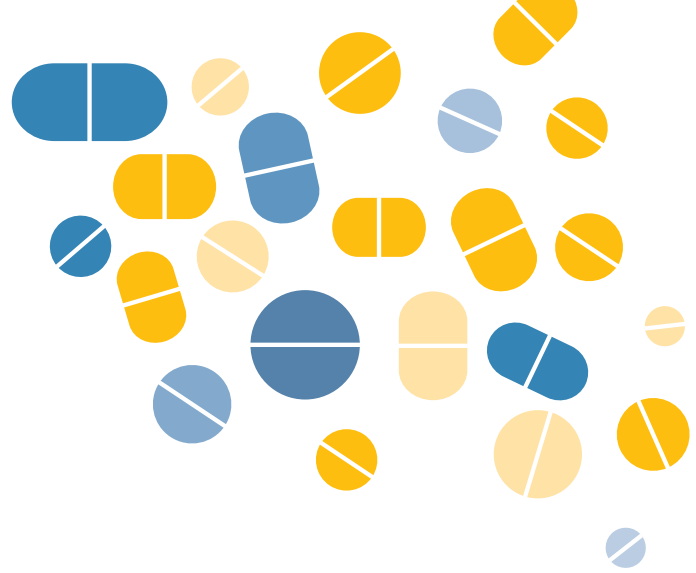


THE
CONVERSATION

SUN LIFE MAKES IT POSSIBLE



A Discussion about Specialty Drugs



Life's brighter under the sun



Group Benefits

PAGE 3

SPECIALTY DRUGS – Cost management strategies for group benefit plans

PAGE 4

TODAY'S drug benefits landscape

PAGE 5

A CLOSER LOOK at prescription drug types

PAGE 7

ABOUT SEBS

PAGE 8

HELPING YOUR CLIENTS manage prescription drug costs

PAGE 10

HELPING YOUR CLIENTS sustain their plans

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.

SPECIALTY DRUGS

Cost management strategies for group benefit plans



TRENDS CAN BE A TRICKY BUSINESS – especially in the group benefits world where money and health collide. What starts as a barely noticed “trickle” can escalate quickly to become an issue that defines the financial health and effectiveness of a plan.

THE USE OF SPECIALTY DRUGS – specifically the new generation of specialty drugs that treat complex diseases such as cancer and arthritis – is a prime example. What was just a blip on the drug radar screen only 10 years ago, is now a significant drug expense that many group benefits plans are grappling to cover.

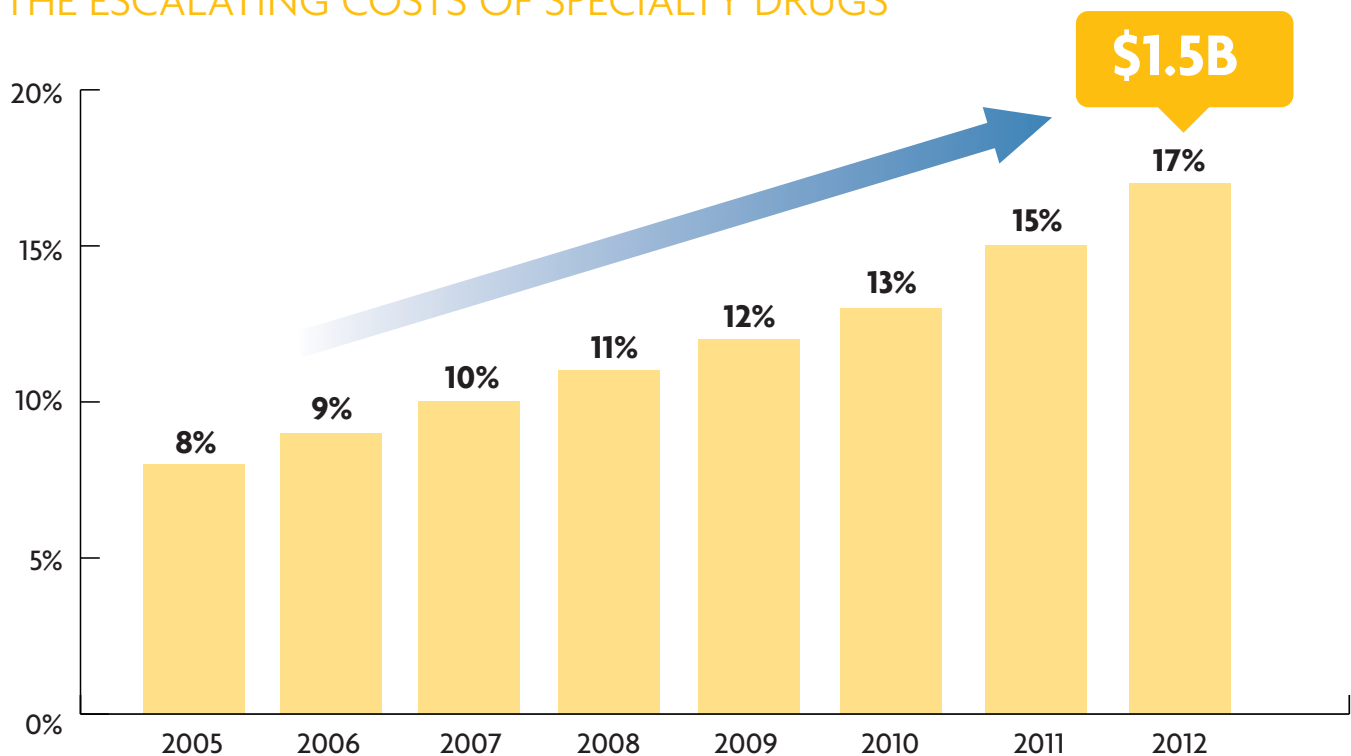
CONSIDER THE NUMBERS. While specialty drugs made up only 1 to 2 per cent of prescription drug reimbursement claims at Sun Life Financial in 2012, they represented 15 to 20 per cent of the drug costs that we covered. The average cost per claimant for a non-specialty drug was \$185 versus \$10,753 for specialty drug claims. And the cost and usage of specialty drugs is increasing each year.¹

