was a reversal from the upward trend in cost per script that was consistently seen during the past decade, thanks to generic price reforms, as well as patent expires. Overall, the cost per prescription is influenced by three key components — days of supply per prescription, inflation (fee, brand and generic), and brand-generic mix.

FIGURE 6 Decrease in Cost per Script

Noteworthy Decline After Years of Increases



Days of Supply per Prescription

A decrease in the average days supply per prescription from 38.9 days to 38.6 days contributed to the decrease in the average cost per prescription in 2011. This decrease was partly due to drug shortages as health-care workers across the country rationed existing stock and, in some cases, dispensed fewer days of supply per prescription (smaller quantities) to service more patients. The decrease in days of supply per prescription also contributed to the increase in utilization, and resulted in an increase in the number of dispensing fees paid in 2011.

INFLATION

Inflation drove an overall net increase in spend of 0.8% in 2011. This was influenced by three main components — dispensing fee inflation, brand-drug inflation, and generic-drug inflation.

Dispensing Fee Inflation

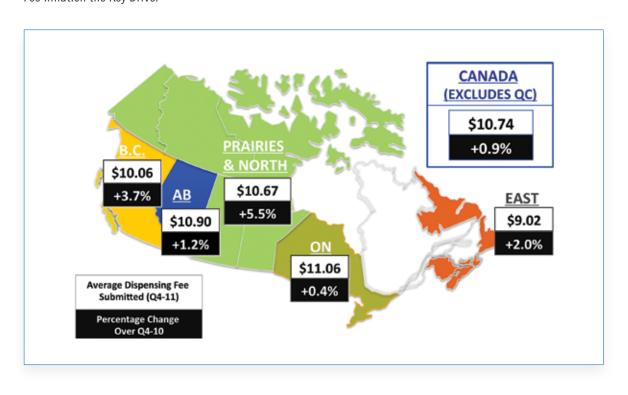
Increases to dispensing fees across Canada continue to put upward pressure on the average cost per prescription. From a regional perspective, the Prairies & North posted the highest increase for the average fee submitted at 5.5%, followed by British Columbia, with an increase of 3.7%. By comparison, Ontario, which has the highest dispensing fees in Canada, posted a slight increase of 0.4%, which took the average dispensing fee to \$11.06 and 16 cents higher than Alberta, which had the country's second-highest average dispensing fee at \$10.90.

Brand Inflation

Increases to the price of brand medications put upward pressure on the average cost per prescription. This was driven by an increasing use of specialty drugs, as well as changes in therapeutic mix of traditional medications. Overall, the average cost per brand-name prescription increased to \$96.54 in 2011 from \$94.77 in 2010.

FIGURE 7 Upward Pressure on Costs

Fee Inflation the Key Driver



SPECIALTY DRUGS

Express Scripts Canada defines a specialty drug as "an injectable or non-injectable drug that is typically used to treat chronic, complex conditions". To be classified as a specialty drug, a medication should meet one or more of the following characteristics:

- Requirement for frequent dosage adjustments and intensive clinical monitoring to decrease the potential for adverse effects, and increase probability of improved outcomes
- Need for intensive patient training and compliance assistance

- Limited or exclusive product availability and distribution
- Specialized product handling and/or administration requirements
- Generally, cost more than \$500 per month

Although specialty drugs comprised just 0.99% of all drug claims, they contributed to almost 20% of the total spend. In addition, specialty spend increased by 12% in 2011, compared with traditional drugs which had a negative trend of 1.9%, largely due to generic price reforms, as well as patent expiries.

FIGURE 8 Specialty Trend Higher Than Traditional
Results Driven by Higher Cost per Script

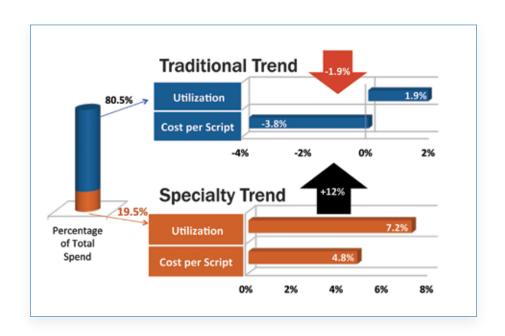
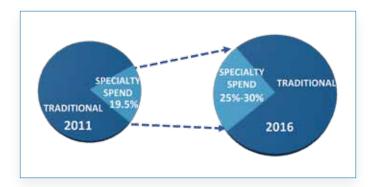


FIGURE 9 Rapid Growth for Specialty Spend
Key Driver to Overall Drug Spend Through 2015



One of the factors that drove an increase in specialty trend was the number of new specialty drug approvals by Health Canada in 2011. Among the 51 key new drugs that came to market, 17 were specialty medications.

As a result, it is estimated that specialty spend will increase from 19.5% of all drug spend in 2011 to 25%-30% in 2015, which is expected to continue to put upward pressure on drug costs.

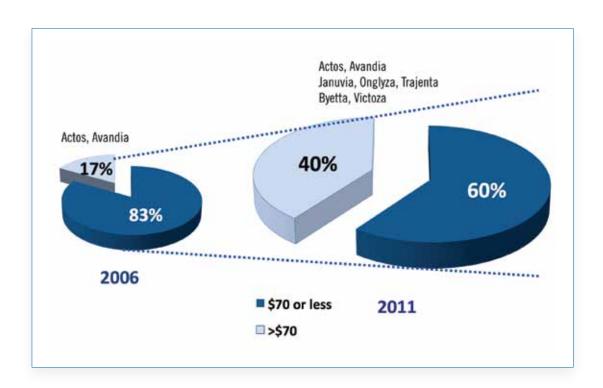
CHANGES TO THERAPEUTIC MIX

Therapeutic mix encompasses both the change in the mix of disease conditions within the population, and the change in the mix of drugs used to treat those conditions. Therapeutic mix produces an upward pressure on cost per prescription due to a shift to newer, high-cost medications within both traditional and specialty categories. Case in point — in 2006, only 17% of all diabetes drug claims cost more than \$70 per script, because most

drugs prescribed to treat this condition were low-cost generics, such as metformin and glyburide. However, with the increasing prevalence of diabetes and, with new, more expensive therapeutic options available, such as Januvia and Victoza, about 40% of all diabetic claims cost more than \$70 in 2011. The growth in both utilization and cost per script led to an 8% trend for the Diabetes therapy class.

FIGURE 10 | Drivers of Brand Inflation

Changes in Therapeutic Mix (Example – Diabetes)



Therapeutic mix encompasses both the change in the mix of disease conditions within the population, and the change in the mix of drugs used to treat those conditions

FIGURE 11 ■ Noteworthy New Drug Approvals – 2011

More Specialty Drugs Enter the Market

The following table documents new drugs that came to market in 2011 that were noteworthy due to potential uptake in utilization, inherent high cost per treatment, or unique place in therapy.

BRAND NAME	GENERIC NAME	MANUFACTURER	INDICATION(S)	ANNUAL INGREDIENT COST/PATIENT*
Abstral	Fentanyl	Paladin	Breakthrough cancer pain	\$3,960 - \$46,080
Banzel	Rufinamide	Eisai	Seizures associated with Lennox-Gastaut syndrome	\$3,800 - \$9,600
Benlysta†	Belimumab	GlaxoSmithKline	Systemic lupus erythematosis	\$22,750
Brilinta	Ticagrelor	AstraZeneca	Acute coronary syndrome	\$1,100
Byetta	Exenatide	Eli Lilly	Type 2 diabetes	\$1,740
Certican†	Everolimus	Novartis	Kidney transplant	Pricing not available
Edurant†	rilpivirine	Janssen	HIV	\$5,240
Eliquis	apixaban	Bristol Myers Squibb	Prevention of deep vein thrombosis (DVT) in orthopedic surgery	\$40 -\$170
Gelnique	oxybutynin	Watson	Overactive bladder	\$1,060
Gilenya†	fingolimod	Novartis	Multiple sclerosis	\$32,000
Halaven †	eribulin	Eisai	Breast cancer	Pricing not available
Incivek†	telaprevir	Vertex	Chronic hepatitis C	\$35,000
Jevtana†	cabazitaxel	Sanofi Aventis	Prostate cancer	Pricing not available
Lodalis	colesevelam	Valeant	High blood cholesterol	\$2,800
Mozobil†	plerixafor	Genzyme	Stem cell transplantation	Pricing not available
Onbrez Breezhaler	indacaterol	Novartis	Chronic obstructive pulmonary disease (COPD)	\$810
OxyNeo	oxycodone	Purdue	Pain	\$690 - \$3,280
Ozurdex†	dexamethasone	Allergan	Macular edema associated with central retinal vein occlusion	\$2,700
Rapaflo	silodosin	Watson	Benign prostatic hyperplasia (BPH)	\$672
Resotran	prucalopride	Janssen	Chronic idiopathic constipation in women	\$820 - \$1,310
Revolade†	eltrombopag	GlaxoSmithKline	Idiopathic thrombocytopenic purpura (ITP)	\$23,660 - \$70,980
Samsca†	tolvaptan	Otsuka	Hyponatremia	\$96,270 - \$192,540
Saphris	asenapine	Merck/Lundbeck	Schizophrenia and bipolar disorder	\$1,430
Sublinox	zolpidem	Valeant	Insomnia	\$460
Tactuo	adapalene/benzoyl peroxide	Galderma	Acne	\$1,020
Tobi Podhaler†	tobramycin	Novartis	Cystic fibrosis	\$20,000
Trajenta	linagliptin	Boehringer Ingelheim	Type 2 diabetes	\$980
Victrelis†	boceprevir	Merck	Chronic hepatitis C	\$27,000 - \$49,000
Vimovo	naproxen/esomeprazole	AstraZeneca	NSAID-associated gastric ulcers	\$1,600
Visanne	dienogest	Bayer	Endometriosis	\$700
Xgeva†	denosumab	Amgen	Prevention of skeletal related events associated with bone metastases	\$7,400
Zenhale	mometasone/formoterol	Merck	Asthma	\$850 - \$1,340
Zytiga†	abiraterone	Janssen	Prostate cancer	\$57,000

Specialty Drug.

