

November 2015

Specialty Drugs: Trends, Challenges and Solutions



Join **THE CONVERSATION**, brought to you by Sun Life Financial – Group Benefits.

Life's brighter under the sun



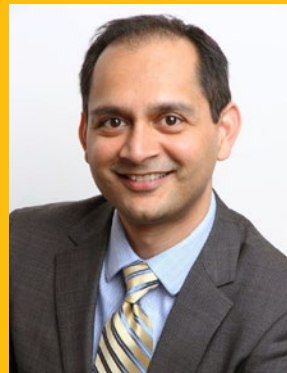
Foreword

As someone tasked with ensuring plan sponsors have a sustainable drug plan that provides their plan members with access to the coverage they need, I can say with conviction that we're on the brink of a major challenge – of a magnitude perhaps not seen before in our industry.

I am talking about specialty drugs. The experience with new hepatitis C drugs last year was the wake-up call – this was only the beginning of a trend that is accelerating at lightning fast speed. Many new drugs are set to enter the market with the same potential to impact drug plan costs as we saw with hepatitis C drugs.

In my discussions with plan sponsors, advisors and others over the past year, I've seen a growing need for clarity and understanding about the potential impact of these new drugs on plan costs. As a plan sponsor, you need the facts about specialty drugs – so you can make the right decisions to help ensure your plan's sustainability.

This Bright Paper provides you with a clear view of the specialty drug trend, including forecasts, potential impacts on plan costs and pooling and the steps you can take to help protect your plan.



Atul Goela, B.Sc. Phm., R.Ph

Director, Pharmaceutical Benefits
Sun Life Assurance Company of Canada

THE CONVERSATION.

At Sun Life, we know that it takes many voices to have a great conversation. That's why we are working with a wide range of people – inside and outside of Sun Life – to bring the best thinking in Group Benefits to the marketplace. These are subject experts, visionaries and leaders in best practices and innovative ideas – coming together to take benefits to the next level. We will be using our resources, expertise and relationships to facilitate the dialogue. We understand the power of great minds. We want everyone to contribute.

Join **THE CONVERSATION.** Brought to you by Sun Life Financial.

Introduction



Specialty drugs target specific, complex and chronic conditions such as multiple-sclerosis, rheumatoid arthritis and hepatitis C. With efficacy that was only dreamt of a decade ago, these new therapies give patients with debilitating conditions the possibility of normal lives, and, in some cases, even outright cures. We have truly entered an exciting new era of possibilities in health care.

But this comes at a high cost – **often in the tens of thousands of dollars per plan member and sometimes much more.** With many new drugs set to enter the market, and a research and development pipeline that is forecast to be increasingly dominated by specialty drugs, the cost pressures on drug plans will be unprecedented.

In 2014, two new drugs to treat hepatitis C (Sovaldi® and Harvoni®) underscored the challenge ahead. With 90%+ cure rates and fewer side effects than traditional treatments, the

use of these drugs exploded. With a price tag of \$60,000 or more per claimant for a course of treatment, the amount spent on drugs used to treat hepatitis C tripled over the previous year. Within the first quarter of 2015, total costs for hepatitis C products continued to escalate and had already accounted for over half of the total costs of drugs for the condition in 2014.¹

Fortunately, we are not left without tools to face this challenge. As a plan sponsor, there are many practical options available to you now that can help make a difference. By ensuring that your overall drug plan operates as efficiently as possible, as well as employing solutions directly aimed at managing specialty drugs, you can make significant progress toward protecting the drug coverage your employees need into the future. The time to act is now.

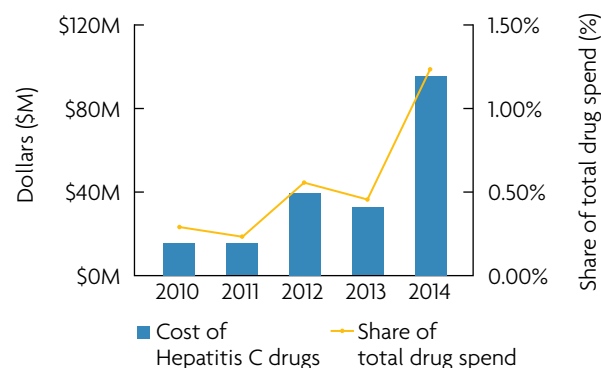
HEPATITIS C IN FOCUS

Last year, new treatments introduced for hepatitis C, Sovaldi® and Harvoni® (priced at \$60,000 plus), offered an eye-opening example of the potential impact of specialty drugs on workplace plans.