There's a simple and compelling reason for this increased usage: specialty drugs are highly effective. They offer plan members with complex health issues good health outcomes, such as less chronic pain, a better quality of life, a healthier and quicker return to work, the potential for increased work productivity and, in some cases, a longer life expectancy. And these drugs have changed the treatment for many disease categories including (but not limited to) oncology, autoimmune disorders, inflammation, and neurology.

But all of this comes at an increasingly high cost – one that your clients will bear unless appropriate drug cost management strategies are put in place. This report provides an overview of:

- what specialty drugs are and why their costs are high
- how new forms of specialty drugs (Subsequent Entry Biologics or SEBs) are changing the drug landscape
- ways that your clients can combat escalating drug plan costs to keep their plans both effective and affordable.

THE ESCALATING COSTS OF SPECIALTY DRUGS



Source: IMS Brogan

TODAY'S drug benefits landscape



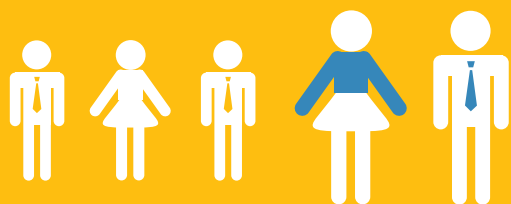
Before we look at how the drug landscape is changing, we need to examine the environment that your plan sponsor clients are currently facing.

Prescription drug spending overall continues to increase, with the Canadian prescription drug spend of \$27.7 billion increasing by 3.3% since 2011. More importantly for your clients, prescription drug costs are rising significantly faster in the private sector (4.1% in 2012) than in the public sector (just 1.9% in 2012).²

AND COSTS WILL CONTINUE
TO RISE.

2 in 5

CANADIANS HAVE AT LEAST **one**
CHRONIC CONDITION FOR WHICH
A PRESCRIPTION IS REQUIRED.



THESE INCLUDE CONDITIONS SUCH AS
HIGH CHOLESTEROL, HIGH BLOOD
PRESSURE, DIABETES, ASTHMA, AND
CARDIOVASCULAR DISEASE.

The result?

CANADA HAS THE WORLD'S
second-highest LEVEL OF TOTAL
DRUG SPEND PER CAPITA AT

\$947²



The reasons for higher prescription drug spending are many:

AGING POPULATION – Our Canadian population is getting older, and with age comes more chronic conditions, diseases and prescription drugs.

