THE BENEFITS ALLIANCE GROUP Better Advisors. Better Advice.™

JANUARY 2020

AdvisorsForum

GROUP BENEFITS ROUNDTABLE

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UPFRONT

Navigating the World of High-Cost Drugs

With a Focus on Biologics

Almost 20 years have passed since private drug plans in Canada first experienced claims for high-cost biologic drugs. They quickly came to represent a sea-change in both medical practice (due to their effectiveness) and drug plan management (due to their costs). Other non-biologic high-cost drugs have since joined biologics, and Canada's drug pipeline is now dominated by these highly targeted, life-changing treatments.

The Benefits Alliance Group invited some of its members to participate in an educational session and roundtable discussion on key issues in drug plan management for high-cost drugs, with a focus on biologics and biosimilars. This report summarizes key messages and recommended actions.

"Reimbursement scenarios for high-cost drugs will only become more complex, province by province. Benefits advisors can really differentiate themselves by translating what it all means for plan sponsors, and what we can do to manage the impact."

Richard Mototsune Principal, River Oaks Insurance

The Plan Member's Journey

A plan member or patient typically takes a biologic drug after trying at least several other available treatments. The patient's condition may have steadily worsened over the years, sometimes to the point of disability. The potential effect of a biologic could be life-changing for a patient. The improvement in quality of life, including productivity at home and at work, can be dramatic.

Manufacturers of biologic drugs provide direct support to patients through patient support programs that help coordinate coverage as well as access to the medication (including the scheduling of appointments for drugs that need to be infused). These support programs often also educate patients about their condition and ensure that the drug is taken as prescribed.

Yet the patient's treatment journey is not necessarily over. The complexity of both the human body and the biologic drug means that treatment may not be as effective after a period of time, to the point that a patient's condition becomes unstable. This is referred to as "treatment failure." While treatment failure depends on the drug and the person, studies show that it may occur after two years for more than half of patients.[1] At that point, the patient could start using another biologic, if available.

When changing to another biologic, patients and their physicians may choose one that has a different mechanism of action (MOA). Essentially that means it works differently in the body. Fortunately, different biologic drugs include multiple MOAs. As clinical guidelines evolve to support the use of a different MOA in the case of treatment failure, in some cases, physicians are more likely to take this approach rather than have patients try another biologic with the same MOA.

> "As advisors we really need to stay on top of things and our role as educator is increasingly important. The reality of treatment failure for example is an eye-opener. Plan members may have no choice but to change to a biologic that does not have biosimilar options."
>
> **Chad Donnelly**, Principal, Peak Benefit Solutions

Several MOAs are available in the largest category of biologic drugs, for the treatment of immunological diseases such as rheumatoid arthritis, psoriasis and Crohn's disease. New patients will often start with a drug that uses the first MOA that came to market in Canada, referred to as anti-TNF drug (named after the protein that's targeted in the body). The anti-TNF class of drugs contains five originator biologics and four commercially available biosimilars (for more on biosimilars, see "Where Biosimilars Fit In").

If a plan member experiences treatment failure with an anti-TNF drug, he or she can try another anti-TNF drug or move on to a new MOA. Since several more MOAs are available, the prescriber and patient may decide that a different MOA offers the best chance for positive results. These drugs with a different MOA are currently originator biologics only; that is, biosimilars are not yet commercially available.

GLOSSARY

High-cost drugs – Complex drugs, including but not exclusively biologics, with potential costs of $10,000 or more per year per claimant. Also referred to as specialty drugs.

Originator biologic – First-to-market biologic drug, made within living organisms. Also referred to as innovator or reference biologic.

Biosimilar biologic – A biosimilar biologic drug, or biosimilar, is a biologic drug that is highly similar to an originator biologic drug that was already authorized for sale. A biosimilar is produced after the patent expiry of the originator biologic. There are no expected clinically meaningful differences in efficacy and safety between a biosimilar and the originator biologic drug that was already authorized for sale.