- In a few short months, these drugs captured the majority of the market share for hepatitis C therapies, tripling annual private drug spending on the condition, reaching \$100 million.²
- Since these new drugs and others set to enter the market offer a cure and are well tolerated, utilization among the estimated 250,000 Canadians living with chronic hepatitis C will likely increase dramatically this year and next. In just the first three months of 2015, the amount spent

on hepatitis C drugs by private plans had already exceeded \$50 million.³

Figure 1: Costs of Hepatitis C drugs 2010-2014



Source: Recreated from IMS Brogan



What are *specialty drugs*?

There is no standard scientific definition for specialty drugs – the definition has been evolving as the drugs evolve. However, the presence of two or more of the following features generally indicates that a drug is a specialty drug:

- **Special manufacturing techniques** (e.g., using bacteria or viruses to produce the drug).
- **Special distribution** (e.g., requiring monitoring and refrigeration while the drug is distributed from manufacturing sites to pharmacies or administration sites).
- **Special administration** (e.g., IV infusion or subcutaneous injection).
- Generally used by a small percentage of the population.
- Cost of a typical annual treatment is \$10,000 or greater per claimant.
- Typically prescribed by a specialist physician (not a family doctor).

UNDERSTANDING THE TERMINOLOGY

The specialty drug phenomenon has introduced a range of new terminology into the drug plan conversation. Three terms you will often hear are: **biologics**, **subsequent entry biologics (SEBs)** and **rare disease/orphan drugs**. There has been confusion about what these terms mean – and they have often been used interchangeably with “specialty drugs,” even though not all of the drugs that fall under these categories may actually be specialty drugs. To provide some clarity, here are definitions of the three terms:

- **Biologics:** A large proportion of specialty drugs are biologics. These are “innovator” drugs, developed under patent by one drug company. Rather than being made chemically (like conventional brand name and generic drugs), they are made with living cells. The first generation of biologics included insulin and vaccines (these are not generally high cost therapies). More recently, new biologics produced using the latest genetic science include monoclonal antibodies and proteins such as Remicade® and Humira® – highly effective drug therapies to treat debilitating inflammatory conditions such as rheumatoid arthritis and Crohn’s disease.⁴

Table 1: Examples of biologics

Drug name	Conditions treated	Annual treatment cost
Remicade®	Crohn’s disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis	\$20,000-\$95,000
Humulin® (insulin)	diabetes	\$300-\$600

Source: TELUS Health, pricing based on the province of Ontario as of September 2015

The annual treatment cost can vary based on a number of individual patient factors such as indication, weight, clinical response, treatment duration, presence of other medical conditions, etc.



With many new drugs set to enter the market,

and a research and development pipeline that is forecast to be increasingly dominated by specialty drugs, the cost pressures on drug plans will be unprecedented.

- **Subsequent Entry Biologics (SEBs):** A SEB is a biologic drug that is similar (but not identical) to an innovator biologic drug (the “reference drug”) and enters the market after the innovator drug’s patent has expired. SEBs are produced using similar leading-edge genetic science as the reference drug. SEBs are not identical to their innovator products because their characteristics cannot be precisely duplicated during the manufacturing process. Therefore, SEBs may have unique efficacy and safety profiles and may not be considered equivalent to the innovator drug.⁵

As more biologic drugs begin to come off patent, we will see more SEBs come to market. SEBs typically cost less than the reference drug – for example, the SEB Inflectra™ costs approximately 30% less than its reference drug Remicade® when dosing and indications are the same.⁶

Table 2: Examples of SEBs

Drug name	Conditions treated	Annual treatment cost
Inflectra™	rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis	\$15,000-\$30,000
Omnitrope™	small for gestational age, idiopathic short stature and Turner Syndrome (conditions affecting a child's normal growth)	\$5,700-\$10,500

Source: TELUS Health, pricing based on the province of Ontario as of September 2015

The annual treatment cost can vary based on a number of individual patient factors such as indication, weight, clinical response, treatment duration, presence of other medical conditions, etc.

- **Rare disease drugs:** Also known as orphan drugs, these drugs target diseases that affect a very small proportion of the population (a threshold that is commonly used is 5 in 10,000 people). Examples of rare diseases include cystic fibrosis (treated with Kalydeco®) and the blood disease paroxysmal nocturnal haemoglobinuria (treated with Soliris®). Between 6,000 and 8,000 rare diseases are thought to exist.⁷

Canada’s Orphan Drug Regulatory Framework is pending approval by Health Canada. This framework is designed to significantly speed up the approval of rare disease drugs here in Canada, where approvals have significantly lagged behind the US and Europe.⁸

Table 3: Examples of rare disease drugs

Drug name	Conditions treated	Annual treatment cost
Kalydeco®	cystic fibrosis	\$325,000
Soliris®	paroxysmal nocturnal haemoglobinuria, atypical hemolytic uremic syndrome (rare blood disorders)	\$560,000

Source: TELUS Health, pricing based on the province of Ontario as of September 2015

The annual treatment cost can vary based on a number of individual patient factors such as indication, weight, clinical response, treatment duration, presence of other medical conditions, etc.