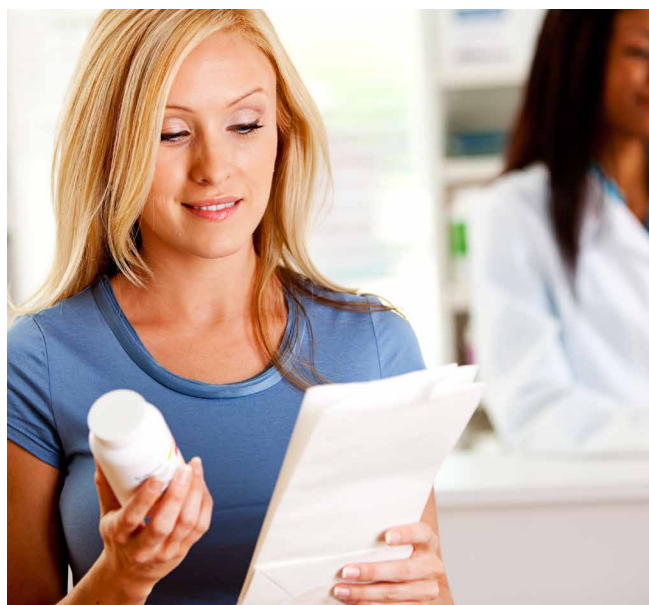
NEW TREATMENT GUIDELINES – Screening guidelines for a number of conditions (such as high cholesterol) have changed, resulting in more Canadians being diagnosed at an earlier age.

COST SHIFTING – Many specialty drugs previously administered at a hospital or doctor's office can now be taken at home, shifting the coverage for these types of drugs from the public payer to the private payer.

UNMANAGED FORMULARIES – If new, higher priced drugs are routinely added to a formulary – even when they have no therapeutic value over previously available, less expensive drugs – plan costs will rise. Active management is essential.

LACK OF EMPLOYEE AWARENESS AND UNDERSTANDING – Canadians continue to not understand their conditions, their medications, how to properly manage their conditions and how to prevent a number of chronic diseases through healthy behaviours. Health education and promotion is more important than ever.

NEW HIGHER COST DRUGS – Specialty drugs are significantly more expensive than traditional brand and generic drugs – and they are increasing in use. That is the focus of this report.



A CLOSER LOOK at prescription drug types



With the use of specialty drugs growing, it's important to understand what they are and how they fit into the prescription drug landscape. Generally, prescription medications can be classified into four different categories:

Small molecule (conventional drugs)