Immunological conditions – Diseases that involve the immune system, including rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis. Also referred to as autoimmune conditions.

Mechanism of action – How a drug works in the body, e.g., by targeting a specific receptor or inflammatory pathway.

TNF – Tumor Necrosis Factor alpha is a common protein involved in the inflammatory pathway of certain immunological diseases.

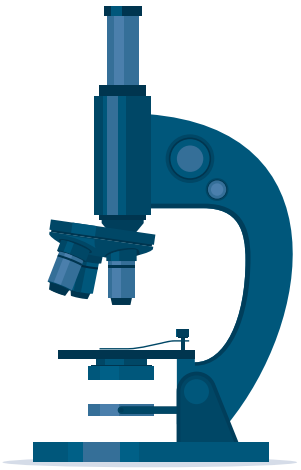
Anti-TNF – A class of biologic drugs that treat immunological disease. This class of biologics has a common mechanism of action, which involves targeting the TNF protein (tumour necrosis factor alpha).

The connections to cost management

The possibility of treatment failure is an important factor when considering cost-management strategies for coverage of biologic drugs, for two reasons:

1. Since patients may have to change their biologic drug after a few years due to treatment failure, savings from policies that require the use of lower-cost biosimilars may be short-lived and therefore not as high as expected.
2. Commercially available lower-cost biosimilar drugs are available in the anti-TNF class of drugs only; if treatment failure occurs and the patient moves on to a biologic with a different mechanism of action (MOA), biosimilars are no longer an option.

BIOLOGICS 101



Biologic drugs come from living organisms or from their cells. They are often made using biotechnology.

Biologic drugs are complex. Unlike traditional small molecule drugs that are synthesized chemically, biologics come from living organisms or from their cells. They may require refrigeration and can be infused or self-injected. Vaccines and insulin are examples of biologic drugs.

Almost 20 years ago, the first high-cost biologic to treat a painful and debilitating condition, ulcerative colitis, entered the Canadian market. The drug came to be used for a number of other immunological conditions, such as rheumatoid arthritis, and other biologics for other disease categories have since emerged.

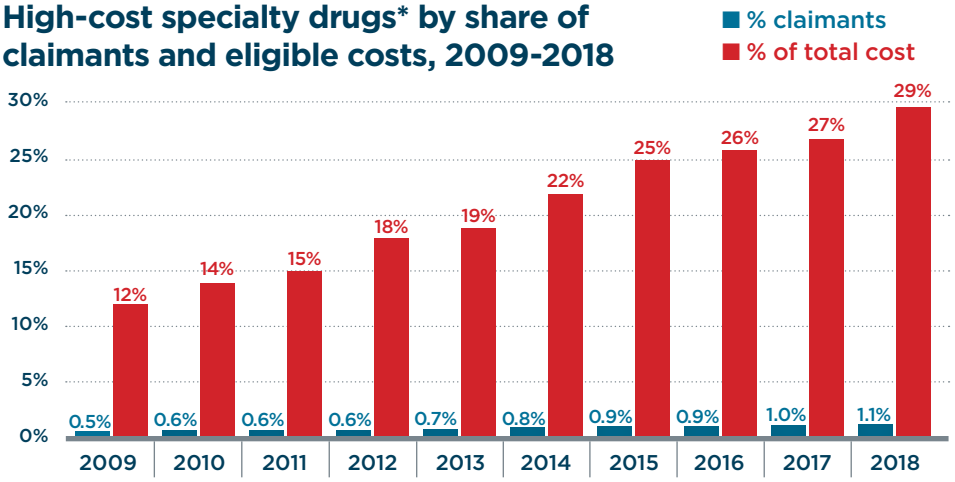
Until recently, annual treatment costs for a biologic typically ranged from $20,000 to $40,000, depending on the drug, the condition and the patient. However, only a very small percentage of patients use biologic drugs (see "Quick Stats: High-Cost Drugs"). The last few years have seen biologic drugs with annual costs below $10,000, for conditions with relatively larger patient populations, such as chronic migraines, eczema and low cholesterol. To ensure appropriate access and utilization, drug plans have put in place prior authorization processes, with strict eligibility criteria.