The economics of specialty drugs

Just what is behind the high prices of specialty drugs? The following provides insight into the factors at play.

Since specialty drugs target smaller patient populations, higher prices per treatment may be required for manufacturers to recoup research and development (R&D) costs and provide return on investment. However, it is important to point out that not all R&D costs are fixed – working with a smaller patient population can make parts of the process less costly. For example, clinical trials (a significant R&D expense) are typically less expensive for specialty drugs, for the simple reason that fewer patients are involved in the trials. This is why phase III orphan drug trials are about half the cost of those for traditional drugs.⁹

Specialty drugs are often more expensive to manufacture than conventional drugs. For example, manufacturing a biologic drug can take up to 100 different steps involving living organisms, which significantly increases costs compared to traditional drugs. Similarly, the distribution of specialty drugs is often more expensive, demanding skilled management due to special requirements for handling, delivery, storage and preparation.¹⁰

Finally, part of the picture is “the price the market will bear.” Many specialty drugs are breakthrough therapies – they provide substantial improvements in the treatment of serious or life threatening illnesses. With no close substitutes in the marketplace, manufacturers are able to command high prices for these drugs.



In Canada, the maximum price

a drug manufacturer can charge is set by the Patented Medication Prices Review Board (PMPRB). For breakthrough drugs such as specialty medications, the PMPRB strives to set prices at the median of 7 OECD comparator countries (including France, Germany, Italy, Sweden, the UK and the US).¹¹ This then becomes the manufacturer's list price — the price the market in Canada bears.



Trending towards an expensive future

The effects that specialty drugs can have on drug plan costs could be seen with the introduction of several high cost drugs (e.g. Remicade®), as far back as a decade ago. However, due to the “patent cliff” (a large number of blockbuster drugs coming off patent), as well as provincial generic drug reform, the growing impact of new specialty drugs has been masked in recent years. This cost reprieve for drug plans is quickly coming to an end as fewer traditional drugs come off patent, but, more importantly, as an increasing number of specialty drugs are introduced into the market.



The cost per claim for specialty drugs is on average 25 times more than traditional drugs.¹²



Specialty drugs accounted for less than 2% of total claims, but 26% of total drug costs in 2014.¹³



The fundamental shift in spending towards specialty drugs is well underway in Canada.

The last several years clearly show the trend:¹⁴

- From 2011 to 2014 the total amount spent on specialty drugs by private drug plans increased by 70%.
- Specialty drugs accounted for virtually all of the growth in drug plan spending from 2011 to 2014 – as spending on traditional drugs remained virtually flat, increasing by less than 2% over this period.
- The percentage of drug plan spending accounted for by specialty drugs increased from 17% to 26% from 2011 to 2014.



SPECIALTY DRUGS WILL INCREASINGLY DRIVE SPENDING GROWTH

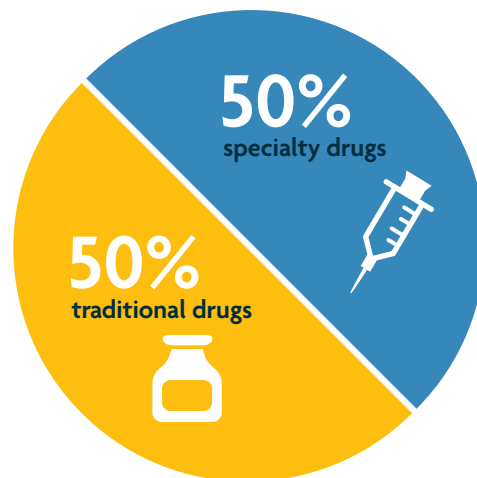
Specialty drug spending forecasts vary somewhat, depending on the methodology and definitions being used; however, they all point clearly in the same direction – **specialty drugs will be the driver behind growth in drug spending in the coming years, accounting for an increasing share of drug plan costs.**

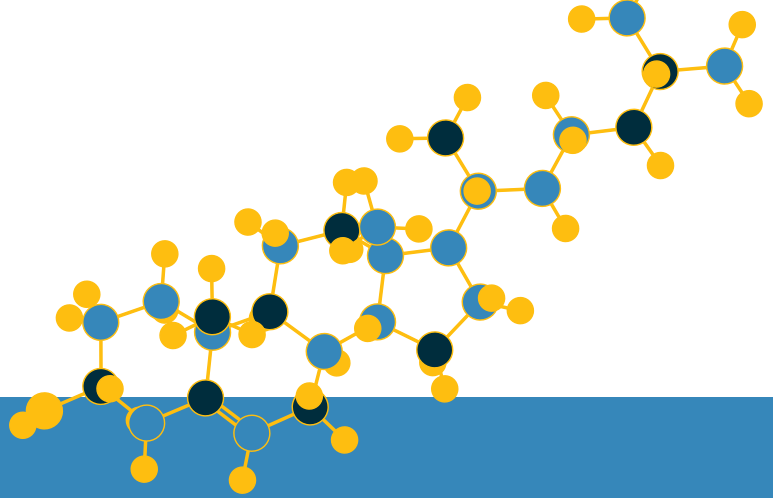
The following estimates for the US market provide a picture of what the near term future might look like in Canada:

- The proportion of specialty drugs in the new drug development pipeline is forecast to climb to 8 in 10 by 2016.¹⁵
- At least 60 percent of new drugs expected to be approved by the FDA for marketing in the near term (3-5 years) will be specialty drugs.¹⁶
- By 2018, an estimated 7 out of the 10 top-selling drugs (by dollar value) will be specialty drugs.¹⁷

- Specialty drug spending is forecast to grow by 21% per year to 2020.¹⁸
- By 2020 specialty drugs will account for 50% of total drug plan spending.¹⁹

2020 forecast for total drug plan spending





Advances *in science*

Specialty drugs are the product of a wave of relatively recent scientific developments, made possible, in large part, due to the sequencing of the human genome and resulting genomic science (analysis of the structure and function of genes). A deeper understanding of

how diseases work at the molecular, as well as the genetic, level has allowed researchers to pursue new targets for therapy as well as better predict how a given drug will affect a specific population of patients.

KEY ADVANCES IN DRUG DEVELOPMENT:²⁰

Molecular targeting – The ability to design drugs that specifically attack the molecular pathways that cause disease, without disrupting the normal functions in our cells and tissues.

Biomarkers – Every disease leaves a signature of molecular “biomarkers” in our body – genes that turn on and off or proteins released into the bloodstream. Biomarkers are used to measure the presence or progress of disease or the effects of treatment. The identification of biomarkers is the first step in developing precision medicine.

Precision medicine – New genetic knowledge is allowing the development of “targeted” therapies for people with specific gene sequences, and it can help physicians choose the best treatments based on individual genetic, lifestyle and environmental factors. Additionally, researchers are developing genetic tests that can determine whether we are susceptible to developing certain diseases, potentially offering precise treatment in the advanced or in the early stages of the disease.

PUTTING IT ALL TOGETHER – BREAKTHROUGH TREATMENT FOR CYSTIC FIBROSIS

Kalydeco®, a breakthrough specialty drug approved in 2012 to treat the underlying cause of a rare form of cystic fibrosis, exemplifies the possibilities that these new scientific developments bring. Individuals with this condition were found to have gene mutations that result in a malfunctioning version of a protein required for proper lung functioning – typically leading to death by early adulthood. Researchers were able to understand, at a molecular level, the reasons why the protein fails to function and at the genetic level which patients are impacted. This led to the development of a medicine specifically to improve the protein’s function, and the creation of a genetic test to select the right patients for the drug.²¹



In the pipeline: A few highlights

THE FIGHT AGAINST HIGH CHOLESTEROL MAY BE THE NEXT GREAT CHALLENGE TO DRUG PLAN COSTS

A new class of innovative biological medications called **PCSK9 inhibitors** – used to lower low density lipoprotein (LDL), or “bad,” cholesterol in high risk patients²² – are set to take centre stage. Repatha™ (evolocumab) is the first PCSK9 inhibitor to be approved in Canada (approved in September 2015). Currently, treatment costs for PCSK9 inhibitors as a class are expected to be over \$7,000 annually.²³ This is compared to an annual cost of approximately \$400 per year, per patient, for drugs considered to be the current standard of therapy for high cholesterol.²⁴

Unlike other specialty drugs that have high annual treatment costs and are claimed by a limited number of individuals, the PCSK9 class of drugs could end up being used by a large patient population, where they can potentially address significant unmet medical needs.²⁵

Given the combination of relatively high annual treatment costs and potential for significant utilization, public and private sales in Canada for this class of drugs have the potential to reach \$2.6 billion by 2026, according to TELUS Health.²⁶

CANCER DRUGS ARE MOST PROMINENT IN THE SPECIALTY PIPELINE

Cancer is the top clinical category in the specialty pharmaceutical pipeline – almost half of drugs in development are oncology therapies.²⁷ A class of cancer drugs showing particular promise in clinical trials is called **programmed death-1 receptor monoclonal antibodies (PD-1)** – by activating the body’s immune system to target tumor cells, these drugs have shown promise in treating a variety of cancers including melanoma, lung and bladder cancers. The first PD-1 drug to be approved in the US was Keytruda® for the treatment of advanced melanoma patients. The price of the drug is \$12,500 per month per patient or about \$150,000 per year.²⁸ Although treatment duration varies based on the stage of the patient’s disease, it can last a year or longer.²⁹ The PD-1 drug class is likely to generate billions of dollars a year for manufacturers once approved across multiple indications.³⁰