^{*}Pricing obtained from Express Scripts Canada's database (excludes retail mark-up and dispensing fees). Calculations are based on manufacturer's recommended dosing.

DRUG REFORM

Generic prices have greatly been influenced by the provincial generic drug-pricing reforms over the past two years, and this trend is expected to continue into 2013. Each province took a slightly different approach to institute these changes, and this added complexity to the pricing structure across Canada.

In 2011, Ontario and British Columbia continued with their phased-in reforms, while three other provinces — Quebec, Saskatchewan and Nova Scotia — initiated reforms. By the end of 2011, generic prices in these five provinces decreased from approximately 60% of brand price to 30%-45%. The generic cost reductions may appear substantial; however, this change was limited to formulary generics (approximately 15% of the total spend). In addition, many formulary generics were exempted from the generic-reform pricing legislation.

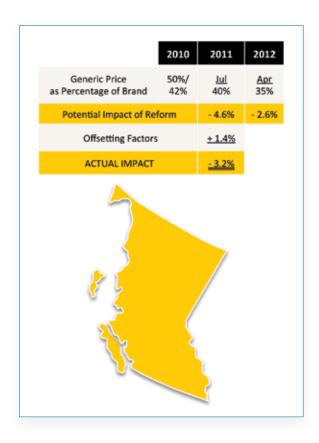
BRITISH COLUMBIA

In October 2010, British Columbia initiated the implementation of a three-phrase generic reform, by lowering the price of new generics to 42% of brand and existing generics to 50%. The prices for both were subsequently lowered to 40% in July 2011 and to 35% in April 2012. As a result, private plans had the potential to save 4.6% in 2011; however, similar to the offsetting factors faced by Ontario, private plans in B.C. actually saved 3.2%. It is further anticipated that private plans in British Columbia could save another 2.6% in 2012.

In looking forward, although British Columbia reduced its generic pricing to 35% of brand in April 2012, the province communicated in February 2012 that through legislation, the province will aim for a reduction to 25% of the cost of the brand - name drugs by April 1, 2013. This would bring B.C. in line with reductions instituted in Ontario and Quebec.

FIGURE 12 | British Columbia

Further Reductions on the Way

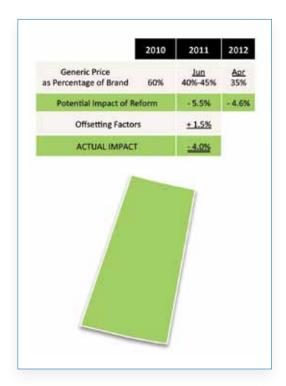


SASKATCHEWAN

Saskatchewan initiated the first phrase generic-drug price reforms on June 1, 2011 by lowering the price of existing generics to 45% of brand and new generics to 40%. These prices were further lowered to 35% on April 1, 2012. Private plans in the province could have saved 5.5% in 2011 due to these reforms; however, offsetting factors of price increases for non-formulary generics and exempted formulary generics resulted in an actual savings of 4%. Private plans in Saskatchewan could potentially save another 4.6% in 2012.

FIGURE 13 | Saskatchewan

Greatest Impact on Overall Savings



ONTARIO

Ontario began to implement generic price reform in mid-2010 when generic prices for the public sector were dropped to 25% of the brand price.

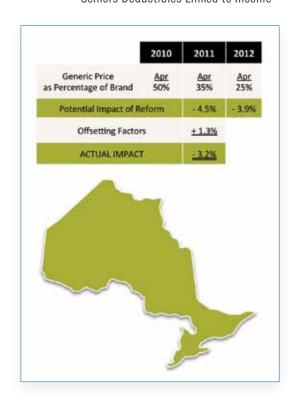
Prices for the private sector, however, were phased in — with reductions to 50% of brand price in July 2010, to 35% in April 2011 and, finally, to 25% in April 2012. These price decreases could have potentially saved private plans 4.5% in 2011; however, these price cuts were partially offset by price increases for non-formulary generics, and the

fact that several formulary generics were exempted from drug reform by Ontario. As a result, generic price reform drove down drug spend in 2011 by 3.2%. These reforms have the potential to save private plans in Ontario another 3.9% in 2012; however, these savings again may be partly offset by price increases for non-formulary generics, and exemptions for formulary generics from drug reform.

Looking ahead, the Ontario government may make another change to its Drug Benefit Program based on changes announced by Ottawa in the 2012 Federal Budget tabled in March. Starting in August 2014, the province is considering changes that will require high-income seniors (single seniors with an annual income over \$100,000, or couples with a combined income above \$160,000) to pay a deductible of 3% of their income on top of the existing deductible of \$100 for singles or \$200 for couples. The Ministry of Finance said 5% of all seniors in the province would pay an average of \$665 a year more toward the cost of their prescription drugs. As a result, plans that cover individuals who are 65 and older will experience an increase in costs.

FIGURE 14 | Ontario

Seniors Deductibles Linked to Income



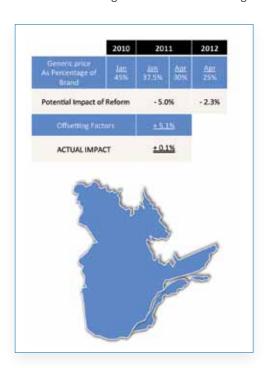
QUEBEC

Quebec stipulates that drug prices in the province must match the lowest price on any provincial formulary. Therefore, Quebec should have started to benefit from lower generic prices once Alberta reduced the price for new generics to 45% of brand in the fourth quarter of 2009. However, with resistance from different stakeholders, the official reform was delayed to December 2010 when prices were reduced to 37.5%; these reductions were followed with cuts to 30% in April 2011, and to 25% in April 2012. In 2011, the formulary generic prices in Quebec were set lower than those for other provinces (e.g., 40% in British Columbia and 35% in Ontario). As such, private plans in Quebec could have potentially saved 5% in 2011.

Despite government efforts to the contrary, generic prices in Quebec increased in 2011. These increases can, in part, be attributed to the fact that the drug-claim amount submitted to private payers is inclusive of dispensing fee, mark-up, and drug cost. As such, pharmacies may opt to set higher mark-up and dispensing fees to recoup lost revenue. There were also substantial price increases for non-formulary generics and generics that are exempted from the reform.

FIGURE 15 | Quebec

Offsetting Factors Curtailed Savings



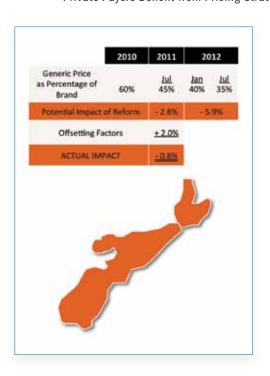
Prices charged by pharmacies in Quebec have come under scrutiny. Using atorvastatin 20mg (generic Lipitor) as an example, claims data from Express Scripts Canada for the three months ended March 31, 2012 showed that 33% of these claims for this cholesterol mediacation charged at least a 20% mark-up, plus a \$10 dispensing fee above the actual ingredient cost. As well, approximately 0.04% of these claims submitted the claim with brand prices.

NOVA SCOTIA

Generic price reform came into effect in Nova Scotia on July 2, 2011, with prices for existing and new generics lowered to 45% of brand. These prices were subsequently reduced to 40% in January 2012, and will be further cut to 35% on July 1, 2012. Although the reforms were meant to apply to residents covered under Nova Scotia Pharmacare, the consensus among all private payers is that the generic-reform pricing strategy will also be applied to private claims, thus plan sponsors can benefit from the lower-cost generics. These changes could have potentially reduced overall spend by 2.8%, but with the offsetting factors, the actual saving was just 0.8%.

FIGURE 16 | Nova Scotia

Private Payers Benefit from Pricing Strategy



OTHER PROVINCES

Alberta was the first province to implement the generic drug reform in Canada in 2009 when it reduced its prices for both existing and new generics to 45% of brand. Since Alberta has not generated the savings it anticipated and other provinces have taken a more aggressive approach with respect to generic pricing, the province has announced that it will further reduce the price of generics to 25% of brand price by April 2013.

New Brunswick recently disclosed its two-step approach to generic drug-price reform, whereby prices will be dropped to 40% of brand price on June 1, 2012, and to 35% on December 1, 2012. The province will also implement other strategies to lessen the impact on pharmacy revenues; among them an increase to the dispensing fee, incentive initiatives (additional \$2 dispensing fee) for rural pharmacies, and the implementation of a medication-review program. Based on the current pricing structure, the potential downward impact on spend in 2012 is forecast to be 5.7%.

Newfoundland and Labrador has also communicated its plan on generic price reform. The three-step approach began April 16, 2012 with a reduction for existing and new generics to 45% of brand;

these prices will drop to 40% on October 1, 2012, and be further reduced to 35% on April 1, 2013. Based on the current pricing structure, the potential downward impact on spend is 5.5% in 2012 and 5.7% in 2013.

• • •

Only two provinces — **Manitoba** and **Prince Edward Island** — have not yet announced any generic-drug-price reforms. Overall, pricing in Manitoba is still much higher than other provinces. Using generic Lipitor as an example, it is priced at 50% of brand in Manitoba, but in Ontario and Quebec, the generic is priced at 25% of brand. It is anticipated that Prince Edward Island will follow the lead of other provinces in Atlantic Canada by reducing generic prices to 35% of brand.

The accompanying table summarizes the various provincial generic price-reform strategies, and the timing of each phase of price reductions along with the percentage of the brand price at which generics will be priced. Timing and pricing strategies vary by province, but it is anticipated that most provinces will move to generic pricing that is either 25% or 35% of brand pricing by 2013.

FIGURE 17 | Generic Price Reform

Lower Prices for Private Payers Phased In Through 2013

	Formulary Generic Prices as a Percentage of Brand									
Province	2010			2011				2012		
Alberta	45%									
Ontario	60% 50%		35%				25%			
British Columbia	60% 42 -			50%		40%		35%		
Quebec	45%			37.5%	30%			25%		
Saskatchewan	60%				40 - 4	15%		35%		
Nova Scotia	60%					45%	40%		35%	

BRAND-GENERIC DRUG MIX

Generic fill rate (GFR) continues to be a key metric for gauging the efficiency through which drug plans are taking advantage of providing lower-cost, clinically equivalent medications to their plan members. All factors being equal, higher GFRs translate to lower costs and solid clinical outcomes. In 2011, patent expiries helped drive up the national GFR by 2.1% to 50.8%. As expected, patent protection from the BAP-15 rule in Quebec resulted in a GFR of 48.2%, which is the lowest in Canada.