Quick Stats: High-Cost Drugs

High-cost specialty drugs, defined by TELUS Health as complex drugs with potential costs of $10,000 or more per year per claimant, accounted for 29 percent of all eligible costs considered by private drug plans for reimbursement in 2018. That's up from 12 percent 10 years ago, in 2009.

Yet just 1.1 percent of claimants used a high-cost specialty drug in 2018, compared to 0.5 percent 10 years ago. The growing gap between costs and claimants illustrates an accelerating average price point for specialty drugs—a trend that is not entirely due to biologic drugs. "About eight years ago, you could say that biologic drugs accounted for well over half of high-cost drugs. Today they represent less than half. Today we are seeing claims for cancer and rare disease drugs that cost more than $500,000, and let's not forget the Hep C drugs that shook the market in 2015. The majority of high-cost claims today are not for biologic drugs," says Martin Chung, Assistant Vice-President, Strategic Health Management, Equitable Life of Canada.

High-cost specialty drugs* by share of claimants and eligible costs, 2009-2018



Source: 2019 TELUS Health Drug Data Trends & National Benchmarks report
*Defined as complex drugs, including but not exclusively biologics, with potential costs of $10,000 or more per year per claimant.

Where Biosimilars Fit In

Biosimilar biologics represent an opportunity for savings for drug plans, since they are priced lower than the originator biologic. A biosimilar may come to market when the patent expires for an originator biologic.

Currently, private drug plans in Canada can see claims for a number of different biosimilars. So far, the biggest experience of savings has come from Grastofil, used for a blood disorder associated with cancer treatment.

> "Whatever we do to get cost savings, we always want to look at how this is affecting employees. For people who are diagnosed with these conditions, is everything seamless for them and their doctors? We don't want employers to have to be answering questions from employees who are confused or upset by any changes."
>
> **Keaton Turkiewicz**, Associate, Green Benefits Group

With a list price that is 17 percent lower than the originator biologic, Grastofil's uptake reached 58 percent of claimants and 49 percent of eligible costs in 2018, according to TELUS Health claims data.[2]

However, other biosimilars in Canada tell a very different story, in part because they treat ongoing, chronic conditions rather than an acute illness. As well, biosimilars cannot automatically replace an originator (see sidebar, "Interchangeability & Switching"). With these two factors in mind, the most immediate opportunity for savings from biosimilars comes from new patients, i.e., the patient starts treatment with a biosimilar rather than an originator biologic. However, the number of new patients is relatively small each year, and physicians may still prefer to continue prescribing the originator because they are familiar with both the drug and the manufacturer's patient support program.

As well, four commercially available biosimilars treat immunological diseases and belong to the anti-TNF class of drugs. As outlined in "The Plan Member's Journey," if a patient experiences treatment failure while taking an originator anti-TNF biologic, he or she may be more likely to try another originator biologic with a different mechanism of action, rather than another anti-TNF biosimilar. This scenario further limits the extent of savings from anti-TNF biosimilars.

Patient experience and choice are also important considerations. Patients who switch from an originator to a biosimilar would also have to switch to another patient support program. For those who require an infusion, the location of the infusion clinic may be a consideration. Patients may also be fearful that any change in treatment will destabilize their condition. A 2018 study found that subjective complaints were the main reason why patients discontinued a biosimilar after switching, despite objective results showing that health outcomes were the same.[3] This is referred to as the "nocebo effect."

INTERCHANGEABILITY & SWITCHING

As detailed in Health Canada's fact sheet on biosimilars, "interchangeability" refers to "the ability for a patient to be changed from one drug to another equivalent drug, by a pharmacist, without the intervention of the prescriber who wrote the prescription."