New oral drugs to treat cancer will increase the cost pressure on plans

Approximately half of specialty drugs in development are treatments for cancer and a large proportion of these (about 30%) are oral medications.³¹ These drugs will likely not be administered in a hospital setting, but will instead be taken at home.³²

The ability to take cancer drugs at home offers obvious benefits to patients, but, depending on the province, this can shift coverage for these treatments from the public sector to private plans – further increasing the cost pressures on plan sponsors.

RARE DISEASE DRUGS ARE SET TO CAPTURE AN INCREASING SHARE OF THE MARKET

The number of rare disease drugs approved to enter the market has been growing rapidly, and this trend shows no signs of slowing down.

Worldwide, this subset of specialty drugs is forecast to increase by over 10% per year from 2014-2020, accounting for almost 20% of drug sales.³³ The average cost of a rare disease drug treatment in 2014 was USD 137,782.³⁴

While rare disease drugs address small populations of patients, the growth in the number of these drugs coming to market increases the probability of a claim occurring on an individual employer's plan. The duration of the treatments for many rare diseases can be indefinite, resulting in annually recurring claims, which increases the potential impact to plan costs.

New rare disease drugs recently approved in the US include pirfenidone (Esbriet®) and nintedanib (Ofev®); these are used in the treatment of idiopathic pulmonary fibrosis, a rare lung disease. Currently under study are experimental drugs for the treatment of Duchenne muscular dystrophy – eteplirsen (Sarepta) and drisapersen (Prosensa).³⁵



Rising to the challenge

There is no one silver bullet for the challenge posed by specialty drugs. The good news is that there are many opportunities that, taken together, can go a long way towards helping you manage the cost pressures to come.

Tightening your plan

To face the challenge posed by specialty drugs, plan sponsors should make sure that their **entire drug plan** is running at maximum efficiency. Traditional therapies still account for 70 to 80% of drug plan costs and there are tools at your disposal that can reduce this spending significantly. These savings will help offset costs attributed to specialty drugs, while not affecting your plan members' access to effective drug therapies.

EVIDENCE-BASED MANAGED FORMULARIES

Many higher cost traditional drugs are often no more effective at treating a given condition than lower cost alternatives. Evidence-based managed formularies are based on a drug's demonstrated clinical effectiveness, as well as its cost, to determine the level at which it will be covered. Drugs that provide a high level of effectiveness at a low cost are reimbursed at a higher amount compared to those that do not provide the same level of value.

By encouraging the use of drugs that provide the best value, these formularies have the potential to **save plan sponsors 10% or more** on their drug plan.³⁶

MANDATORY GENERIC SUBSTITUTION

This program ensures that all claims for brand name drugs with a generic alternative are reimbursed to the lowest-priced generic equivalent, even if "no substitution" is indicated on the prescription. Plan members can still choose to have the brand name drug dispensed; however, they are required to pay the difference. Generic drugs provide the same quality, purity and effectiveness of treatment, but offer better value, and are therefore a great option to help manage drug plan spending.

Between 2012 and 2013, Sun Life plan sponsors in Canada who switched to mandatory generic substitution, saw **savings between 1.5% and 3.8% in their drug plan costs.**³⁷

DISPENSING FEE FREQUENCY LIMITS AND CAPS

Significant savings can be gained by limiting the number of dispensing fees for maintenance drugs (long-term drug therapies to treat chronic conditions) that will be reimbursed by the plan in each year. This strategy promotes the dispensing of larger day supplies for these prescriptions – for example, plan members may elect to obtain refills every 90 days instead of every 30 days. Dispensing fee caps can provide further savings by putting a limit on the dispensing fee that is reimbursed by the plan.

Plan sponsors in Canada can see **savings between 10% and 19% on dispensing fee amounts; this represents 1% to 4% of total drug plan costs.**³⁸



As the availability and utilization of specialty drugs increase, adopting prior authorization has the potential to offer significant protection against increasing drug plan costs.



Initiatives that specifically target specialty drugs

There are several measures directly aimed at managing the impact of specialty drug costs on your plan. Of fundamental importance is:

- Ensuring that specialty drugs are being used only by the right plan member at the right time;
- Maximizing opportunities to obtain favourable pricing; and
- Supporting patient adherence to maximize treatment efficacy.

PRIOR AUTHORIZATION

Prior authorization is an essential plan design element to ensure that plan members are approved for coverage of the appropriate specialty drugs – “the right drug for the right plan member at the right time.”

