Understanding The World Of Specialty Drugs… And Why We Should Care?
What Are Specialty Drugs?

Specialty Drugs are drugs used for the treatment of complex conditions and they often require special storage, handling, monitoring and administration. As a result, they are expensive. Most insurance companies and payers define Specialty Drugs as those drugs with an expected cost greater than $10,000 annually.

Conditions Commonly Treated With Specialty Drugs:
- Cancer
- Rheumatoid Arthritis
- Crohn's Disease
- Plaque Psoriasis
- Hepatitis C
- Multiple Sclerosis

What Is The Value?

Despite their high cost, Specialty Drugs represent important advancements in medicine and they can often significantly improve the quality and longevity of an individual's life.

What We Should Ask Ourselves:
- What is the overall impact of Specialty Drugs on our benefit plan?
- How will private plans remain financially sustainable as the Specialty Drug class expands and grows?
- Who should be financially responsible for the cost of Specialty Drugs?
How Much Do Specialty Drugs Cost The Average Private Drug Plan?

Although, Specialty Drugs represent less than 1% of claims, they represent over 20% of the total drug expenditure for employers and plan sponsors.1

Specialty Drugs are forecasted to rise to 50% of total drug cost by 2022!

What Have The Past Five Years Shown Us?

Specialty Drug spending, between 2012 and 2015 grew at an alarming rate of 18%. This double digit growth was the stimulus that generated concern regarding the sustainability of employer sponsored drug benefit plans.

As spending grew, industry experts and plan sponsors, realized that they needed to take action to ensure Specialty Drug claims were being closely monitored and managed. Specialty Drugs were now seen as a major risk that could not only jeopardize the sustainability of a drug plan but also in some cases the viability of a company as a whole.

In 2016, the growth in Specialty Drug spending was more moderate. Plan sponsors and claims payers had implemented plan design changes to limit financial exposure.

Also, demand for Hepatitis C drugs, at $60,0001 per treatment, has decreased as the majority of patients with the genotype 1 condition completed their treatment course in 2015.

1 Source: Specialty Drug Expenditure – ClaimSecure Book of Business
What Is Driving The Growth
Specialty drug spending slowed in 2016 but it did not stop.

Existing specialty drugs in newly developed oral format

Traditionally, specialty drugs have been administered through an injection or intravenous infusion. The pharmaceutical industry is currently developing future specialty drugs in pill format. With the greater availability of “pills”, drug utilization and cost to private plans is expected to increase. In 2012, only 38% of all Specialty Drugs funded by ClaimSecure were in a pill format. In 2016, the volume of drugs dispensed in pill format increased to 49% and that growth is expected to continue.

Funding for cancer treatment shifting from public to private plans

Traditionally, cancer medications have been marketed in the form of injections; with many requiring intravenous infusion and monitoring. These highly specialized, complex medications are typically administered in hospital clinics or in cancer care centers resulting in a large portion of the cost being paid for by the province. Many of the drugs under development are expected to be manufactured in a pill format enabling self-administration. As manufacturing of these medications migrate from injection to pill format funding will inevitably fall on the shoulders of private payers.

Drug Pipeline in Canada, Top Disease States

Source: QuintilesIMS Lifecycle

50% Of new drugs are Specialty Drugs

Source: QuintilesIMS Lifecycle
New indications

New indications for existing specialty drugs are a key driver for the rise in costs. In 2016, ClaimSecures’ data indicates there were over 20 new approved indications for existing medications in the Specialty Drug category. For example, Stelara was first introduced in 2009 for the treatment of plaque psoriasis. Today, Stelara® also treats active psoriatic arthritis and moderate to severe Crohn’s Disease.

Slow Uptake of Biosimilar Products

Biosimilars, or Subsequent Entry Biologics, are drugs that have active properties similar to an original patented biologic drug. The original biologic drug is often referred to as an “originator”. Biosimilars are NOT generic versions of the originator and pharmacists cannot substitute a biosimilar for the originator. Not only are they not interchangeable, biosimilars carrying their own high price tag. Biosimilar’s are priced at 53-85% of the originator’s cost.

