

Emerging Costs

New cholesterol therapies

Is your drug plan ready?



The rapidly evolving specialty drug market has created a need for extra vigilance in managing drug plan costs. Hepatitis C medications, drugs targeting rare diseases, and oral cancer treatments are clear examples of drug categories that have contributed to escalating drug plan costs in the last two years.

In the second half of 2015¹ new cholesterol drugs, called PCSK9 inhibitors, will be the latest entrants to the specialty drugs market and are expected to make a further, sizeable impact.

This emerging category presents a challenge for plan sponsors. How can the costs associated with the new cholesterol drugs be contained? **Sun Life can**

help plan sponsors to manage these claims through our Enhanced Prior Authorization program, which can be implemented at no extra cost to you or your plan members. If you currently have Enhanced Prior Authorization, the new category of cholesterol drugs is being added.



Did you know that treatment of high cholesterol could drastically impact your drug plan costs?

New, injectable medications targeting cholesterol are set to have a major impact on the ever-increasing drug plan costs faced by plan sponsors. Sun Life's **Enhanced Prior Authorization** program can potentially offer significant **protection**.

How do PCSK9 inhibitors work?

As mentioned above, PCSK9 inhibitors are a new category of specialty drugs used to treat high cholesterol. They work by targeting the gene that regulates the body's cholesterol receptors, resulting in a significant reduction in low density lipoprotein (LDL), or “bad”, cholesterol in high-risk patients².

Plan sponsors can expect two new drugs to be approved in Canada in the next few months—Repatha® (evolocumab) and Praluent® (alirocumab)³. Both of these have been shown to sharply lower LDL cholesterol^{4,5}.

Potential impact of PCSK9 inhibitors on drug plan costs

Currently, the most commonly prescribed and effective cholesterol medications are known as “statins”. They are relatively inexpensive (approximately \$400 per year⁶) as the category is now genericized. In comparison, the average cost of treatment with PCSK9 inhibitors is expected to be around \$10,000 per year⁷.

Given the high prevalence of cholesterol-lowering treatments (there were just over 600,000 claimants using at least one cholesterol-lowering drug in 2014¹⁰), it is expected that there will be high sales of PCSK9 inhibitors, once they become available. According to TELUS, the potential sales in Canada could be in the range of \$250 million, growing to \$2.5 billion by 2026¹¹.

Unlike other specialty drugs that have high annual treatment costs and are claimed by a limited number of individuals, the PCSK9 class of drugs may be indicated for uses that encompass a large patient population. This is where the **Enhanced Prior Authorization** program can bring value—it aims to ensure that not all members who need cholesterol treatment will be treated with these new expensive therapies, if they can be managed well on other therapies that are established, effective and more affordable.



Statins
The average cost of treatment is approximately \$400/per year⁸

PCSK9 inhibitors
The average cost of treatment is expected to be around \$10,000 per year in Canada⁹

Using Enhanced Prior Authorization to mitigate the impact of PCSK9 inhibitors on drug plan costs

The Enhanced Prior Authorization program requires that certain types of drugs be pre-approved before coverage, based on recognized medical criteria. This makes sense because not all drugs should be used for everyone as first line treatments. Some drugs that are either more expensive, or intended as second line treatments, need to be evaluated on a case-by-case basis. With the escalation of prescribing medications for “off label” use, Enhanced Prior Authorization also helps to ensure that these medications are being used for Health Canada-approved indications.

This is good governance for your drug plan: the right drug, for the right plan member at the right time. Furthermore, this due diligence on high cost drugs could also be a valuable fraud prevention initiative.

Since Enhanced Prior Authorization requires certain drugs to be approved before use, to be eligible for reimbursement, it helps to ensure that PCSK9 inhibitors will be used only when necessary, (e.g., for those who have familial hypercholesterolemia¹²). By limiting the use of these drugs to those who really need them and can't take other highly effective, proven and more affordable alternatives, Enhanced Prior Authorization helps to keep drug plan costs down.

An easy implementation

To help ensure a smooth transition for plan sponsors implementing the Enhanced Prior Authorization program, there is a 120-day grandfathering period. Grandfathering means that members who have received reimbursement under the plan for a drug on the Enhanced Prior Authorization list within 120 days prior to the effective date of the Enhanced Prior Authorization program won't require pre-approval if they claim the drug after the program is implemented¹³.

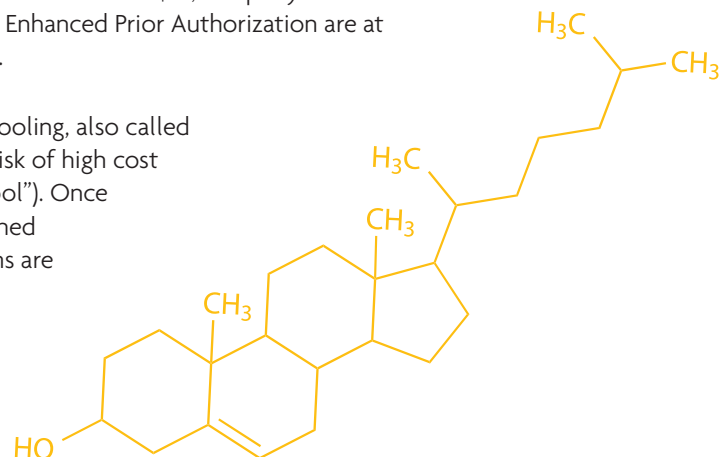
A simple plan member experience

Once the Enhanced Prior Authorization program is implemented, we provide sponsors with communication material to help make members aware of the program and know what to do in the rare event that they are prescribed one of the drugs included in the program. Drugs in the program are typically prescribed by specialists (not family doctors) whose teams are well versed with the practice of verifying prescription drug coverage for their patients before prescribing a specialty drug. In most cases, these drugs also require specialized instruction for administration, which can be provided by patient assistance programs offered by pharmaceutical manufacturers. As a result, unlike acute medications (antibiotics, for example), these drugs are typically scheduled to commence treatment in the first few weeks after they are prescribed, which generally allows time for the Enhanced Prior Authorization process to take place.