Prior authorization programs require that coverage for certain drug therapies be pre-approved based on clinical criteria. If an employee is prescribed a specialty drug requiring prior authorization, the plan member’s prescribing doctor must complete a form to validate that these criteria have been met before treatment can be initiated.



Step therapy is often a key part of prior authorization program criteria. It requires that patients first try more cost-effective therapies before being able to move onto pricier ones. Cost effectiveness is determined by clinical experts through the evaluation of medical literature and clinical guidelines and generally based on a drug's cost, efficacy, need and safety.

In 2013, before the rapid uptake of specialty drugs to treat hepatitis C, Sun Life plan sponsors in Canada who had introduced prior authorization experienced **savings of 1.2% on specialty drugs**, compared to plan sponsors who had not implemented this solution.³⁹ **As the availability and utilization of specialty drugs increase, adopting prior authorization has the potential to offer significant protection against increasing drug plan costs.** One of the largest pharmacy benefits managers in the US sees prior authorization ultimately **saving plan sponsors 10-15% on specialty drug costs.**⁴⁰

PREFERRED PHARMACY NETWORK (PPN)*

A Preferred Pharmacy Network (PPN) encourages the use of a network of select pharmacies that offer reduced drug costs and clinical management patient services. A key advantage of a PPN is lower markups on specialty drugs, negotiated by the benefits carrier with the pharmacy network. For plan sponsors, this can mean a decrease in the cost of claims, while plan members can experience lower out-of-pocket expenses. Services to help patients manage their medical conditions, such as education and counselling as well as assistance with navigating and applying for government and manufacturer financial assistance programs, are also a valuable part of the PPN model.

Introduced in October 2014, Sun Life's PPN has been shown to **save participating plan sponsors in Canada 2% on the cost of specialty drugs.**⁴¹

* Due to Quebec's specific market context, the network cannot be offered to Quebec participants at this time.

Pooling can help *protect your plan* from high cost claims



Pooling, also called stop-loss, is a form of insurance designed to spread the risk of high cost claims between a large number of plan sponsors (the “pool”). Once the claims of a given plan member exceed a pre-determined annual threshold (for example, \$20,000), the excess claims are transferred to the pool and are borne by the insurer.

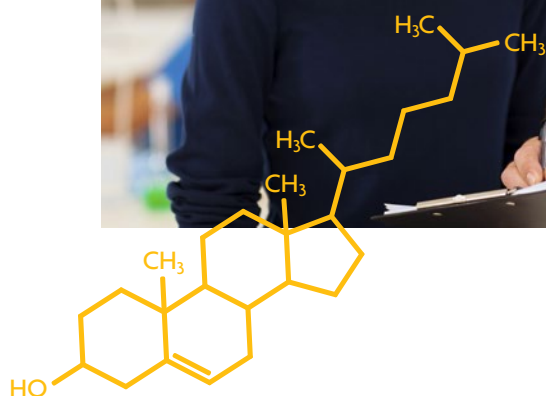
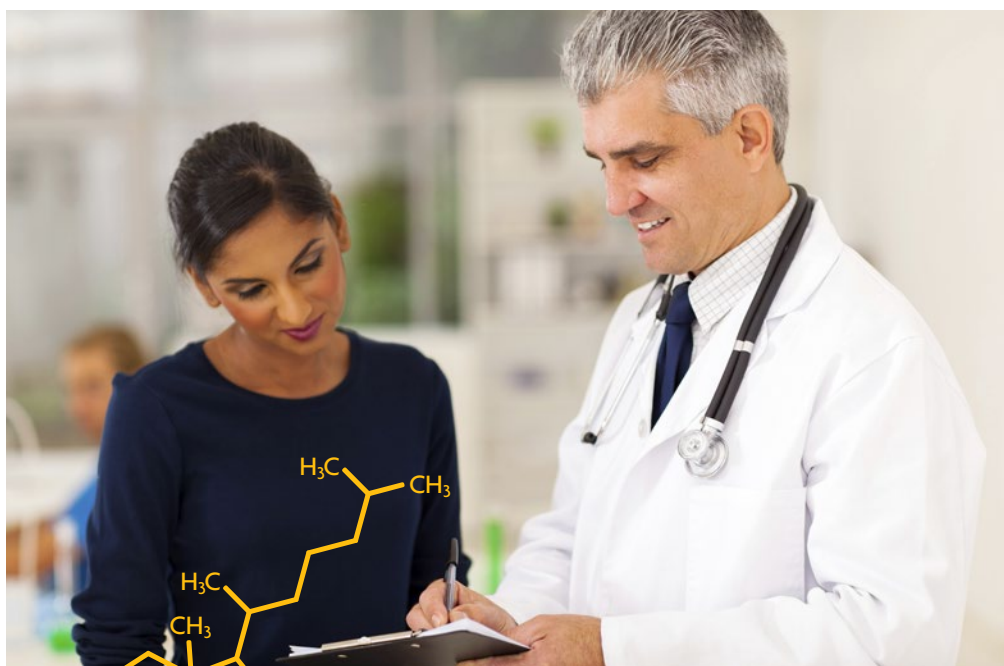
Plan sponsors pay a pooling premium to participate in the pool. The premium is based on the pool’s collective experience, i.e., the amount that is paid out by the pool each year. If the pool experiences a significant increase in high cost claims, e.g., due to specialty drugs, this increase is reflected in the premiums that sponsors have to pay in subsequent years.