GFR in Canada reached an all-time high in 2011, thanks to patent expiries of several highly utilized drugs, including a full year of availability of atorvastatin (generic Lipitor, which lost its patent protection in the third quarter of 2010). The first-time generic availability of such brand drugs as Avapro (high blood pressure) and Zomig (accute treatment of migraine headaches), also contributed to the increases in GFR in 2011. For a complete list of noteworthy first-time generics, see **Figure 19** on page 16.

FIGURE 18 Generic Fill Rate (GFR) Grows in All Regions
Higher GFR Brings Lower Costs

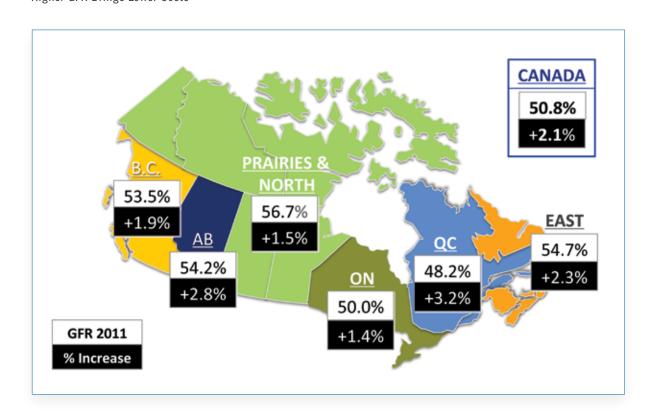


FIGURE 19 Noteworthy First-Time Generics — 2011

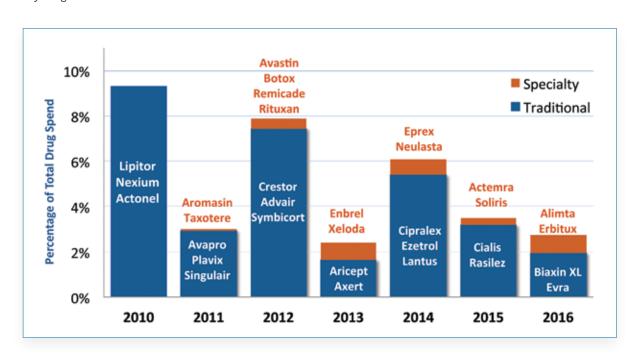
More Savings Opportunities for Private-Plan Sponsors

nregahalin			BY CLAIMS
hioganaiiii	Neuropathic pain	18	59
clopidogrel	Prevention of thromboembolic events	25	70
montelukast	Asthma, Allergic rhinitis	33	73
irbesartan	High blood pressure	44	45
zolmitriptan	Migraine	105	182
amlodipine/atorvastatin	High blood pressure High cholesterol	157	265
latanoprost	Glaucoma	224	167
rosiglitazone	Type 2 diabetes	282	376
rosiglitazone/metformin	Type 2 diabetes	327	462
sirolimus	Renal transplant rejection prevention	393	705
exemestane	Breast cancer	414	573
brinzolamide	Glaucoma	596	408
	montelukast irbesartan zolmitriptan amlodipine/atorvastatin latanoprost rosiglitazone rosiglitazone/metformin sirolimus exemestane	Prevention of thromboembolic events Asthma, Allergic rhinitis Migraine Allergic rhinitis Migraine Allergic rhinitis Asthma, Allergic rhinitis Asthma, Allergic rhinitis Asthma, Allergic rhinitis Asthma, Allergic rhinitis Migraine Allergic rhinitis Allergic rhinitis Allergic rhinitis Allergic rhinitis Asthma, Allergic rhinitis As	Clopidogrel Prevention of thromboembolic events 25 montelukast Asthma, Allergic rhinitis 33 irbesartan High blood pressure 44 colmitriptan Migraine 105 amlodipine/atorvastatin High blood pressure High cholesterol 157 latanoprost Glaucoma 224 rosiglitazone Type 2 diabetes 282 rosiglitazone/metformin Type 2 diabetes 327 sirolimus Renal transplant rejection prevention 393 exemestane Breast cancer 414

Express Scripts Canada believes that the years ahead continue to hold significant promise for private-plan sponsors in terms of lower overall drug costs, along with scheduled generic-price reductions. In 2012, there will be a number of key patent expiries, including Crestor in the High Cholesterol therapy class, and Advair for Asthma/COPD (chronic obstructive pulmonary disease). Given the brands losing patent protection over the next five years contributed to 24% of the total drug spend in 2011, Express Scripts Canada believes the generic fill rate, and savings generated by generic drug use, will continue to increase.

FIGURE 20 | Brand Patent Cliff Continues

Key Drugs Lose Patent Over Next Five Years



TREND OVERVIEW



THERAPY CLASS REVIEW

CHANGING LANDSCAPE 31

REDUCE WASTE 11



Therapy Class Review

Express Scripts Canada determines therapy classes by grouping drugs with different mechanisms of actions that treat the same medical condition. For example, the therapy class, High Cholesterol, is comprised of six drug classes. More specifically:

- HMG-CoA Reductase Inhibitors (also known as statins, e.g., Lipitor, Crestor)
- HMG-CoA Reductase Inhibitor Combinations (e.g., Advicor)
- Fibric Acid Derivatives (e.g., Lipidil)
- Intestinal Cholesterol Absorption Inhibitors (e.g., Ezetrol)
- Bile Acid Sequestrants (e.g., Questran)
- Nicotinic Acid Derivatives (e.g., Niaspan)

Overall, the Top 30 therapy classes in 2011 accounted for 91% of total claims cost, and 85% of total prescription volume. Figure 21 ranks the Top 30 by total cost; Figure 22 ranks them by total claims. The most dominant medical conditions are those that are most prevalent in the working population — namely, the cardio-metabolic triad of High Blood Pressure, High Cholesterol, and Diabetes, as well as Depression. Of note is Inflammatory Conditions, which occupies second place in the 2011 ranking, up from the fourth in 2010.

A number of the highly utilized therapy classes experienced

a negative trend — High Blood Pressure, High Cholesterol, Depression, Ulcer/Reflux, and Antibiotics/Anti-Infectives. The declines can be attributed primarily to patent expirations of many of the highly utilized brands in these classes. In the High Cholesterol therapy class, for example, Lipitor® went off patent in 2010 with generic brands becoming readily available shortly thereafter. The rapid availability of multiple generics, combined with provincial generic drug price reforms, resulted in a 17% drop in the cost per prescription, with 2011 being the first full year for which this trend can be seen.

On the other hand, Inflammatory Conditions, Diabetes, and Asthma/COPD (chronic obstructive pulmonary disease) experienced positive trends in their respective percentages of the total drug spend. The Inflammatory Conditions therapy class is dominated by high-cost drugs. There has been a trend to initiate therapy with these drugs earlier in the therapeutic pathway due to clinical evidence that earlier intervention can reduce or delay long-term progression of a disease — and perhaps disability. And many of these drugs are being approved and used for multiple indications, including rheumatoid arthritis, psoriasis, and Crohn's disease. As such, while the prevalence of each condition is relatively low, slight increases in utilization will result in large increases in total drug spend.

Overall, the Top 30 therapy classes in 2011 accounted for 91% of total claims cost, and 85% of total prescription volume

FIGURE 21 ■ Top 30 Therapy Classes – 2011

Ranked by Total Cost

When looking at the ranking of the Top 30 Therapy Classes by Total Cost, these classes accounted for 91% of the total prescription drug spend in Canada.

RANK BY TOTAL COST	THERAPY CLASSES	PERCENTAGE OF TOTAL COST		RANK BY TOTAL COST	PERCENTAGE OF TOTAL CLAIMS		RANK BY CLAIMS		TREND
2011		2010	2011	2010	2010	2011	2010	2011	2011
1	High Blood Pressure	9.93%	8.98%	1	13.09%	13.18%	1	1	-10.1%
2	Inflammatory Conditions	6.89%	8.30%	4	0.21%	0.23%	44	44	14.3%
3	High Cholesterol	9.04%	7.80%	2	6.06%	6.16%	4	4	-14.1%
4	Depression	7.00%	6.93%	3	7.65%	7.72%	3	3	-1.5%
5	Diabetes	5.64%	6.12%	6	5.28%	5.41%	6	6	8.0%
6	Ulcer / Reflux	6.22%	5.67%	5	4.61%	4.61%	8	8	-9.2%
7	Antibiotics / Anti-Infectives	5.29%	5.21%	7	8.67%	8.62%	2	2	-2.0%
8	Asthma / COPD	5.06%	5.15%	8	4.50%	4.43%	9	9	1.3%
9	Pain, Narcotic Analgesics	3.24%	3.28%	9	5.74%	5.70%	5	5	0.5%
10	Neurological Disorders	2.73%	2.76%	10	2.59%	2.67%	14	13	0.5%
11	Anti-Cancer	2.61%	2.68%	11	0.58%	0.59%	32	34	2.0%
12	Birth Control	2.49%	2.52%	12	4.02%	3.81%	10	10	0.5%
13	Multiple Sclerosis	2.31%	2.39%	14	0.08%	0.08%	51	51	2.8%
14	NSAIDs - Pain and Inflammation	2.32%	2.33%	13	4.74%	4.66%	7	7	-0.2%
15	Allergy	2.16%	2.25%	15	2.75%	2.74%	11	12	3.5%
16	Cardiovascular Disease	2.04%	2.01%	16	1.57%	1.49%	17	18	-2.0%
17	Attention Deficit Disorder	1.73%	1.90%	17	1.05%	1.11%	22	22	9.5%
18	Blood Disorders	1.35%	1.81%	22	0.49%	0.59%	34	33	33.7%
19	Hormone Replacement	1.53%	1.62%	19	1.90%	1.90%	15	15	5.5%
20	Skin Conditions	1.63%	1.62%	18	2.61%	2.48%	13	14	-0.9%
21	HIV / AIDS	1.48%	1.60%	20	0.12%	0.12%	47	48	7.5%
22	Migraine	1.44%	1.42%	21	0.66%	0.63%	31	30	-1.5%
23	Anti-Psychotic	1.25%	1.27%	23	1.24%	1.32%	20	19	1.1%
24	Osteoporosis	1.13%	0.96%	24	1.26%	1.16%	19	21	-15.3%
25	Gastrointestinal	0.89%	0.87%	25	0.94%	0.93%	24	24	-2.4%
26	Organ Transplant	0.73%	0.75%	27	0.18%	0.18%	45	45	2.8%
27	Kidney / Bladder Disease	0.69%	0.73%	28	0.88%	0.90%	25	25	4.4%
28	Erectile Dysfunction	0.65%	0.71%	32	0.38%	0.38%	37	37	7.6%
29	Topical Antibiotics / Anti-Infectives	0.69%	0.70%	29	1.22%	1.19%	21	20	1.5%
30	Preventative Vaccines	0.74%	0.70%	26	0.67%	0.60%	30	32	-5.7%

FIGURE 22 | Top 30 Therapy Classes – 2011

Ranked by Total Claims

When looking at the ranking of the Top 30 Therapy Classes by Total Claims, the list is again dominated by drugs used to treat chronic medical conditions.