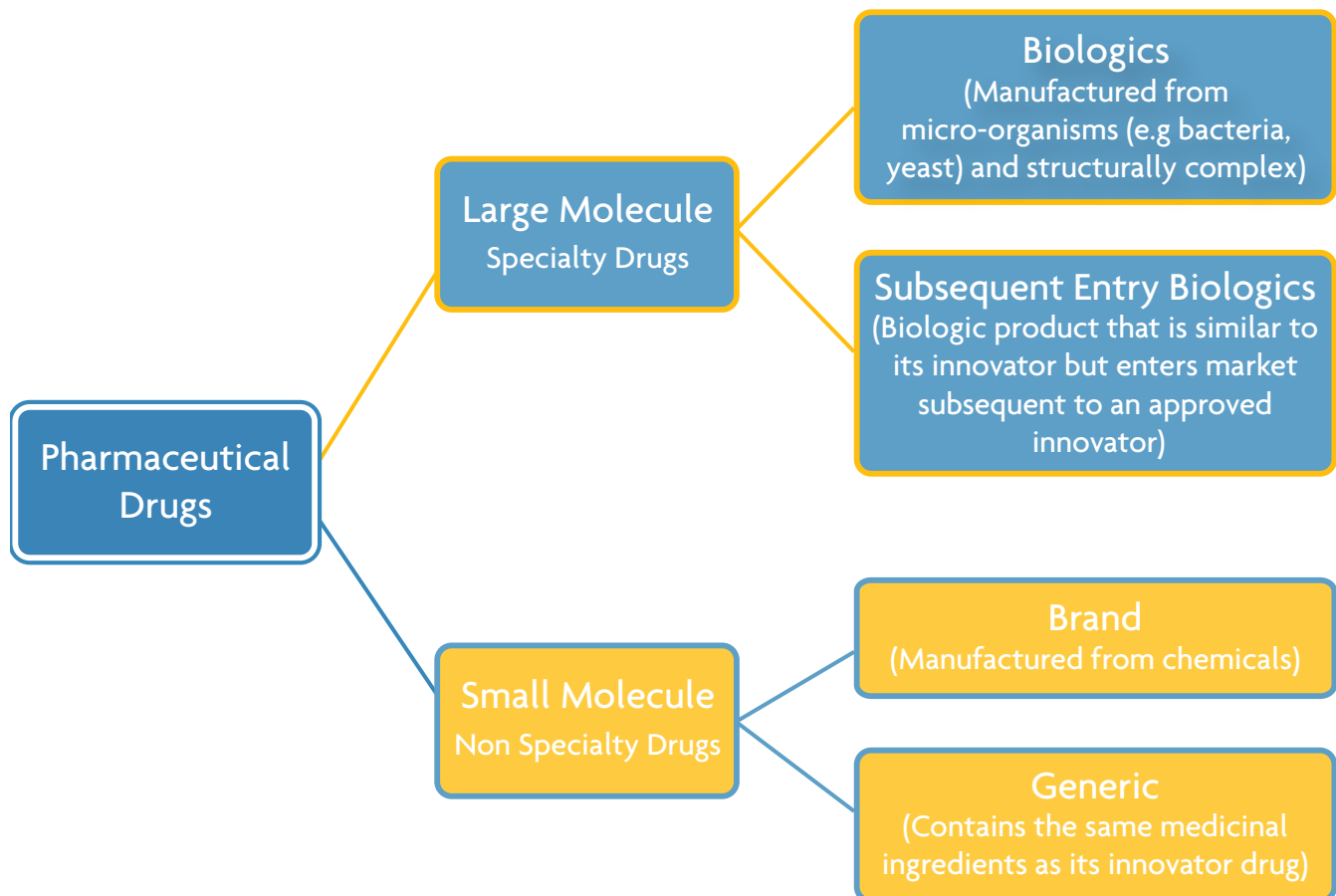
BRAND NAME DRUGS: These are “innovator” drugs developed under patent by one drug company. These drugs work with small, chemically manufactured active-substance molecules.

GENERIC DRUGS: When the patent expires on a brand name drug, generic equivalent drugs are often produced. These are less expensive, but have the same medicinal ingredients as the brand drug. Generic drugs are named using the active chemical ingredient as reference.

Large molecule (specialty drugs)

BIOLOGICS: These are also innovator drugs, but are made with large protein molecules. Rather than being made chemically (like brand name and generic drugs), they are made with living cells. The first generation of biologics included insulin and vaccines. More recently, new biologics produced using the latest genetic science include monoclonal antibodies and proteins.

SUBSEQUENT ENTRY BIOLOGICS (SEBs): This is a biologic drug that is similar (but not identical) to the innovator drug, and enters the market after the innovator has been approved. Unlike generic drugs, SEBs will have proper names (even if they share a common biologic ingredient), mostly for monitoring purposes once on the market.



THE OUTLOOK FOR SPECIALTY DRUG COSTS

AS THE CHART AT THE BEGINNING OF THIS REPORT SHOWED, THE PERCENTAGE OF PRESCRIPTION DRUG COSTS ATTRIBUTABLE TO SPECIALTY DRUGS IS INCREASING EACH YEAR, AND WE EXPECT THAT TREND TO CONTINUE.

IN ADDITION TO SPECIALTY CANCER DRUGS (WHICH ARE A MAJOR FOCUS OF DEVELOPMENT), THE PIPELINES OF MOST PHARMACEUTICAL COMPANIES ARE COMPOSED OF MULTIPLE SPECIALTY DRUGS BEING DEVELOPED FOR HIV, INFLAMMATORY DISEASES, AND HEPATITIS AMONG OTHERS – AND THESE WILL CONTINUE TO DRIVE DRUG SPENDING.

BY 2018 WE EXPECT
50% OF THE SALES OF
THE TOP 100
PHARMACEUTICAL PRODUCTS
ARE EXPECTED TO COME
FROM BIOLOGICS.³

IN ADDITION, MORE ORAL CANCER MEDICATIONS ARE CURRENTLY BEING DEVELOPED, ALLOWING PLAN MEMBERS TO TAKE THESE MEDICATIONS AT HOME RATHER THAN THE HOSPITAL. THERE ARE OBVIOUS BENEFITS FOR THE PATIENTS, BUT AS A COLLATERAL RESULT, COVERAGE FOR THESE DRUGS WILL MOVE FROM THE PUBLIC SECTOR TO PRIVATE PLANS, FURTHER INCREASING THE COST PRESSURES ON PLAN SPONSORS.