Plan sponsors may sometimes hear the term “leveraging.” Leveraging means that the cost of claims in excess of the pooling threshold grows at a faster pace than the cost of the overall claims. This means that regardless of your overall drug spend in a given year, your pooling premiums may still increase because a small number of high cost claims have impacted the amount that the pool has to pay out. An example of leveraging is shown in Table 4.

Table 4: Example of a plan sponsor with a \$15,000 pooling threshold

	2014	2015	Percentage change
Claimant total drug spend	\$25,000	\$27,500	10%
Pooling threshold	\$15,000	\$15,000	N/A
Pooled claims	\$10,000	\$12,500	25%

From Table 4 above, it can be seen that the percentage increase in overall drug spend is 10%, while the percentage increase in pooled claims is 25%. This demonstrates how a plan sponsor’s pooling premiums can potentially grow at a higher rate than their overall drug plan spending.



Additional initiatives

In addition to partnering with you to design and implement the right specialty drugs strategy for your organization, group benefits carriers are working to develop additional opportunities that will help manage the impact of specialty drugs on group benefit plan costs. Examples include:

CLINICAL MANAGEMENT SERVICES

Offering the right support to plan members can be crucial to making sure maximum value is attained from their specialty drug therapy. Clinical management services that include individualized, disease-specific patient education and support can have a significant impact on medication adherence and therapy outcomes.⁴²

Clinical management services help patients understand their condition, the expected side effects of their specialty drug treatment, and the expected long-term outcome. Patients are taught how to take their medication properly (e.g., in the right order and on time) to maximize treatment effectiveness. Medications to alleviate potential side effects can be ordered in advance to help the drug treatment go smoothly. Clinical management services can also check in with patients on an ongoing basis and provide counselling as needed.

PPNs are well positioned to provide clinical management services. Studies have shown that clinical supports offered by specialty pharmacies are associated with improved adherence (e.g., 13% greater for oral oncology) and improved patient outcomes, such as a reduction in multiple sclerosis relapse.⁴³

NEGOTIATED DISCOUNTS WITH PHARMACEUTICAL COMPANIES

Your carrier may negotiate with pharmaceutical companies to receive discounts for certain specialty drugs, which can save money for your plan, while providing a broader range of drug options at higher coverage levels to employees. For example, Sun Life has negotiated an agreement with Janssen to provide plan sponsors and plan members located outside of Quebec⁴⁴ with increased value and access through reduced costs for Remicade®. Remicade® is a specialty drug, indicated by Health Canada for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis. The agreement between Sun Life and Janssen (the first of its kind in Canada) has resulted in both plan sponsors and plan members benefitting from **savings of up to 1% of their specialty spend.**



PROVINCIAL INTEGRATION

Provincial integration ensures that, where appropriate, eligible plan members have applied for the available government programs for specialty drug coverage. Your carrier can establish a claims processing protocol that ensures that appropriate claims are made for government programs before any reimbursement is made from the plan. It is important that provincial integration is an active process whereby the carrier can react to government program changes, such as the addition of new drugs, as they occur. Provincial integration helps manage overall drug claim costs, while also enabling plan members and their dependents to maximize their drug coverage.

Take steps to protect your plan

The specialty drug trend is shifting into high gear and its potential to impact drug plan costs is unprecedented.

You can rise to this challenge. The strategies discussed in this paper are offered to help you to continue to provide the drug coverage your employees need, including access to specialty drugs. And you don't need to do it alone – your carrier is there to partner with you along the way.

This trend is developing quickly, so it is important that you act now. Have the conversation with your carrier today about putting a strategy in place that is right for your organization.

Notes

Notes



About Sun Life

A market leader in group benefits, Sun Life Financial serves more than 1 in 6 Canadians, in over 16,000 corporate, association, affinity and creditor groups across Canada.

Our core values – integrity, service excellence, customer focus and building value – are at the heart of who we are and how we do business.

Sun Life Financial and its partners have operations in 22 key markets worldwide including Canada, the United States, the United Kingdom, Hong Kong, the Philippines, Japan, Indonesia, India, China and Bermuda.