Three challenges facing the adoption of Biosimilars are:

1. Physicians are conditioned to prescribe the Originator product and/or reluctant to prescribe a Biosimilar.
2. The number of initial approved indications for Biosimilars is typically less than the Originator drug, which ultimately impacts physician prescribing behavior.
3. Biosimilars do not provide the magnitude of savings experienced by the introduction of a generic drug.

<table>
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<tr>
<th>Originator Product</th>
<th>Average Annual Patient Cost*</th>
<th>Biosimilar Product</th>
<th>Average Annual Patient Cost*</th>
<th>Savings</th>
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Source: *Ontario pricing June 2017, used for comparative purpose
Accessing Traditional Drugs

Traditionally, drug companies market their products to doctors based on their effectiveness, side effect profile, and dosage convenience. Doctors then prescribe these drugs to patients whom get it dispensed at their local pharmacy.

Local retail pharmacists are responsible for providing the necessary counselling to the patient on how to take and store the medication. Traditional medications are sold by drug companies to wholesalers, who in turn distribute the products to local pharmacies.

Accessing Specialty Drugs

Specialty Drugs are not marketed to General Practitioners in the same manner as traditional drugs due to their cost, complex treatment protocol, and storage/monitoring requirements.

As many specialty drugs treat rare or complex conditions they are primarily marketed to Specialists. Specialists are required to complete multiple of forms to request drug coverage for their patients... a cumbersome process but necessary when managing such high priced medications.

Distribution and dispensing of Specialty Drugs is also very different. An individual cannot simply walk into their local pharmacy with a prescription and walk out with a specialty drug. Accessing a specialty pharmacy network, case management services and possibly a closed distribution model is a far more likely scenario.
Specialty Drugs are Different…

It is important for plan sponsors to understand the unique distribution model and Patient Assistance Program “PAP” services prior to implementing a closed Specialty Pharmacy Provider Network (PPN) and Case Management service.

Specialty Drugs may be distributed through a limited network of pharmacies selected by the manufacturer, due to the administration of the drug, stability issues, and/or regulatory requirements. A limited network means that not all Specialty Drugs are available to all Specialty Drug Service Providers.

It is essential that a Case Management team working on behalf of a plan sponsor have protocols in place to accommodate drugs, which have preferred arrangements and/or limited distribution. Without the correct protocols in place there is a real risk that a patient may not be able to access the medication that they require.

Specialty Drug Distribution Model

Examples of drugs requiring limited distribution consideration:

- Kuvan®
- Revlimid®
- Remicade®
- Inflectra®
- Lemtrada®

Who are the Major Specialty Drug Service Providers in Canada?

Some of the well-known Specialty Drug service providers in Canada are McKesson Specialty Health, Innomar Strategies, Bayshore Specialty Rx, BioScript Solutions and Shoppers Drug Mart Specialty Health Network. These five companies control the majority of distribution and fulfillment business in the Canadian Specialty Drug market.
As Specialty Drugs are managed and supported by the drug manufacturer. The manufacturer is required to set up concierge services for both physicians and their patients, known as a **Patient Assistance Program** or “PAP”. These programs include call center support services and offer all stakeholders an additional layer of expertise when managing these complex drugs.

Drug manufacturer sponsored PAP’s have two objectives, first to minimize the administrative burden placed on physician's, and second to provide direct support services to patients. The PAP assists with navigating any barriers to treatment, monitors the patient's health, and provides appropriate use and product storage information.

To adhere to privacy laws pertaining to patient confidentiality, a drug manufacturer typically hires a third party firm – a **Specialty Drug Service Provider** to deliver the administration services required for its PAP.

**A Patient Assistance Program often consists of 4 service components**

- Coverage & Reimbursement Assistance
- Financial Assistance
- Drug Distribution & Dispensing
- Monitoring & Education

**Coverage and Reimbursement Assistance**

Navigating medication coverage and access can be challenging for patients while trying to cope with a serious illness. The PAP provides Reimbursement Coordinators to help their patients investigate coverage options prior to initiating therapy.