Because biologics and SEBs are created using living cells, they require a number of steps and standards that must be approved before the drug comes onto the market. Unlike the approval of generic drugs, some level of clinical studies are required for an SEB to be approved on the market and a much stronger post-marketing surveillance and risk management plan will be in place. Additionally, the end product is more likely to be sensitive to the environment, like the temperature. These key factors are behind the high cost of these medications.

For example, a conventional brand name drug tablet might be manufactured using a 10-step approach (things like measuring ingredients, mixing, drying, compacting, and coating) and could be protected by a few patents on the main ingredients.

With a biologic, the entire process can take closer to 100 different steps involving living organisms. The end product (the ingredient) might be protected by numerous patents, but more importantly the manufacturing process (the steps in the process) is protected by trade secret. This is the why the replication process does not always result in an equivalent biologic. As mentioned, these drugs are highly sensitive and must be stored in a safe environment (many have to be refrigerated or stored at a constant temperature).



About SEB's (Subsequent Entry Biologics)



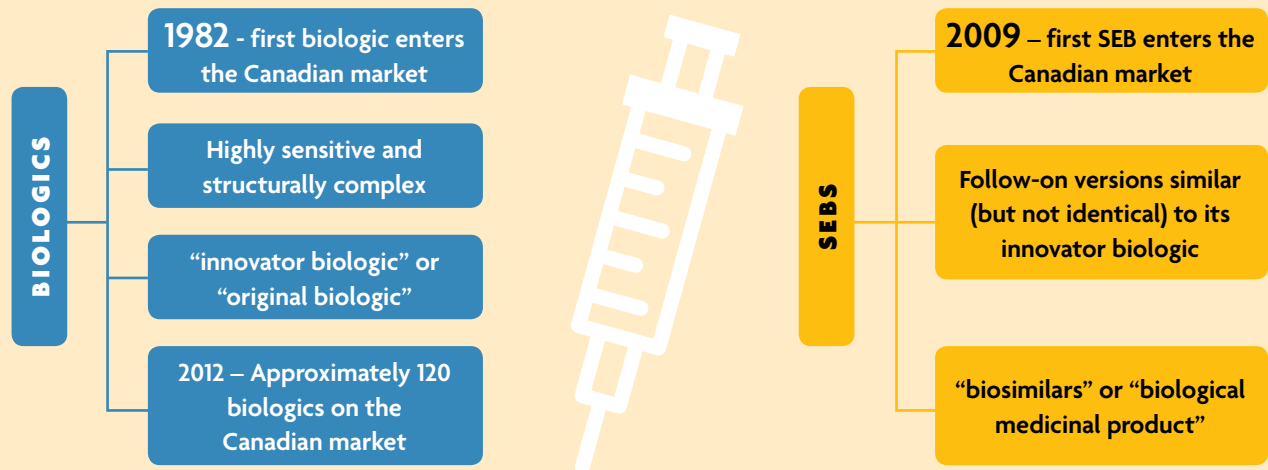
It might be easy to think of SEBs as a “generic equivalent” of an innovator biologic drug, but this is far from the case.

A true generic drug is equivalent in strength, form and dosage to its innovator drug, and, because of this, pharmacists and doctors are able to move their patients onto a generic drug from the innovator brand version.

for the ingredient infliximad (REMICADE®) were approved by Health Canada in January 2014.

Formal guidelines for approval of SEBs are currently in the works. Since SEBs will most likely be evaluated as new products – and not generic versions where approval is abbreviated and shorter – we expect Health Canada’s approval process for SEBs to be more complex than for generics.

THE EVOLUTION OF BIOLOGICS AND SEBS



This interchangeability cannot happen with SEBs and biologics. The cell line that creates a biologic drug is unique to each manufacturer and each manufacturer has different processes that produce distinctive characteristics in the product. As such, a manufacturer cannot duplicate another manufacturer’s biologic cell line. This means that a SEB is actually its own drug when compared to its innovator reference drug.

For this reason, Health Canada will not issue a declaration of bioequivalence and does not currently support automatic substitution of a SEB for its reference biologic drug.