- 1 IMS Brogan File, The Dynamics of the hepatitis C Market, 2015
- 2 Ibid
- 3 Ibid
- 4 Sun Life Financial, March 2014, A discussion about specialty drugs
- 5 Guidance For Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs), Health Canada, March 5, 2010
- 6 Canadian Drug Expert Committee (CDEC), January, 2015 (https://www.cadth.ca/media/cdr/complete/cdr_complete_SE0384_Inflectra_Dec-23-14.pdf)
- 7 Canadian Organization for Rare Disorders (CORD), Canada's Rare Disease Strategy
- 8 Canadian Organization for Rare Disorders (CORD) (<https://www.raredisorders.ca/currentissues.html>)
- 9 EvaluatePharma Orphan Drug Report, 2014
- 10 Sun Life Financial, March 2014, A discussion about specialty drugs
- 11 Patented Medication Prices Review Board, Compendium of Policies, Guidelines and Procedures - Updated June 2015
- 12 TELUS Health block data, 2014 calendar year
- 13 TELUS Health block data, 2014 calendar year
- 14 TELUS Health block data, 2011-2014 calendar years
- 15 Prime Therapeutics, as cited in Managed Care Outlook, Volume 26, Number 15, August 2013; and CVS/Caremark, Insights 2014.
- 16 Ian Spatz, Nancy McGee, Troyen A. Brennan, Ernst Berndt, and Rob Lott, "Specialty Pharmaceuticals. Complex new drugs hold great promise for people with chronic and life-threatening conditions. The drugs are also a driver of spending growth," Health Affairs, Health Policy Brief (November 25, 2013): 1-4.
- 17 Connecting Patients with Specialty Products, Part 2: The future of specialty drug distribution, Biotechnology Healthcare, Fall 2012, 9 (3): 13-16.
- 18 PricewaterhouseCoopers Health Research: Behind the Numbers 2015
- 19 CVS/Caremark, Insights 2014. AND Prime Therapeutics (as reported in "The Looming Rx Threat," HR Magazine, March 2014)
- 20 Pharmaceutical Research and Manufacturers of America, Medicines in Development, Biologics, 2013 Report
- 21 US Food and Drug Administration, "Paving the Way for Personalized Medicine," 2013
- 22 Harvard Health Publications (<http://www.health.harvard.edu/blog/pcsk9-inhibitors-a-major-advance-in-cholesterol-lowering-drug-therapy-201503157801>)
- 23 Harvard Health Publications (<http://www.health.harvard.edu/blog/pcsk9-inhibitors-a-major-advance-in-cholesterol-lowering-drug-therapy-201503157801>) and <https://www.optum.com/thought-leadership/4-things-about-PCSK9-inhibitors.html>
- 24 <http://www.cbc.ca/natureofthings/features/statins-question-and-answers>
- 25 TELUS Health, Drug Conference, March 2015
- 26 TELUS Health, Drug Conference, March 2015
- 27 American Health and Drug Benefits, Special Feature Fifth Annual Payers' Guide to New FDA Approvals March 2014 Volume 7
- 28 Datamonitor Healthcare, September 2014
- 29 <http://www.mercknewsroom.com/news-release/oncology-newsroom/treatment-advanced-non-small-cell-lung-cancer-nscl-keytruda-pembrol>
- 30 Datamonitor Healthcare, September 2014
- 31 American Health and Drug Benefits, Special Feature Fifth Annual Payers' Guide to New FDA Approvals March 2014 Volume 7
- 32 Discovery Medicine, 2013 Apr;15(83):231-41
- 33 EvaluatePharma, Orphan Drug Report, 2014
- 34 Ibid
- 35 <http://www.pharmacist.com/specialty-drug-approvals-review-2014-and-forecast-2015>
- 36 Sun Life Pharma Facts and Figures, 2013 (Sun Life block of business data, 2013)
- 37 Ibid
- 38 Ibid
- 39 Ibid
- 40 Express Scripts, as cited in "The Looming Rx Threat," HR Magazine, March 2014
- 41 Sun Life block of business data, based on the first six month of Sun Life's PPN (October 2014 to March 2015)
- 42 UnitedHealth Centre for Health Reform and Modernization, The Growth of Specialty Pharmacy, Current trends and future opportunities, Issue Brief, April 2014
- 43 Ibid
- 44 This program does not currently apply to plan members based in Quebec, as provincial regulations prohibit the manufacturers of drugs on the RAMQ formulary to have agreements exclusively with a single payer.

Life's brighter under the sun

Group Benefits are offered by Sun Life Assurance Company of Canada, a member of the Sun Life Financial group of companies.

GB00230-E 11-15 ny-vb-mm