Are originator biologics and biosimilars interchangeable? Clinical research as well as public policy help drive answers to that question. Health Canada indicates that its authorization of a biosimilar is "not a declaration of equivalence to the reference biologic drug," and "the authority to declare two products interchangeable rests with each province and territory according to its own rules and regulations."

The term "switching" carries a different meaning, according to Health Canada. Switching refers to changing from the routine use of one specific product to the routine use of another specific product. If a patient and his or her physician decide to switch from an originator biologic to a biosimilar, Health Canada states that "no differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication." The agency further advises patients to speak with their healthcare provider if they have any questions about changing from one biologic drug to another.

Biologic Savings Partnership: Choice and Sustainability

Private drug plans can access biosimilar-level pricing on a number of originator biologics used to treat immunological diseases (such as rheumatoid arthritis), if their insurer is part of the Biologics Savings Partnership.

Introduced by Janssen—maker of several originator biologics for immunological diseases—the Biologics Savings Partnership takes into account the fact that patients will likely require a number of originator biologics or biosimilars over the course of their disease. "The Partnership provides a potential solution for the issue of rising cost when a patient has a medical reason to switch therapy. Patients can seamlessly flow from one family or mechanism of action of drug to another at price similar to the biosimilars," said Christopher Fearman, Field Director, Private Insurance, Government Affairs and Market Access at Janssen, who was a guest speaker at a roundtable discussion hosted by The Benefits Alliance Group.

Currently, even if a plan member starts treatment with a lower-cost anti-TNF inhibitor biosimilar, savings may be limited if the patient later needs to switch to another biologic due to treatment failure, where there is no corresponding biosimilar. Under the Partnership, Janssen agrees to provide access to their successive originator biologics, which include different mechanisms of action, at biosimilar-level price points.

As well, if a plan member starts treatment with an originator biologic, pricing would still be comparable to available biosimilars. "The Partnership provides access to both Janssen brand and biosimilars at a price point that's predictable to the plan sponsor. Perhaps most important, it enables the patient and physician to make decisions based on what they feel is the best course for disease management," said Fearman, who added that the BSP concept is not exclusive to Janssen products (i.e., other biologic manufacturers can participate).

Roundtable participants agreed that the BSP could be a positive step and suggested that advisors check in with their insurance carriers to see if it's part of their tool kit for cost management. If so, advisors should get more details since its application and financial impact could vary by province or insurers, as is the case with any manufacturer's program. For more details, see "A Carrier's Perspective."

"As members of The Benefits Alliance Group we are able to engage more with manufacturers and insurers to get more information. When there is something new, we want to know about it, so that we can distill the key points to share with clients."

Rodger Johnson, Principal, Johnson Insurance Consulting Inc.

WHAT'S HAPPENING IN B.C.?

In May 2019, B.C. became the first public payer in Canada to implement a mandatory switching policy for biologic drugs. PharmaCare beneficiaries taking one of three originator biologics have three choices in order to continue to receive coverage:

- switch to a biosimilar;
- prove there is a medical need to stay on the originator biologic; or
- seek alternative sources of reimbursement, which may include a private plan.

This situation represents a significant consultative opportunity for advisors in B.C. Advisors can help their clients evaluate the pros and cons of maintaining originator eligibility versus switching plan members to a biosimilar (for the applicable health indications).

Advisors also need to stay on top of insurers' options for plan sponsors. Some may bring forward a mandatory switching policy, some may not. An insurer's approach may also vary based on the drug, particularly if an agreement has been made with the manufacturer of the originator biologic (for example, see "Biologic Savings Partnership"). Greater clarity will emerge as patients respond to B.C.'s policy change.

A CARRIER'S PERSPECTIVE

Equilibrium in a World with Many Moving Parts

The past two decades have seen an unprecedented level of innovation in medical research, resulting in new drugs that test the very foundation of both public and private traditional health benefit plans.