As you can see from the graphic above, SEBs are quite new, with the first SEB approved in Canada in 2009. In Europe – where the European Union has been a global leader in establishing an approval framework for SEBs – there are currently less than 10 approved. However, many are expected to launch in Canada in the next few years, including an important one in 2014. In fact, two second entry biologics

This means that while SEBs should result in lower costs to plan sponsors (and potentially plan members), SEBs will still be fairly costly drugs, with savings that won’t be as significant as we’ve seen with generic drugs. SEBs still require significant trial runs, research and development, whereas generic drugs simply take the “recipe” of their brand name counterpart and create a more affordable version.

In addition, switching patients from an original biologic drug to a SEB equivalent requires more precautions than changing to a generic drug. Even when initiating new patients to a SEB, healthcare professionals will want to pay particular attention as the SEB is not identical in its formulation to the innovator biologic drug. This means more controls and closer monitoring will be needed, which could ultimately increase the cost of the overall treatment (including the drug ingredient) and reduce the potential savings. We can expect physicians’ associations to take position and provide guidance on utilization of SEBs as part of their treatment guidelines.

HELPING YOUR CLIENTS manage prescription drug costs



Although costly to public and private payers, biologics and SEBs have a high value for the individuals using them. Not only can they significantly improve the management of chronic conditions, they have positively changed how we treat and live with certain diseases such as diabetes, cancer and rheumatoid arthritis. Participants can often stay at home instead of going to the hospital, might require less frequent interventions and possibly be back to an active lifestyle faster than with the standard treatment. For these reasons, specialty drugs are here to stay, and will play an increasingly important role in the health of Canadians. But with the high cost of these drugs, cost management will be critical for plan sponsors to make sure drug plans are sustainable for the future.

There are a number of ways that you can help your clients contain prescription drug costs and ensure a sustainable drug plan. These strategies are focused on three main areas:

- 1 **DISEASE PREVENTION** through health promotion and education
- 2 **DISEASE MANAGEMENT** through targeted programs and education
- 3 **PRESCRIPTION DRUG MANAGEMENT STRATEGIES**, such as prior authorization, tiered formularies (such as the Evidence Based Drug Plan), generic substitution, and preferred pharmacy network.

DISEASE PREVENTION AND MANAGEMENT STRATEGIES

Although many individuals who take specialty medications require them for survival, a number of chronic conditions can be improved through lifestyle changes. For example, obesity and type 2 diabetes can be improved through an active lifestyle and healthy eating, which plan sponsors can promote through their wellness programs.

Health promotion and onsite wellness offerings are strategies many plan sponsors are considering to help ensure a productive workforce – and to provide their employees with necessary tools to make positive health decisions and better manage existing conditions.

For example, Sun Life's **HealthyRETURNS** suite of wellness offerings provides a variety of targeted health promotion

strategies and preventative/disease management techniques to plan sponsors. Our in-house team of health and wellness experts work closely with plan sponsors to:

- assess the overall health of the organization
- ensure provided programs target any at-risk behaviours that members might be managing.

A HealthyRETURNS PROGRAM CAN INCLUDE A NUMBER OF OFFERINGS, SUCH AS:



**ONSITE CARDIOVASCULAR
SCREENING CLINICS**



HEALTH CHALLENGES



ONSITE FLU VACCINATION CLINICS



NUTRITION WORKSHOPS



SMOKING CESSATION PROGRAMS



**STRESS MANAGEMENT
PRESENTATIONS**



In addition, all **HealthyRETURNS** initiatives include customized promotional material, registration tools, reporting tools, and evaluation and analysis relating to return on investment and cost avoidance opportunities.

PRESCRIPTION DRUG MANAGEMENT STRATEGIES

While prevention and disease management can reduce drug costs through lower usage, drug plan design changes can be instrumental in reducing the cost of claims.

PIVOTAL TO THE SUCCESSFUL IMPLEMENTATION OF ANY SOLUTIONS, THE PAY-DIRECT-DRUG (PPD) CARD SHOULD BE A STANDARD DESIGN OF EVERY DRUG PLAN.

Solutions fall into two categories – some that address **traditional drug** claims and others that address the **specialty drug** area, such as the biologic drugs discussed in this report.

Traditional drugs

TRIAL PRESCRIPTION PROGRAM: Encourages the dispensing of a “trial-size” supply when a new drug therapy is prescribed.