Why is Enhanced Prior Authorization so important for plan sponsors in 2015 and beyond?

- **PCSK9 inhibitors are set to enter the Canadian market.** Enhanced Prior Authorization can help contain the costs associated with increased claims, making it particularly effective for the new cholesterol medications (PCSK9 inhibitors) expected to be in the Canadian market by Q4 2015 to Q1 2016. Given that the price tag of these medications is expected to be around \$10,000 per year in Canada (i.e., under the pooling threshold), plan sponsors without Enhanced Prior Authorization are at risk of experiencing higher trend increases in their claims.
- **Other specialty drugs will impact pooling premiums.** 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 claims, e.g., due to high cost 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.

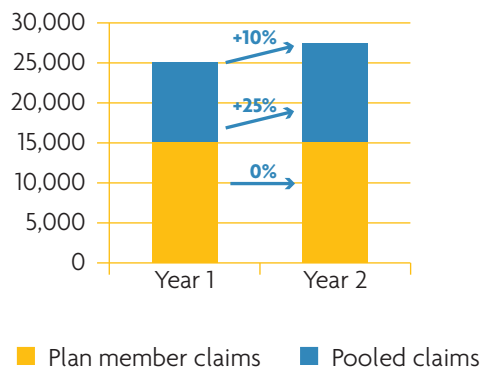
This means that regardless of your overall drug spend in a given year, your pooling premiums may still increase because a small number of high cost claims has impacted the amount that the pool has to pay out. An example of leveraging is shown in the table below.

Example: Plan sponsor with a \$15,000 pooling threshold

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

From the table above, it can be seen that the percentage increase in overall drug spend is 10%; while the percentage increase in pooled claims is 25%.

Effect of Leveraging



- **Enhanced Prior Authorization has been shown to be effective in contributing to cost savings for plan sponsors.** Today, the vast majority of Sun Life plan sponsors with pay-direct drug cards have implemented Enhanced Prior Authorization. In 2013, for the same subset of drugs requiring Enhanced Prior Authorization, plan sponsors with this option experienced savings of 1.2% on their drug experience cost versus those who did not implement it¹⁴. The market availability and increased prevalence of high cost medications has materially grown over the last two years. As such, the future cost savings to plan sponsors are expected to be even higher with Enhanced Prior Authorization. Additionally, Enhanced Prior Authorization can help lessen the impact of pooling premium increases.

Complementing Enhanced Prior Authorization with the Preferred Pharmacy Network

The Sun Life Preferred Pharmacy Network (PPN) is a comprehensive network of over 2500 participating pharmacies across Canada, excluding Québec. It is designed to help reduce claim costs for plan members when they shop for most specialty drugs that require prior authorization at one of the participating pharmacies using their Sun Life drug card. Members are advised by phone of the locations near them. By filling their prescription at a Sun Life PPN Pharmacy, plan members not only benefit from potentially reduced claim costs for specialty drugs but also receive personalised and dedicated counselling from experienced pharmacists participating in the network.

Join the vast majority of plan sponsors who currently have Enhanced Prior Authorization

To implement Enhanced Prior Authorization on your plan, speak to your Sun Life Group Benefits representative. Benefits include:

- Lower risk of unintended costs in your drug plan
- An easy implementation
- A great plan member experience

- 1 Praluent was approved in the US by the FDA on July 26, 2015 but for a narrow patient population, which does not include patients deemed intolerant to statin therapy (see http://www.pharmatimes.com/Article/15-07-26/Sanofi_Regeneron_s_Praluent_first_US-approved_PCSK9_inhibitor.aspx)
- 2 Harvard Health Publications (<http://www.health.harvard.edu/blog/pcsk9-inhibitors-a-major-advance-in-cholesterol-lowering-drug-therapy-201503157801>)
- 3 Praluent was approved in the US by the FDA on July 26, 2015 but for a narrow patient population, which does not include patients deemed intolerant to statin therapy (see http://www.pharmatimes.com/Article/15-07-26/Sanofi_Regeneron_s_Praluent_first_US-approved_PCSK9_inhibitor.aspx)
- 4 New England Journal of Medicine (<http://www.nejm.org/doi/full/10.1056/NEJMoa1500858>)
- 5 New England Journal of Medicine (<http://www.nejm.org/doi/full/10.1056/NEJMoa1501031>)
- 6 <http://www.cbc.ca/natureofthings/features/statins-question-and-answers>
- 7 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>
- 8 <http://www.cbc.ca/natureofthings/features/statins-question-and-answers>
- 9 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>
- 10 Sun Life book of business
- 11 TELUS Health, Drug Conference, March 2015
- 12 This is an example only. Full criteria will be established based on the Health Canada-approved product monograph and best available clinical evidence.
- 13 Please note, if a group deviates from this, all patients in existing treatment will be grandfathered indefinitely when a DIN is added to the program, regardless of the group's choice at implementation.
- 14 Sun Life Financial, Group Benefits, Pharmaceutical, 2013

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.
PDF6629-E 08-15 vb-mp



Group Benefits