"Today is about getting a clearer view of the many moving parts, so that we can thoughtfully reflect and understand the real-world value and relevance of any solution," said Martin Chung, Assistant Vice-President, Strategic Health Management, Equitable Life of Canada, a guest speaker at the Benefits Alliance Group roundtable discussion. "Advisors are going to have to keep up, and it won't be easy," he added.

Pharmacoeconomic assessment, prior authorization, provider networks and managed formularies are among the tools to manage access, utilization and costs. Partnerships or agreements with provider partners are also increasingly part of the mix. "Every carrier has a variety of partnerships—with pharmacy, with pharma, with a host of entities. But we have to keep in mind there can be a whole bunch of variables based on the client, the plan design, the carrier and the province. These variables can have significant impact," said Chung.

For example, pharmacare provinces (i.e., B.C., Saskatchewan and Manitoba) may limit the value of manufacturers' programs. "If the public plan delists or pays nothing when it used to pay most of the cost, then the savings program will not completely offset the change in exposure for the private drug plan," explained Chung. "As public drug plan eligibility divergence continues, it is critical for advisors and their clients to consider all consequences prior to deploying any drug plan solution."

To better engage employers in decision-making, Chung recommended that advisors broaden the conversation about high-cost drugs. "I don't hone in on just the drugs that cost $10,000 a year or more, or even the ultra-high-cost drugs for cancer or rare diseases that cost hundreds of thousands of dollars," noted Chung. "What's more relatable is the fact that we've entered an era of high-cost 'regular' drugs for larger patient populations." For example, a drug for type 2 diabetes can be $5,000 or $6,000 a year. That's below stop-loss, but a notable increase in spend.

"Even in a 20-life group, at least half the time we find a high-cost regular drug that accounts for more than 10 percent of spend. These are the data points we need to pull out for clients, to create a sense of urgency that will translate into better preparedness and drug plan management," emphasized Chung.

In short, it's complicated—yet moving in the right direction. "There is no one silver bullet for sustainability; instead there are numerous options, which must take into consideration the client's objective and inter-provincial differences in opportunity and risk, including how pharma partnerships are structured and executed," summarized Chung.

THE SAVINGS CONTINUUM

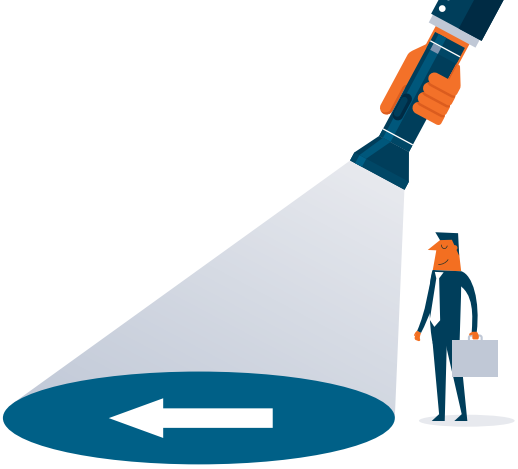
Participants at the roundtable noted that any discussion around cost management comes around to one inevitable question from clients: will pooling charges, which have steadily increased in recent year, stabilize or even go down?

Initiatives such as the Biologic Savings Partnership and product listing agreements between manufacturers and insurers could blunt the rate at which pooling charges go up, said Martin Chung, Assistant Vice-President, Strategic Health Management, Equitable Life. "However, with everything that is going on around high-cost drug trends, managing pooled claims will continue to be challenging and require a myriad of blunting tools."

What is a plan sponsor to do? Be ready for high-cost drug claims by working with their advisors to maximize savings and value throughout the employee health benefits plan.

For many, the process may need to begin with heightened awareness. "One thing we've done under pooled benefits in general is during the renewal process every year, we specifically talk about stop-loss and emphasize that it is not a case of 'if' but 'when' a high-cost claim hits. Repetition is important for education, and a light switch does go on," said Doug Calow, Principal, Calow Benefits Group Inc.