RANK BY CLAIMS	THERAPY CLASSES		PERCENTAGE OF TOTAL CLAIMS		PERCENTAGE OF TOTAL COSTS		RANK BY COST		TREND
2011		2010	2011	2010	2010	2011	2010	2011	2011
1	High Blood Pressure	13.09%	13.18%	1	9.93%	8.98%	1	1	-10.1%
2	Antibiotics / Anti-Infectives	8.67%	8.62%	2	5.29%	5.21%	7	7	-2.0%
3	Depression	7.65%	7.72%	3	7.00%	6.93%	3	4	-1.5%
4	High Cholesterol	6.06%	6.16%	4	9.04%	7.80%	2	3	-14.1%
5	Pain, Narcotic Analgesics	5.74%	5.70%	5	3.24%	3.28%	9	9	0.5%
6	Diabetes	5.28%	5.41%	6	5.64%	6.12%	6	5	8.0%
7	NSAIDs - Pain and Inflammation	4.74%	4.66%	7	2.32%	2.33%	13	14	-0.2%
8	Ulcer / Reflux	4.61%	4.61%	8	6.22%	5.67%	5	6	-9.2%
9	Asthma / COPD	4.50%	4.43%	9	5.06%	5.15%	8	8	1.3%
10	Birth Control	4.02%	3.81%	10	2.49%	2.52%	12	12	0.5%
11	Thyroid Disorders	2.70%	2.77%	12	0.58%	0.62%	35	34	6.0%
12	Allergy	2.75%	2.74%	11	2.16%	2.25%	15	15	3.5%
13	Neurological Disorders	2.59%	2.67%	14	2.73%	2.76%	10	10	0.5%
14	Skin Conditions	2.61%	2.48%	13	1.63%	1.62%	18	20	-0.9%
15	Hormone Replacement	1.90%	1.90%	15	1.53%	1.62%	19	19	5.5%
16	Anti-Anxiety	1.88%	1.84%	16	0.40%	0.40%	40	41	0.6%
17	Sedative / Hypnotic	1.50%	1.53%	18	0.64%	0.69%	33	32	7.0%
18	Cardiovascular Disease	1.57%	1.49%	17	2.04%	2.01%	16	16	-2.0%
19	Anti-Psychotic	1.24%	1.32%	20	1.25%	1.27%	23	23	1.1%
20	Topical Antibiotics / Anti-Infectives	1.22%	1.19%	21	0.69%	0.70%	29	29	1.5%
21	Osteoporosis	1.26%	1.16%	19	1.13%	0.96%	24	24	-15.3%
22	Attention Deficit Disorder	1.05%	1.11%	22	1.73%	1.90%	17	17	9.5%
23	Eye Disease (Miscellaneous)	1.03%	1.05%	23	0.33%	0.38%	43	43	14.8%
24	Gastrointestinal	0.94%	0.93%	24	0.89%	0.87%	25	25	-2.4%
25	Kidney / Bladder Disease	0.88%	0.90%	25	0.69%	0.73%	28	27	4.4%
26	Steroids Anti-Inflammatory	0.86%	0.86%	26	0.24%	0.24%	48	47	0.4%
27	Benign Prostatic Hyperplasia	0.70%	0.77%	28	0.56%	0.52%	37	38	-7.7%
28	Acne	0.82%	0.76%	27	0.66%	0.66%	30	33	-0.7%
29	Muscle Relaxant	0.69%	0.70%	29	0.66%	0.69%	31	31	4.7%
30	Migraine	0.66%	0.63%	31	1.44%	1.42%	21	22	-1.5%

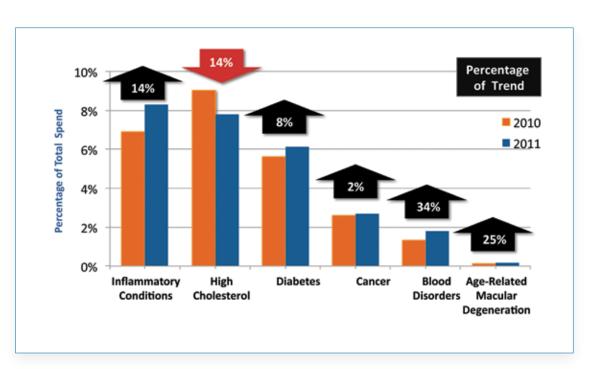
THERAPY CLASSES TO WATCH

In-depth reviews of selected therapy classes offer insight from Express Scripts Canada with respect to the key influencing factors of the utilization and cost per script, along with what may be ahead:

- Inflammatory Conditions. Although this therapy class comprised just 0.2% of total prescriptions, drugs that treat inflammatory conditions contributed to 8.3% of total overall spend in 2011. This class is expected to continue to grow with increasing therapeutic options and the expanding approved indications for key biologics.
- High Cholesterol. This therapy class had the largest overall decrease in trend in 2011, yet its drug-development pipeline includes biological drugs that may cause costs to increase in the future.
- Diabetes. The increasing prevalence of diabetes, as well as the advent of higher cost therapeutic options drove an 8% increase in the diabetes drug spend in 2011. It is anticipated

- that the aging population will result in further increases in future years.
- Cancer. Despite the increasing number of new cancer drugs available, this therapy class experienced a modest trend of 2% in 2011. The increase can be mainly attributed to the availability of generic versions of two popular oral cancer drugs, which helped drive down the overall cost per script.
- Blood Disorders. This therapy class experienced a 33.7% increase in spend in 2011, mainly due to an increase in the use of high-cost specialty drugs one of which, Soliris®, costs \$290,000 per claimant per year.
- Age-Related Macular Degeneration (AMD). The aging population has generated a significant increase in the utilization of AMD drugs, which led to a trend of 25% in 2011.

FIGURE 23 Therapy Classes to Watch
What May Be Ahead - Utilization, Cost per Script

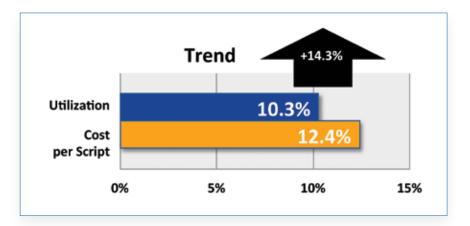


INFLAMMATORY CONDITIONS

The Inflammatory Conditions therapy class comprises several medical conditions that involve the inflammatory cascade in the body — rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and psoriasis. These are the chronic health conditions, which a severe state may require complex and costly specialty drugs to treat. Collectively, there are about 10 specialty medications that belong to this class — some of which, Actemra, Enbrel, Humira, Orencia, Remicade, and Simponi, are approved for multiple indications.

Year In Review

The trend of inflammatory conditions is growing at a fairly fast pace. This increase is driven by the double-digit rises in both the utilization (+10.3%) and cost per prescription (+12.4%).



A Closer Look

There is a number of key drivers in this therapy class:

- Actemra (tocilizumab), the first and only interleukin-6 (IL-6) receptor inhibitor approved in May 2010 for RA and juvenile arthritis, had an 8 times increase in cost and script volume.
- ✓ The nearly 50% utilization growth for both Simponi (golimumab) and Stelara (ustekinumab) in 2011 significantly impacted trend in this category. Both are subcutaneous biologic drugs, with an annual cost of about \$20,000 per patient per year.
- ✓ The drug class tumor necrosis factor (TNF) alpha inhibitors, including Enbrel (etanercept), Humira (adalimumab), Remicade (inflimixmab) continue to grow in script volume, ranging from 4% - 22% in 2011.

KEY FACTS



TREND +14.3%

PERCENTAGE
OF TOTAL SPEND
8.30%

PERCENTAGE
OF TOTAL SCRIPTS
0.23%

PER SCRIPT \$2,178

KEY DRUGS

Actemra Stelara Simponi

What's Ahead

The increase in overall trend in Inflammatory Conditions can be attributed both to recent increases in the number of product options within the class, and to the use of class members for broader indications. Nonetheless, the potential for increasing competition within the class offers plan sponsors new opportunities for clinically responsible, cost-effective utilization management. Other considerations:

Disease-state management may be appropriate. To manage a medical condition comprehensively, one needs to understand and manage both risk factors and aggravating factors. For example, patients with

- moderate to severe psoriasis should be informed of an increased risk for myocardial infarction, and be appropriately screened and managed.
- Oral specialty drugs in the pipeline are on the rise. Two such drugs in development are tofacitinib, an oral Janus-Associated Kinase (JAK) inhibitor for rheumatoid arthritis; apremilast, an oral phosphodiesterase type-4 inhibitor for psoriasis. These types of oral drugs should lead to increased utilization due to convenience and ease of administration.