The PAP Reimbursement Coordinator contacts the public and/or private drug plan on the patient's behalf, or via a three-way conference call. They determine available coverage and provide additional information that may be required for the payer to consider coverage. The Reimbursement Coordinator may also help the physician complete and submit the necessary forms to the insurance company, provincial government, or manufacturer for payment coverage.
Financial Assistance

Financial Assistance programs can bridge the financial gap by offering assistance based on an assessment of the patient’s situation. There is no industry standard for financial assistance or compassionate assistance programs. The amount of financial assistance varies by drug and manufacturer.

When would a person with private coverage utilize a Financial Assistance program?

1. One example where an individual might utilize a Financial Assistance program is when a private plan requires their members to pay a percentage of their prescription drug cost, also known as “co-pay”.

An individual with a copay of 20% who needs to purchase a drug with an annual expected cost of $30,000 would need to contribute **$6,000 out-of-pocket each year**. In many cases a $6,000 co-pay would make the drug unaffordable.

2. Another example would be the benefit waiting period which can be a huge financial hurdle when an individual taking a Specialty Drug changes jobs. During that time, the patient may not be able to afford to pay for their medication.

Drug Distribution & Dispensing

To ensure patient safety due to potential serious side effects and/or prevent product wastage due to complex storage requirements, the manufacturer may require physicians and pharmacists to complete training before they can prescribe or dispense their product.

Manufacturers may also opt to impose a closed distribution model using specialized wholesalers, distributors and pharmacies. Doing so allows the manufacturer to further track patient adverse events and closely monitor access to their product.

Specialty Drugs distributed under a closed distribution model offer a “one-stop” shop service. They act as a wholesaler, provide pharmacy home delivery services, and offer private infusion and injection clinics with trained medical personnel on-site. This new vertically integrated distribution model safeguards delivery timing and quality control.

Monitoring and Education

To ensure patient safety, appropriate use and handling of the medications, the PAP may offer a variety of services such as:

- Training on appropriate storage and self-injection
- Arranging appointments with necessary health care providers for follow-up visits
- Coordinating lab tests before and after treatment
- Providing free storage kits which may include a cooler bag, ice pack and/or sharp container.
As each province is responsible for their respective healthcare budget rules around drug funding programs, drug access and patient copays differ dramatically. Additionally, treatment differences from province-to-province further complicates the private payers’ coordination with various government programs.

**Western Provinces**

In the western provinces, specifically British Columbia, Saskatchewan and Manitoba, universal drug programs or PharmaCare programs are available to all residents. These programs allow employers to be the second payer for eligible prescription drugs. To maximize savings, it is imperative that the drug benefit manager coordinates prescription drug coverage with these government sponsored programs.

Alberta does not provide a universal drug PharmaCare program. The Alberta government does; however, offer a Specialized High Cost Drug Program and an Outpatient Cancer Drug Benefit Program that covers oral cancer and HIV medications free of charge to all residents with no out-of-pocket cost.

**Ontario, Quebec and Atlantic Provinces**

In Ontario, Quebec, and the Atlantic provinces, employer sponsored drug plans are considered the primary payer. As a result, specialty drug spending by private plans is higher in these provinces than the provinces in Western Canada.

![Provincial Proportion Of Total Dollars Paid For Specialty Drugs](image)


**Summary**

The availability of government funding is not likely to change in the near future as government budgets are under financial pressure. Employers in the eastern provinces will continue to be the primary payer for high cost specialty drugs as long as they are eligible under their private drug plans.
What Cost Containment Strategies & Tools Should Plan Sponsors Consider?

There is no simple solution when it comes to managing a drug benefit plan but it is possible to balance affordability and accessibility of new therapies with the right combination of solutions. Plan Sponsors need an integrated approach to maximize their drug benefit dollars. Some solutions that can be amalgamated to reach the perfect combination are plan design, formulary management, preferred pharmacy provider networks, and manufacturer agreements.

**Plan Design**

One of the first cost containment solutions that a Plan Sponsor often considers implementing is a plan design change. Some common plan design changes are the addition or increase; of the per-prescription copayment (copay) or the annual deductible; introducing a mandatory generic program or adding a prior authorization/provincial coordination program.