ACUTE AND MAINTENANCE PROGRAMS: Encourages plan members to purchase a larger quantity of eligible maintenance drugs at one time – for example, purchasing a 100-day supply versus a 30-day supply.

CATEGORY CAPS: Places a dollar limit on drugs reimbursed under the plan for a specific category (eg. smoking cessation, fertility, etc.). These caps help ensure medication is being dispensed and used properly by the plan member – and that the plan sponsor is covering prescription drug costs up to the desired limit.

DISPENSING CAPS: Places a cap on dispensing fees – or on the frequency that dispensing fees are covered each year per drug type.

EVIDENCED BASED FORMULARY: A multi-tiered approach to drug management. Drugs identified as being clinically effective for treatment are placed in the benefit plan in one of three “tiers” with different co-insurance levels. The drugs that will provide the best value for the plan sponsor are placed in the tier that provides plan members with the highest level of reimbursement.

GENERIC SUBSTITUTION: Helps control ingredient costs by limiting coverage of brand name drugs to the lowest-cost equivalent. All claims for drugs with a generic version are cut back to the lowest-cost equivalent.

Specialty drugs

PROVINCIAL INTEGRATION: A standard plan feature at Sun Life, it ensures that, where appropriate, eligible plan members have applied to the available government programs for coverage. Directing drug claims to these programs helps manage the increases in the overall drug claims. It also enables plan members and their dependents to maximize their drug coverage.

HOSPITAL DRUG EXCLUSIONS: Another standard plan feature at Sun Life, it ensures that drugs that are normally administered in a hospital or hospital-like setting because they require special monitoring or handling are covered by a government-funded facility – and aren’t absorbed by the plan sponsor.

MARK-UP MAXIMUMS: Puts a cap on the mark-up amounts covered for any one drug, limiting the mark-ups to a fixed dollar amount and controlling plan costs.

PRIOR AUTHORIZATION: Ensures that plan members are approved for coverage of the appropriate specialty drugs at the right time for the approved indications. Currently, when prior authorization is in place, there are 46 specialty drugs across nine categories that require advance approval for coverage.

PREFERRED PHARMACY NETWORK (PPN): Linked to Sun Life’s Prior Authorization Program, the Sun Life PPN encourages the use of a network of preferred pharmacies that offer reduced claim costs for specialty drugs and discounts on additional patient services.

MAXIMUM ALLOWABLE COST (MAC) PRICING: Categorizes drugs based on their therapeutic effect. Select categories will have a reference drug, which is deemed to be the most cost effective drug in the category, based on clinic experience, pricing and expert opinion. The eligible amount the plan will cover is determined using the price of the most cost-effective drugs in the class.



HELPING YOUR CLIENTS sustain their plans



Sun Life Financial is committed to the development, research and implementation of drug management strategies to help ensure your clients can continue to offer sustainable drug plans to their employees. We also:

- monitor Health Canada's and the provinces' position on new drugs and any communication or regulations that are published
- meet regularly with various stakeholders in healthcare, including the medical community, physicians' and patients' associations to discuss the current practice and guidelines
- monitor the specialty drug spend of Sun Life Financial and our clients and communicate any changes or forecasted trends

As more specialty drugs come onto the Canadian market – and make up an increasingly larger proportion of the drug spend in Canada – it is more important than ever for you to help plan sponsors investigate and implement ways to manage these drug costs. From plan member education, to wellness programs such as **HealthyRETURNS**, to leading drug management strategies such as **prior authorization** and the **Evidence Based Drug Plan**, there are a number of strategies available to accomplish this.

As the cost of these drugs continues to escalate, there is no better time to start the conversation with your clients about potential actions.



NOTES

[illegible]

ABOUT SUN LIFE

A market leader in group benefits, Sun Life Financial serves more than 1 in 6 Canadians, in over 12,000 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 Sun Life Financial, 2012 book of business

2 Canadian Institute for Health Information, Drug Expenditure in Canada, 1985 to 2012

3 “World Preview 2013, Outlook to 2018: Returning to Growth,” Evaluate Ltd. <http://www.newswire.ca/en/story/1189027/return-to-growth-for-pharmaceutical-sector-surge-in-drug-approvals-r-d-productivity-and-investor-confidence-to-drive-expansion-through-2018>

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.

GB00210-E 03-14 rmt-an



Group Benefits