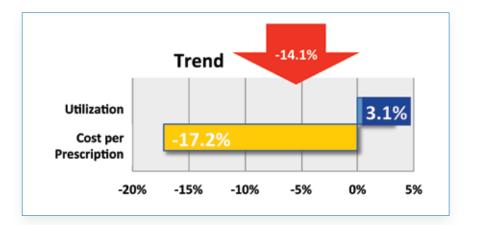
Inflammatory conditions, such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease, experienced fast-paced growth which can be attributed to the increasing number of drug options and their expanding approved indications

HIGH CHOLESTEROL

The *Canadian Health Measures Survey* released in March 2010 by Statistics Canada stated that 47% of Canadian adults between the ages of 40 and 59 had high levels of cholesterol.

Year In Review

The 14.1% decrease in spend in 2011 for the High Cholesterol therapy class was more substantial than the 8% decrease in 2010. This reduction was mainly driven by the 17.2% decrease in average cost per prescription, primarily due to the availability of generic versions of Lipitor®, and only slightly offset by the 3.1% increase in utilization.

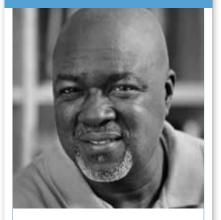


A Closer Look

Statins are the drug of choice for treating high cholesterol. With the exception of Crestor, which went generic in Canada in March 2012, generic versions of all statins were available in 2011. Thus, the availability of lower-cost generics has fully driven the negative trend for high cholesterol.

- The key driver in the decrease in cost per script was generic Lipitor (atorvastatin) which saw a 40% decrease in spend for this chemical entity in 2011
- The 17.2% decrease in cost per script was attenuated somewhat by a 20% increase in claims for Crestor and a 10% increase in claims for Ezetrol (a non-statin drug indicated for the treatment for high cholesterol).

KEY FACTS



TREND -14.1%

PERCENTAGE
OF TOTAL SPEND
7.80%

PERCENTAGE
OF TOTAL SCRIPTS
6.16%

PER SCRIPT \$74.02

KEY DRUGS

Lipitor Crestor

What's Ahead

Express Scripts Canada believes that the availability of generic versions of Crestor should drive the cost per prescription for statin drugs even lower in 2012. Once the generics are listed on provincial formularies and become subject to generic price reforms, Crestor is expected to be the most cost-effective statin among its class.

In 2012, The U.S. National Heart Lung and Blood Institute is expected to release an updated clinical guideline, *Adult Treatment Panel IV*, on cholesterol. In combination with the release of new hypertension guidelines (JNC 8) and obesity guidelines, an integrated cardiovascular risk reduction guideline is also expected. These updated guidelines will likely reinforce the use of statins, along with obesity treatment where appropriate, while diminishing the use of 'fibrates' which new evidence shows its lesser efficacy.

Several new drug classes are in the drug-product development pipeline.

- Cholesterylester transfer protein (CETP) inhibitors are oral agents that show promise for managing the secondary cholesterol target of low high-density lipoprotein (HDL).
- Mipomersen, a unique once-weekly self-injected medication, inhibits apolipoprotein-B (apo-B). Mipomersen could be marketed in 2012 in the United States for treating homozygous familial hypercholesterolemia.
- Early trials of a biological drug for inhibiting proprotein convertase subtilisin/kexin type 9 (PCSK9), REGN727, have been completed for lowering high cholesterol.

Integration of disease-state management for high cholesterol — together with diabetes, obesity and hypertension — can serve to decrease the risk of cardiovascular events, which can result in reduced productivity or disability.

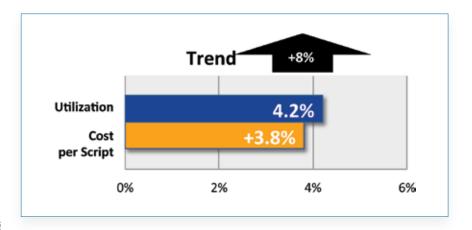
Unhealthy cholesterol levels can be controlled through diet and lifestyle changes and/or the prescription of statin medications. The availabillity of lower-cost generic Statins has fully driven the negative trend for medications in the High Cholesterol therapy class

DIABETES

In 2010, the last year for which statistics are available, the National Diabetes Surveillance System of the Public Health Agency of Canada estimated that 2.7 million Canadians (7.6%) had diabetes. This number is projected to increase to 4.2 million (10.8%) by 2020. The prevalence of diabetes in Canada is much higher than in most countries, and is surpassed only by Portugal, the United States and Mexico. The steadily growing number of people afflicted with this disease can be attributed to a number of factors, including increasing obesity rates due to sedentary lifestyles and poor eating habits, as well as the aging population.

Year In Review

Diabetes continues to increase in both utilization (+4.2%) and cost per prescription (+3.8%). This resulted in an overall trend 8% in 2011, which is similar to the trend of 9.1% in 2010.



A Closer Look

The increase in the cost per prescription was primarily driven by two new classes of medications to treat diabetes — both of which work on the incretin system of gut hormones, the DPP-4 inhibitors and the GLP-1 receptor agonists (GLP-1 RAs).

- ✓ The DPP-4 inhibitors are oral drugs. The first to arrive on the market was Januvia in 2008, followed by Onglyza®, and then Trajenta®. Market share for these drugs in the Diabetes class continued to increase in 2011; for example, Januvia's utilization increased by approximately 60%.
- ✓ GLP-1 RAs consists of two brands Victoza® and Byetta® with the former showing superior efficacy. Although Victoza® has only been on the market since May 2010, its weighted increase in utilization was more than 300% in 2011.

KEY FACTS



TREND +8%

PERCENTAGE
OF TOTAL SPEND
6.12%

PERCENTAGE
OF TOTAL SCRIPTS
5.41%

PER SCRIPT \$69.34

KEY DRUGS

DPP-4 inhibitors e.g., Januvia, Onglyza, Trajenta

> GLP-1 RAs e.g., Victoza

✓ The drug class, thiazolidinediones (Actos®, Avandia®), experienced a steady decline of 20% in utilization partly due to cardiovascular safety concerns. Much of the utilization has shifted to DPP-4 inhibitors.

What's Ahead

Express Scripts Canada believes that disease-state management can play an important role in preventing diabetes and diabetes-related complications.

- Multiple risk factors are reversible and can be managed. According to the Canadian Diabetes Association, the risk of developing diabetes can be reduced by 58% by engaging in moderate physical activity for 30 minutes a day and by losing 5%-7% of body weight. Intervention by a health-care professional can also help guide individuals to lower their risks.
- For someone already diagnosed with diabetes, diseasestate management becomes even more important to

prevent and/or delay complications that can impact almost every organ in the body. These complications can have significant medical conditions that can lead to significant increases in short-term and long-term disability, along with increased absenteeism and decreased productivity.

The growing prevalence of diabetes has stimulated extensive research in the pharmaceutical industry.

- Novel drug classes, such as the sodium glucose cotransporter type 2 (SGLT-2) inhibitors and the free fatty acid receptor 1 (FFAR1) agonist, are in development.
- New GLP-RAs such as long-acting exenatide, albiglutide, and taspoglutide — are being developed.
- Newer insulin analogues such as an ultra-long-acting analogue, insulin degludec, and ultra-rapid-acting analogues – are in the works.

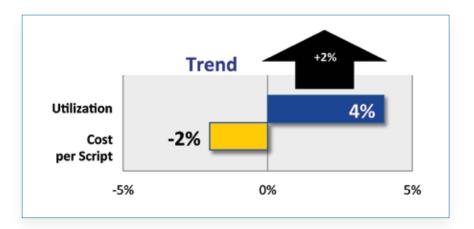
The steadily growing number of people afflicted with diabetes can be attributed to a number of factors, including increasing obesity rates due to sedentary lifestyles and poor eating habits

CANCER

Although cancer treatments have significantly improved over the past couple of years, statistics from the Canadian Cancer Society put the prevalence of cancer among Canadians at about 2.3% of the population — or one out of every 44 people.

Year In Review

The trend has slowed tremendously for drugs to treat cancer - from +12.2% in 2010 to only 2% in 2011. This modest trend can be attributed to the 4% increase in utilization and attenuated by the slight decrease (2%) in the average cost per prescription.



A Closer Look

With the increasing number of oral Cancer medications available, more and more patients can receive treatment at home.

The decrease in the average cost per prescription was mainly driven by the availability of generic versions of two oral Cancer drugs, — Femara (letrozole) for treating breast cancer and Casodex (bicalutamide) for treating prostate cancer. Both are covered by most provincial formularies and, as such, the generics are being priced at 25%-35% of the cost of brand. The total drug spend for both declined 22% in 2011 to \$3 million, from \$3.8 million in 2010.

KEY FACTS



TREND +2%

PERCENTAGE
OF TOTAL SPEND
2.68%

PERCENTAGE
OF TOTAL SCRIPTS
0.59%

PER SCRIPT \$245.74

KEY DRUGS

Casodex Femara Zolinza Votrient Temodal The three key drivers in the positive trend in 2011 are all oral Cancer drugs:

- Zolinza, which is indicated to treat cutaneous T-cell lymphoma (CTCL), with an average cost of \$5,375 per claim.
- Votrient, which is used to treat kidney cancer, with an average cost of \$5,016 per claim.
- Temodal which is indicated to treat brain cancer, with an average cost of \$1,433 per claim.

What's Ahead

Express Scripts Canada expects the Cancer therapy category to continue to grow with new drugs entering the market for existing conditions, as well as areas where there is currently limited or no treatment options.

The risk of cancer increases with age, which correlates with an increase in the prescription and use of Cancer drugs.

Express Scripts Canada further recommends that private payers should always navigate the potential sources of reimbursement. The private-sector drug-trend increase may be attenuated by the expansion of provincial cancer drug coverage, as well as manufacturer patient assistance programs.

Disease-state management is important to prevent and manage the treatment of cancer.

- The World Health Organization estimates that onethird of all cancer cases are preventable; smoking, for example, is the single-greatest avoidable risk factor for cancer mortality. An intervention from a health-care professional can help patients to identify and modify potential risk factors, with the goal of reducing.
- Cancer patients often have many other comorbidities like depression, pain, infections and stroke. Instead of treating cancer by itself, health-care professionals must address the overall health of the patients.