**Copay and annual deductible** – A copay is the portion of a prescription cost that a member is responsible for. A change to the per-prescription co-pay gives plan members a reason to pay attention to the overall prescription drug cost. Members are incented to shop for a pharmacy with a lower dispensing fee or opting for a generic drug.

An annual deductible is an amount of money that an individual must pay out of pocket before their private coverage begins. Plans with front end deductibles are less popular, as they do little to encourage “smart shopping” once the deductible is satisfied.

**Mandatory generics** – With many popular generics now available at a price that is 75% to 85% lower than their brand alternatives, increasing generic penetration will inevitably help plan sponsors reduce their drug cost. Mandatory generic plans reimburse brand name drugs at the price of the interchangeable generic alternative and provide a savings of approximately 3% to 6% from the overall drug budget.

**Prior Authorization/Provincial Coordination** – As high cost Specialty Drugs continue to be introduced, Prior Authorization programs and Provincial Program Coordination become essential. Prior Authorization programs, administrated ideally by trained pharmacists, encourage step therapy and ensure specialty drugs are only covered when prescribed for indications approved by Health Canada, and all lower cost therapeutic alternative drugs have been exhausted. Provincial Coordination ensures all available provincial drug programs are considered and accessed prior to the plan sponsored program paying for a specialty drug.
Manufacturer Agreements

In Canada, prescription drug cost consists of three components – dispensing fee, markup and drug acquisition price (also known as Manufacturer List Price (MLP)). For Specialty Drugs, the MLP represents nearly 90% of the total prescription cost paid by Plan Sponsors.

Provincial governments have been negotiating with drug manufacturers to lower their drug cost for many years. In 2010, the Pan-Canadian Pricing Alliance (PCPA) was announced with the objective of associated provinces conducting joint negotiations with manufacturers to achieve better pricing. In exchange for lower prices, provinces are encouraged to include these drugs on the formularies.

The use of Product Listing Agreements (PLA) for private plans to reduce cost has been common in the US market for decades. However, PLA's between private payers and manufacturers are relatively new in Canada.

Different types of PLA's have been negotiated with drug manufacturers. It is important for Plan Sponsors to understand these mechanisms and be able to quantify the savings achieved as a result of the negotiations between their drug plan management firm and the drug manufacturer. Below are some of the terms that may be outlined in such agreement.

**Preferred Listing** – Typically a manufacturer will ask for preferential treatment status under the formulary when compared to its competitor in order to gain market share. In these cases, the preferred product should be considered comparable in its clinical performance to its competitors and offer the payer a significant pricing discount in order to capture additional market share.

**Utilization Management** – To prevent dose escalation or any unintended use, the drug manufacturer may provide certain guarantees to limit a payer's financial exposure. In such case, the payer is not responsible for the cost associated with any unintended use or any dosing beyond a pre-defined regimen.

**Pay For Performance** – In some cases, manufacturers may provide the initial trial doses free of charge to demonstrate that the product provides the expected outcome. In the event that the product does not perform as expected, the payer is not responsible for the cost of the product.

**Manufacturer Rebates** – The manufacturer would pay a rebate or apply a discount based on the volume of a specific drug being utilized. The amount of rebate available varies according to the potential opportunity.
Formulary Management

A drug plan design begins with an approved list of covered medications referred to as the “drug formulary”. Formularies are commonly described as managed or open, depending on the degree to which drugs are covered or not covered, and are available with or without limitations, restrictions or access criteria. It is no longer reasonable to expect an employer to have an open formulary that covers all drugs prescribed by a physician. Every insurer or benefit plan administrator has its own definitions and suite of formularies.

Well-managed formularies use an evidence-based review process overseen by a team of qualified pharmacists and clinicians. These teams assess each drug based on its clinical merits, its relative cost-effectiveness compared to alternative treatment options, and makes a decision to either list the drug, not list it or list it with limitations. Common managed formularies available in the market place are “Managed” or “Conditional” formularies or “Tiered” formularies.

Managed or Conditional Formularies - typically engage in a step-wised approach to ensure appropriate use and promote the use of cost effective therapy. Prior to accessing higher cost drugs, the patient will be required to use an equivalent lower cost therapeutic alternative.