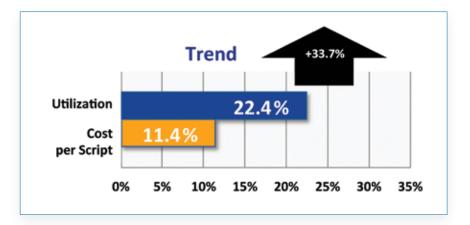
The decrease in the average cost per prescription was mainly driven by the availability of generic versions of two oral Cancer drugs, - Femara (letrozole) for treating breast cancer and Casodex (bicalutamide) for treating prostate cancer

BLOOD DISORDERS

The Blood Disorders therapy class is comprised of a wide range of medical conditions—the common of which are a decrease in white blood cells secondary to chemotherapy use among cancer patients, or a decrease in red blood cells in patients with kidney problems. These also include such relatively rare blood disorders as paroxysmal nocturnal hemoglobinuria (PNH), an anemia caused by the patient's immune system that destroys their red blood cells. It is estimated that there are approximately 90 PNH patients across Canada.

Year In Review

The trend for medications that treat blood disorders was 33.7% in 2011,which is much higher than the 12.5% trend in 2010. Both utilization and the average cost per script had increased by +22.4% and 11.4%, respectively.

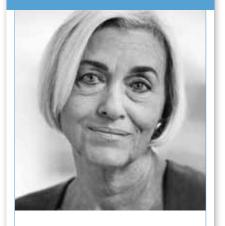


A Closer Look

Nplate and Soliris are the two key drivers for blood disorders.

Nplate (romiplostim) is used to treat chronic idiopathic thrombocytopenic purpura (chronic ITP), a condition which the platelet count is chronically low due to an unknown cause. Romiplostim works by stimulating the cells in the bone marrow to produce more platelets, thereby reducing the risk of bleeding. Although the prevalence is relatively low and Express Scripts Canada only had 31 claimants for Nplate in 2011, it has a relatively high price tag of \$20,000 per patient per year.

KEY FACTS



TREND +33.7%

PERCENTAGE
OF TOTAL SPEND
1.81%

PERCENTAGE
OF TOTAL SCRIPTS
0.59%

AVERAGE COST
PER SCRIPT
\$185

KEY DRUGS

Nplate Soliris Soliris was approved in 2009 for treating the breakdown of red blood cells resulting from paroxysmal nocturnal hemoglobinuria (PNH). Soliris is a human monoclonal antibody that binds to the proteins that make up the complement inflammatory process responsible for PNH. PNH can cause significant morbidity and mortality; generally, patients have a median survival of 15 years. In 2011, Express Scripts Canada processed prescription claims for Soliris for 18 patients; the claims accounted for a total drug spend of \$5.2 million, averaging to about \$290,000 per claimant per year.

Neulasta and Neupogen, which are used to stimulate white blood cell production, had steady increases of 20%-30% in both cost and utilization in 2011.

What's Ahead

One of the possible future treatments for blood disorders is to use gene therapy to correct any abnormal genes in the patient's stem cells. Express Scripts Canada believes that such treatments, which would be paid for by the public sector, are expected to be quite expensive. And they are not expected to be made available for at least couple of years.

By integrating their coverage and formulary plans with potential additional of coverage through the provinces, private plans may be less vulnerable to these high drug costs incurred by a small number of patients.

Treatments for blood disorders can be expensive.

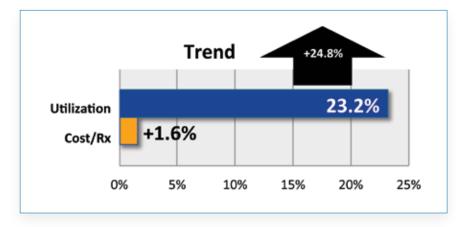
One such specialty drug treatment for the abnormal breakdown of red blood cells can cost hundreds of thousands of dollars per patient – per year

AGE-RELATED MACULAR DEGENERATION

Age-Related Macular Degeneration (AMD) is a degenerative disease of the central portion of the retina (the macula) that results primarily in loss of central vision. AMD is classified as dry or wet (exudative), with the latter form causing the vast majority of severe vision loss. The Eye Diseases Prevalence Research Group (EDPRG) estimated that the prevalence of AMD in adults 40 and over in the United States is 1.47%, and this incidence greatly increases with age.

Year In Review

Drug spend for this class of medications increased almost 25% in 2011, which is about three times higher than the trend of 8.8% in 2010. The 23.2% increase in utilization, due to the aging population, is most likely the key driver for this class of medications.



A Closer Look

Two drugs dominate the prescriptions written to treat age-related macular degeneration in Canadians.

- Lucentis (ranibizumab) is the key driver in this class, with a 27% increase in its utilization and drug spend. This is a monoclonal antibody that suppresses vascular endothelial growth factor A, and prevents formation of abnormal blood vessel growth and leakage in the eye. The leakage and abnormal blood vessel growth can result in vision loss.
- ✓ Lucentis is derived from a fragment of Avastin® (bevacizumab), which is commonly used off-label for wet AMD.

KEY FACTS



TREND +24.8%

PERCENTAGE
OF TOTAL SPEND
0.17%

PERCENTAGE
OF TOTAL SCRIPTS
0.01%

PER SCRIPT \$1,088

KEY DRUGS

Lucentis

Macugen is also available and approved for treating wet AMD. Although it has shown to reduce vision loss, it has not provided actual improvement in vision. Thus, its utilization remains low.

What's Ahead

With a steadily aging population, Express Scripts Canada predicts that the number of Canadians who will be affected by macular degeneration will definitely continue to increase.

Several investigational clinical trials are under way to evaluate treatment options for AMD. These include evaluation of an angiogenesis inhibitor pazopanib administered as eye drops, subconjunctival injection of an anti-proliferative polyamine analog, various combination treatment protocols of photodynamic therapy with intra-vitreal anti-VEGF (Vascular Endotheliat Growth Factor agents, and topical kinase inhibitor with multiple growth-factor targets.

Age-related macular degeneration (AMD) is the most frequent cause of severe vision loss in older Canadians. As the population ages, the number of Canadians affected will continue to increase

THERAPY CLASS REVIEW 17

CHANGING LANDSCAPE



Changing Landscape

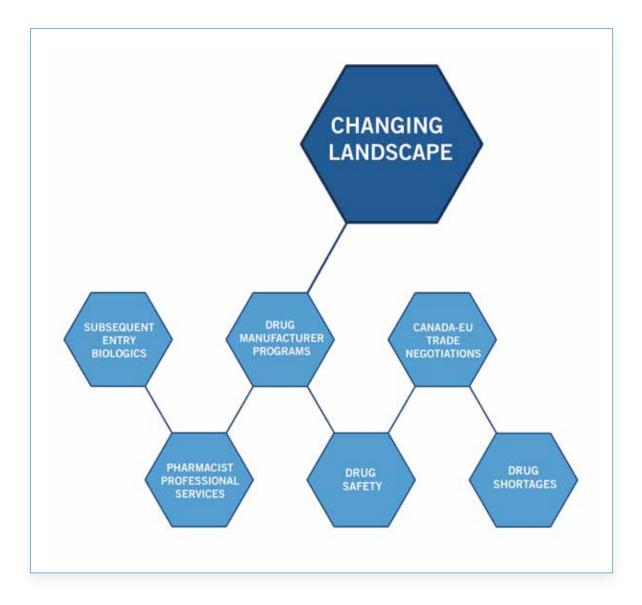
Above and beyond the factors that influenced drug trend for 2011, there are other conditions going forward that will continue to shape the pharmacy landscape in Canada. These conditions include drug safety advisories and warnings issued by Health Canada, the proposed trade reforms by the European Union that could potentially extend brand patents, the emergence of subsequent-entry biologics for specialty medications, the

expansion of pharmacist services, the increasing prevalence of drug-manufacturer programs, and ongoing challenges with drug shortages.

Each of these elements could potentially influence future drug spend for private plans in Canada.

FIGURE 24 | Changing Landscape

Multiple Elements to Impact Future Drug Spend



DRUG SAFETY

Drug-safety concerns will continue to influence the utilization of drugs as well as the brand/generic mix.

With health information being more readily available through different media — Internet, television, radio, newspaper — patients have become more educated, more informed, and more involved in managing their own health. An increasing number of patients may now demand more information from health-care professionals and specify their preference in the choice of drugs. Pharmacists, in collaboration with physicians, are in the best position to provide accurate and unbiased drug information to patients, as well as to empower a well-informed patient to use the most cost-effective medication.

The accompanying table lists some of the drugs (specialty drugs in red, traditional drugs in black) that were issued health advisories and warnings by Health Canada between January 2006 and March 2012. The emergence of safety issues for both these drug classifications highlights the importance of weighing the extensive clinical experience and long-term safety data of the older, lower-cost generics when formulating a managed drug plan.

TRADE TALKS WITH EUROPEAN UNION

Canada and the European Union (EU) are currently negotiating a Comprehensive Economic and Trade Agreement (CETA) which could potentially lead to increase costs for plan sponsors in Canada.

One of the key proposals is to extend intellectual property for pharmaceuticals by an average of 3.5 years, allowing brand drugs to receive market exclusivity for a longer period. Any extension to the patent life for brand-name drugs could delay entry of first-time generics into market; thus, private payers would continue to pay for the higher brand price and drive up the cost per prescription. This change is intended to provide an incentive for research and development of new drugs in Canada, but could cost payers — both private and public — an additional \$2.8 billion per year.

It is still unclear whether this proposal would apply retroactively to expired patents, existing patents, or only to new patents in the future. Both Canada and the EU hope to conclude negotiations by 2012.

FIGURE 25 | Drug Safety Issues

More New Drugs Being Monitored by Health Canada



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SUBSEQUENT ENTRY BIOLOGICS

Subsequent Entry Biologics (SEBs) is an emerging global field that could present a great savings opportunity for plan sponsors.

Health Canada defines an SEB as a biologic product that enters the Canadian pharmaceutical market, and is similar to an existing innovator (brand) product. The Health Canada Patent Registrer indicates that several notable biologics are scheduled to come off patent over the next four years. The patents for Avastin, Botox, Rituxan, and Remicade are scheduled to expire in 2012.

FIGURE 26 Subsequent Entry Biologics (SEB)
Patent Expiries Looming

Remicade	Xeloda	Neulasta	Velcade	
Remicade	Xeloda	Neulasta	Velcade	
Rituxan	Kineret	Neupogen	Soliris	
Avastin Botox	Enbrel	Eprex	Actemra	

There are three key differences between the traditional generics and SEBs-all of which have the potential to make a huge impact on their market penetration.

The first difference is the product availability after the patent for a brand product has expired. Starting from approval, SEBs must be submitted through the New Drug Submission (NDS) pathway, which is a similar, albeit shorter process, to the approval process for brand products. This pathway requires the NDS applicant to present sufficient clinical data on efficacy and safety to demonstrate comparability between the SEB and their relative brands. This requirement has a major impact on research-and-development costs, as well as the timing of product release. Typically, traditional generics may become commercially available within days or weeks after the patent of reference brand expires;

with SEBs, the timing of market availability is still relatively unknown and could take months or even years.

Second is product interchangeability. Unlike most traditional generics that are interchangeable with their brand equivalents, SEBs are not interchangeable, due to variations in the biological manufacturing process.

And it is the status of interchangeability that leads to the third difference: pricing strategy.

Generics versions of traditional brand-name drugs are generally priced at 25%-40% of their brands. Express Scripts Canada anticipates SEBs will be only modestly less expensive than their reference brands, with expected price reductions of approximately 20% to 30%. Since a pharmacist cannot substitute a brand with its SEB during dispensing, private payers would have to reimburse the brand drug cost, despite the fact that a SEB is available.

Generic substitution is unable to capture the potential costsavings provided by SEBs. With several specialty drugs expected to lose patent protection over the next few years, Express Scripts Canada believes that the introduction of SEBs, in key therapy classes, will play a significant role in controlling future increases in drug costs. Plan sponsors that implement trend-management initiatives which promote the use of lower-cost therapeutic equivalents will be in the best position to reap the potential savings from these lower-cost alternatives.

FIGURE 27 | Generics vs. SEB Biologics
Big Differences in Potential Savings

	Availability Post-Patent	Provincial Interchangeability	Percentage of Brand
Generics Traditional	Days to Weeks	Yes	25%-35% \$ \$
Generics SEB/Biologics	Months to Years	No	70%+ \$\$\$\$\$

PHARMACIST PROFESSIONAL SERVICES

The expansion of reimbursement for pharmacist professional services by the public sector could lead to additional pressure for corresponding funding from private payers.

Community pharmacies across Canada have voiced their concerns over the negative financial impact generic drug reforms have had on their operations — more specifically, the elimination, or reduction, of drug rebates from generic drug manufacturers, as well as the reduction of the allowable pharmacy mark-ups. Some provincial governments have promised to reinvest the money saved back into the health-care system; more specifically, in the form of expanding the scope of pharmacists and initiating a funding model for services provided by the pharmacists. Saskatchewan, for example, reimburses pharmacists \$18 for assessments provided to patients for such minor ailments as mild acne, cold sores, and insect bites. As of July 2012, Alberta will reimburse pharmacists \$20 to renew, modify and, in some cases, prescribe medications.

With more provinces reimbursing pharmacists for services provided to patients covered under the public program, more pressure may be brought to bear from community pharmacy groups requesting the same considerations from private payers. Private payers have to weigh the risks and benefits for reimbursing a variety of pharmacy services that are often "value-added", as there is the inherent assumption that pharmacists are knowledgeable and well-equipped to intervene and optimize the drug therapy, a beleif which is keeping with their professional goal to improve patient health outcomes.

DRUG MANUFACTURER PROGRAMS

In Canada, there are an increasing number of drug-manufacturer reimbursement programs — known as Drug Coupons or Patient Assistance Programs — that can lead to increased use of higher-cost drugs. These are usually offered by the brand-name drug manufacturers to provide financial assistance to patients by reducing or eliminating the patient co-pay for a brand drug. At the same time, these programs would drive the market share for a brand product, thus changing the brand-generic drug mix.

Express Scripts Canada recommends that private plans should protect themselves from this practice by using a mandatory generic substitution plan to help ensure they continue to only reimburse the lowest-cost interchangeable item on the formulary — regardless of whether the patient chooses to use the brand-name product.

DRUG SHORTAGES

Drug shortages in Canada lead to a change in dispensing frequency that has resulted in higher total costs for plan sponsors due to a greater number of dispensing fees.

Saskatchewan Drug Information Services tracks drugs for which shortages have been voluntarily reported by manufacturers and whose efforts in this regard are endorsed by Canada's Research Based Pharmaceutical Companies (Rx&D) and the Canadian Generic Pharmaceutical Association (CGPA). As of March 2012, there were approximately 150 Canadian drug identification numbers (DINs) for which shortages were listed — the majority of which are used to treat acute medical conditions. The reasons for these shortages include consolidation within the industry, raw material or active pharmaceutical ingredient issues, supply-chain disruptions, international sourcing, manufacturing delays and regulatory issues.

In response to these shortages, health-care workers across the country have rationed existing stock and, in some cases, have dispensed fewer days of supply per prescription to service more patients. This has resulted in a reduction in the average days of supply per prescription, and a corresponding increase in the number of dispensing fees.

Different stakeholders have acted to mitigate the impact caused by these shortages. To provide alternate sources to the back-order stock, Health Canada has committed itself to expediting the drugapproval process by shortening the review time from six months to one. However, Ottawa has not developed a national strategy that would require manufacturers to report any disruptions in production; reporting of drug shortages continues to be a voluntary process by drug manufacturers.

THERAPY CLASS REVIEW 17

CHANGING LANDSCAPE 35

REDUCE WASTE



Reduce Waste

Express Scripts Canada's proprietary research has determined that there is a huge amount of money being wasted within the drug plans of companies and organizations across Canada.

With respect to waste within the prescription drug benefit, Express Scripts Canada defines waste as "spending more without improving health outcomes." In keeping with this definition, Express Scripts Canada believes that in 2011 alone, private plans in Canada wasted more than \$5 billion in drug spend. In addition, another \$7 billion-\$9 billion was wasted in health-care spend due to non-adherence.

Given that number is not only huge but growing, it is increasingly important to structure interventions and solutions that help protect members and plan sponsors from overspending. To help private payers to better understand just exactly what this waste entails, Express Scripts Canada groups pharmacy-related waste into three categories:

Channel Waste. Waste in the drug spend created by using

suboptimal dispensing intervals for maintenance medications and by not using more cost-effective distribution channels.

- Drug-Mix Waste. Waste in the drug spend created by using a higher-cost medications that generate no additional health benefits.
- Non-Adherence Waste. Waste in the total health-care spend
 that occurs when the patient does not take medications as
 prescribed, which leads to a worsening of condition that
 requires additional health-care spending, such as more
 physician visits, extra laboratory tests, additional drug
 therapy, hospital emergency-room visits, hospital admissions,
 and short-term disability insurance payments.

It is important to reduce pharmacy-related waste. The cost savings realized not only enables a plan sponsor to reduce the cost of delivering and sustaining the health benefit, but it will also provide them with the option of reinvesting those savings into their health-benefits program in ways that will make it more sustainable, more effective and more valuable to plan members.

To optimize the value of the prescription drug benefit, it is mission-critical to reduce waste wherever possible. In 2011 alone, private drug plans in Canada wasted more than \$5 billion in drug spend. Another \$7 billion-\$9 billion was wasted in health-care spend due to non-adherence

CHANNEL WASTE

Channel waste is created by using suboptimal dispensing intervals for maintenance medications and by not using more cost-effective distribution channels. For 2011, Express Scripts Canada estimates channel waste for the private-sector drug spend to be \$1.1 billion.

Maintenance drugs that are used to treat chronic conditions, such as high cholesterol and diabetes, contributed to 67.5% of all claims in the Express Scripts Canada database. These items are filled with an average supply of 46 days per script. For most patients who are stabilized on a maintenance medication, the optimal supply is 90 days. The waste created by refilling a prescription more frequently than necessary can be easily addressed — and avoided — thereby saving plan sponsors and plan members significant amounts of money.

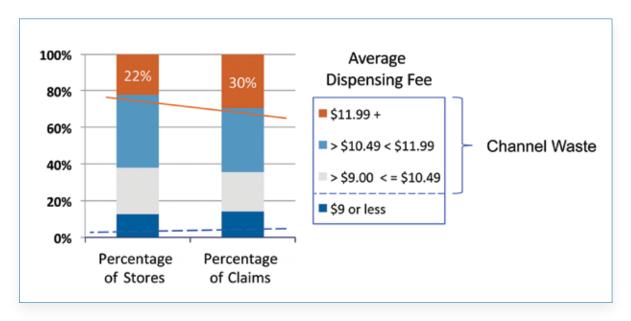
The other component that contributes significantly to channel waste is the high dispensing fees charged by many retail

pharmacies. Express Scripts Canada research has determined that 22% of all pharmacies across Canada charge a dispensing fee of \$11.99 or more, and 30% of all prescriptions paid for by private drug plans are dispensed from these pharmacies. By encouraging patients to obtain their drugs from a pharmacy that charges a lower dispensing fee, this channel waste can be eliminated.

Take for example, the case of the diabetic patient who, since being diagnosed five years ago, has taken 1000mg of metformin twice a day to treat this condition. Like many other diabetics, he goes to his retail pharmacy once a month to pick up a 30-day supply of metformin; on each visit, he pays an \$11.99 dispensing fee to have the prescription filled. Over the course of a year, he will pay \$143.88 in dispensing fees alone. If, on the other hand, he changes his behaviour and receives 90-day supply from a pharmacy that charges a \$9 dispensing fee, he could save \$107.88 a year in dispensing fees — without compromising his health.

FIGURE 28 | Waging War on Channel Waste

Utilization — Skewed to Costly Distribution Channels



DRUG MIX WASTE

Drug-mix waste is created by using higher-cost medications that generate no additional health benefits. For 2011, Express Scripts Canada research estimates the cost of drug-mix waste in the private-sector drug spend to be \$4.2 billion.