Example:
Pervacid Fastab® is used for the treatment of heartburn and costs $2.00 per day but there are alternative, therapies such as generic Losec®, Pantoloc®, Prevacid® and Pariet® which costs as little as $0.20 per day.

With a managed formulary the plan may require the patient to try the lower cost therapy prior to granting access to Pervacid Fastab®.

Tiered Formularies - promote the use of cost effective therapy through varying degree of co-pays assigned to each tier.

Example:
Tier 1 is comprised of a list of clinically-sound and cost effective brand and/or generic medications which are available at a 10% co-pay.

Tier 2 is reserved for drugs that are not cost effective versus comparable treatment options and thus require a 50% co-pay.
Formulary Management Considerations

It is important to consider the limitations a formulary may have. For example a tiered formulary is a great starting point but alone it does not offer any protection in instances where a specialty drug does not have an alternative treatment. A Formulary that excludes some or all Specialty Drugs is a great solution in theory but it can create a very poor member experience on its own.

It is essential that a plan sponsor partner with an experienced clinical team and advisor to provide Plan Sponsors with knowledge of a formularies limitations and more importantly the tools to overcome those limitations. For example, a plan sponsor can provide their Members with navigation support services which assist members in attempting to access delisted medications from alternative sources. A concierge service can help patients enroll in available provincial drug programs and/or coordinate closely with manufacturer sponsored patient support programs to further reduce or eliminate the drug cost for the Plan Sponsor and the member.

As more biosimilar drugs are introduced in Canada each one should be evaluated to determine their coverage status and treatment options under the formulary. Key considerations are: (a) price differences, (b) number of indications, and (c) distribution and support between the biosimilar and originator product. Some options to consider are:

- Reimburse with using the same special authorization protocol as the Originator
- Provide preferential listing whereby all new patients with an Originator brand prescription will be denied and only the Biosimilar product is approved in such case
- Offer access to the originator brand at the price of the Biosimilar drug.
Implementing a preferred provider network will help Plan Sponsors reduce the dispensing fee and drug markup paid to pharmacy providers. Retail pharmacies typically are willing to accept a lower fee or markup in exchange for an increased volume of prescriptions. When considering a preferred pharmacy network, the following must be considered:

- **Availability and Access**
  Plan Members need reasonable access to pharmacy services at convenient locations.

- **Number of Affected Plan Members**
  Although, almost everyone needs prescription medications, only 1% to 2% of the plan members use Specialty Drugs.

- **Pharmacy and Case Management Services**
  Pharmacy and case management service providers deliver value added services to improve both the member and plan sponsor experience. For the member, the additional service ensures appropriate usage, promotes adherence, and influences therapeutic alternatives. For the plan sponsor reports outlining financial value and aggregate member utilization should be provided.

- **Handling of Drugs with Limited Distribution**
  It is important to have a well-defined triage process to identify Specialty Drugs that have distribution limitations. The network of pharmacy services should have the ability to handle injection or infusion services along with associated clinics and nursing support.
Closing Remarks

Specialty Drugs are both complex and costly, but these medications offer a significant benefit and value to patients.

The value these medications provide to Canadians is not in question but the funding of these expensive drugs can shake the financial foundation of some of the country’s largest organizations and be catastrophic to the ongoing operation of an average size Plan Sponsor. For that reason, it is imperative that every Plan Sponsor take the time to understand the world of Specialty Drugs and re-examine their drug management philosophy related to affordability and patient well-being.

We encourage Plan Sponsors to explore strategies that balance the cost of funding the benefit plan with the needs of their members.

In the face of increasing complexity and the trajectory associated with drug benefit spending, remaining status quo is no longer an option for many plan sponsors. Developing a sound drug plan management strategy is critical.

Employers and plan sponsors, more than ever, need to engage their advisors and their benefits plan administrators in order to bring the “right” solutions to the table where the “right” solution may be different for each employer. These solutions should aim to minimize any unintended financial exposure and reduce prescription drug cost while providing employees with the best and most cost effective therapies for their health care needs.