With multiple patent expiries and drug-price reforms introduced by most provinces that have further lowered the prices for generic drugs, it is quite obvious that plan sponsors can benefit financially by simply mandating generic substitution. The substitution of clinically equivalent and/or therapeutically equivalent drugs for more expensive brand-name drugs will result in significant cost savings for both the plan sponsor and the patient.

Take, for example, a drug claim submitted for a 90-day supply of Lipitor®. The price for the brand drug is \$220, compared with \$55 for the generic, which would result in the elimination of \$165 in drugmix waste every three months — or \$660 of drug-mix waste per year. Express Scripts Canada research shows that for every 1% increase in generic fill rate (GFR), a decrease of approximately 1% can be realized in the overall drug spend.

Drug-mix waste can be further reduced by implementing therapeutic substitution through the use of managed formulary or tiered

management programs. Therapeutic substitution requires intervention by the pharmacist who, in turn, would contact the prescriber to receive approval to switch a patient from higher-cost drug to a more cost-effective medication that would provide a similar therapeutic effect.

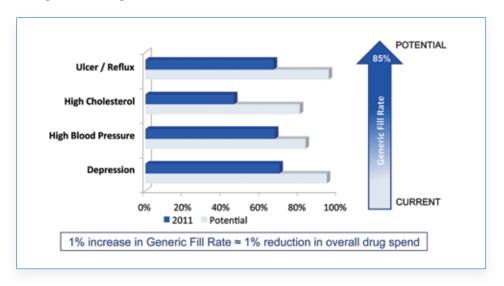
The use of therapeutic switching — for example, changing an gastric ulcer/reflux patient's medication from brand-name Nexium® to generic Pariet® — can further increase the GFR beyond that provided by simple generic-substitution programs, while maintaining patient health outcomes.

Immediate, proactive reaction needs to be taken by health-benefits providers to take full advantage of lower-cost generic drugs. Express Scripts Canada believes that in assessing the brand-generic mix of drugs for treating a specific medical condition, the GFR is often suboptimal based on the generic treatment options that are widely available.

Take for example, the metrics related to drug claims for treating high cholesterol. The current generic fill rate is only about 50% – Express Scripts Canada believes that the GFR has the potential to reach as high as 85%, but only if appropriate changes to patient behaviour take place.

FIGURE 29 | Waging War on Drug-Mix Waste

Taking Full Advantage of Lower-Cost Generics



NON-ADHERENCE WASTE

Non-adherence waste is defined waste in the total health-care spend that occurs when the patient does not take medications as prescribed. The potential consequences of non-adherence, which may lead to worsening patient health and higher treatment costs, include additional physician visits, extra laboratory tests, additional drug therapy, emergency-room visits, hospital admissions, and short-term disability insurance payments. Some sources have estimated the cost of pharmacy-related waste due to non-adherence in the total health-care spend in Canada to be \$7 billion-\$9 billion.

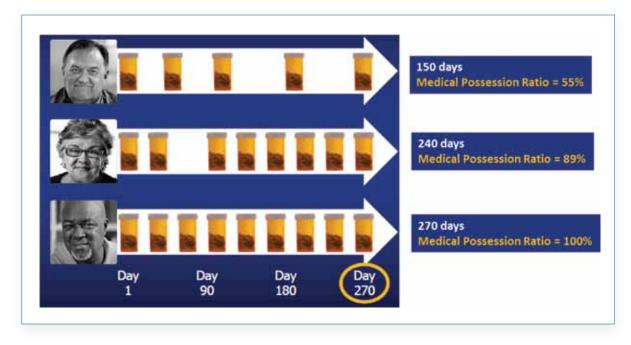
Express Scripts Canada measures medication adherence for patients with chronic medical conditions through the medication possession ratio (MPR), which is defined as the number of days of pills supplied over time. Any patient with a MPR of 80% or above is considered adherent, while MPR less than 80% is considered

non-adherent. For example, if a patient is diagnosed with type 2 diabetes and is prescribed with a drug to be taken once a day, the patient would be expected to possess 270 days of pills in a 270-day period; if he does, his MPR is 100%. If the patient possesses 240 days of pills over this period, the MPR would be 89%, and the patient would still be considered adherent. If, however, the patient only has 150 days on hand during this period the MPR would be 55% and the patient would be considered non-adherent.

The average adherence of patients who take medications for chronic conditions is relatively poor. Express Scripts Canada claims data, for example, shows that the percentage of claimants who are adherent (as defined by MPR of 80% or above) for high-cholesterol patients is 57%, 48% for high blood pressure, and 43% for diabetes.

FIGURE 30 | Adherence - Measured by Medical Possession Ratio (MPR)

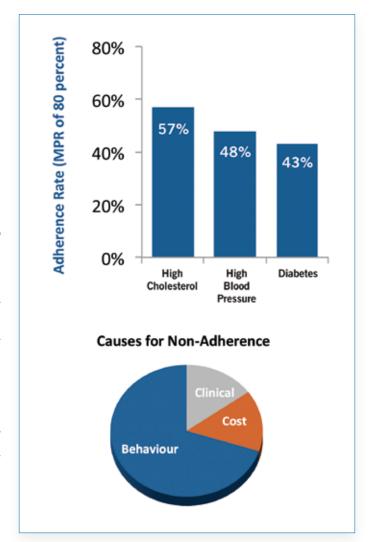
Number of Days Supplied Over Time



Poor adherence can be as a result of cost concerns (i.e., the ability to afford the co-pay) or clinical concerns (i.e., patient perception of need of the drug prescribed, or perceived side effects). In most cases, however, poor adherence is simply the result of poor behaviour (i.e., forgetfulness, and procrastination to obtain refills at the retail pharmacy) that can easily be overcome. As a result, non-adherence waste can be reduced by simply helping patients to understand the importance of adherence, and empowering them to stay compliant with the medication regimen prescribed for them.

Express Scripts Canada believes such behaviour changes can save billions of dollars per year in related health-care costs.

FIGURE 31 | Poor Adherence
A Frequently Prevalent Occurrence



SOLUTIONS TO REDUCE WASTE

To eliminate waste from the pharmacy benefit, plan sponsors need to drive significant member behaviour changes. Effective health care begins with clinicians who diagnose patients and design treatment regimens to deliver the best possible health outcomes. But despite the best efforts of health-care providers to diagnose and treat ongoing medical conditions, optimal health outcomes are possible only through the behaviour of patients.

Private plans must engage members to unlock their good intentions and, where necessary, encourage and help them to change their behaviour. Patients have a tremendous opportunity to help reduce waste while maintaining and, where possible, improving their health outcomes Express Scripts Canada believes that this can be accomplished by engaging in three simple pharmacy-related behaviours:

- Use safer, more cost-effective delivery channels. This
 means using a higher number of days of supply, where
 clinically appropriate, for maintenance prescription
 medications, and securing the medication through more
 cost-effective delivery channels.
- Use lower-cost, clinically effective medications. Patients should not pay higher prices for medications that generate no additional health benefit. Private payers need to empower the patients to optimize the use of lower-cost, clinically effective medications through the use of generic substitution and therapeutic substitution.
- Take medications as prescribed. Adherence to therapy is an extremely important behaviour: get a prescription filled, take it as required, and renew/refill as directed. Patients need to understand and eliminate the barriers they wittingly, and unwittingly, put between themselves and adherence to the treatment regimen they have been prescribed.

FIGURE 32 | Good Intentions Not Always Enough
People are Wired for Inattention and Intertia



When it comes to the behaviour of plan members, consumer behaviour is a crucial factor in health outcomes and plan cost, but it does not always reflect underlying intentions. Express Scripts research has shown that the vast majority of patients want exactly what plan sponsors want: lower costs and optimal health. These findings upend conventional thinking. The disparity is not between the goals of plan sponsors and patients; rather, it is between what consumers want and what they do. While people have good intentions, they are wired for inattention and inertia.

Traditional tools, such as education and financial incentives, will not close this gap between intent and behaviour because they focus on changing patients' minds rather than activating the good intentions that already exist. The advanced application of the behavioural sciences to health care leverages proven strategies to activate consumer intent. Fortunately, services are now available that will allow plan sponsors to better manage the cost of the prescription drug benefit while actually providing plan members with an enhanced prescription drug service.

Express Scripts Canada's expanded pharmacy benefit management (PBM) service, for example, uses tools that apply behavioural sciences to health-care decision-making to influence plan-member behaviour and, ultimately, the decisions that affect the prescription-drug benefit. Plan members, with the support of their physician, are proactively encouraged to interact with a team

of highly qualified professionals to learn about their maintenance medication alternatives so that they can make more informed choices. The result will be decisions that offer the best possible health outcome while reducing costs for both the plan member and the plan sponsor.

Over the past few years, Express Scripts research has repeatedly demonstrated that better care and zero waste often go hand-in-hand — the most effective care often costs the least. Thus the challenge is not simply to make these two goals compatible, but rather to do so in a manner that is acceptable to both members and plan sponsors. Surprisingly, the biggest gap is not between what plan sponsors want and what people want, but rather between what people want and what people do.

To activate good intentions, Express Scripts leads the way in the convergence of the behavioural sciences and health care — an approach we call Consumerology®. This unique approach provides plan sponsors with practical solutions that deliver better health and lower costs while *preserving individual choice*.

ABOUT EXPRESS SCRIPTS CANADA

Express Scripts Canada, a registered business name of both ESI Canada and Express Scripts Canada Services, each an Ontario partnership indirectly owned by Express Scripts, Inc., is one of Canada's leading providers of health benefits management services. From its corporate headquarters in Mississauga, Ontario, Express Scripts Canada provides a full range of integrated pharmacy benefit management (PBM) services to insurers, third-party administrators, plan sponsors and the public sector, including health-claims adjudication and processing services, home delivery pharmacy services, benefit-design consultation, drugutilization review, formulary management, and medical and drug-data analysis services, to better facilitate the best possible health outcomes at the lowest possible cost. For more information about Express Scripts Canada, visit its Website at www.express-scripts.ca.

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