Know Your Purpose



The reality of high-cost drugs—and their value to employees who would otherwise likely be very ill—raises important questions about the purpose of employee health benefits.

"Even five years ago, plan sponsors could avoid having these conversations by changing providers as a way to manage costs. But that option is disappearing. The best advisors today will do the hard work and have the tough conversations to help clients determine the purpose of their plan, and from there navigate the best options based on specific goals, needs and capabilities," said Gord Hart, Principal, Selectpath Benefits & Financial Inc. "Otherwise, when something like a high-cost claim happens employers may react in ways that may not be in the best interest of all the stakeholders."

Advisors can ask a series of questions to help clients determine the purpose or philosophy behind their employee health benefits plan. "You're really getting at the culture of the organization, and how the benefits plan reflects that culture," explained Hart. Employers will not only find it easier to make the right decisions, but members are also more likely to accept those decisions because there is greater transparency. "The group retirement business has done a great job on risk management in terms of the stakeholders' responsibilities, including plan members', and we have to get there on the benefits side," summarized Hart.

"Our job as advisors is to continuously educate plan sponsors on what's coming in the drug pipeline, and how this will affect their benefits plan. Each company has a philosophy behind why they have the coverage that they do. If they know what the future has in store and if they have a sound philosophy for their benefits plan, they are in a good position to make decisions and weather any storms."

Gianluca Spirito, Associate, Penmore Benefits Inc.

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The Benefits Alliance Group thanks the following individuals who participated in the roundtable discussion for this report:

Doug Calow
Calow Benefits Group

Martin Chung
Equitable Life of Canada

Chad Donnelly
Peak Benefit Solutions

Chris Fearman
Janssen Inc.

David Frank
Bell Financial

Gord Hart
Selectpath Benefits & Financial

Rodger Johnson
Johnson Insurance Consulting

Richard Mototsune
River Oaks Insurance

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Keaton Turkiewicz
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THE ADVISOR'S TOOLKIT

A summary of best practices to help clients navigate the evolving world of high-cost drugs.

- **Use a checklist of questions** to help clients determine and embrace the purpose of their health benefits plan. This becomes the "North Star" for setting strategy and making decisions—for high-cost and other drugs, and the rest of the benefits plan.
- **Subscribe to industry resources** and attend industry events to stay up-to-date on issues related to coverage of high-cost drugs, including biologics.
- **Translate learnings** into easy-to-understand, easy-to-access educational content for plan sponsors (e.g., one-page summaries, webinars).
- **Include education** around the plan member/patient experience regarding the drug's profound impact on quality of life, including productivity and absenteeism. Highlight issues that may affect cost-management strategies (e.g., treatment failure for patients taking biologics).
- **Produce educational content** for plan members as well, for clients to distribute.
- **Share what insurers are doing** in this space, including partnerships with pharmaceutical manufacturers, and outline the pros and cons.
- **Know the similarities and differences** between carriers' policies for coverage of high-cost drugs.
- **Keep clients informed** about drugs in the pipeline that may have an impact on private plans (resources include The Drug Pipeline report from TELUS Health and the Meds Pipeline Monitor from the Patented Medicine Prices Review Board).
- **Be careful not to bombard clients** with too much information at once; the key initial message is to let them know you have the tools on hand and are ready when they are. Put out reminders at renewal meetings and all interactions in between, as repetition sets the stage for education and action.

"Education needs to include the plan member experience and go beyond cost implications. There are quality-of-life considerations as well, and we do not want cost management to negatively affect absenteeism and the employee's ability to do their job."

David Frank, Principal, Bell Financial

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The Benefits Alliance Group, Canada's largest group of independent benefits advisors, is pleased to produce *Advisors Forum* as part of its commitment to serve as a strong national advisory voice, providing tools for members to advocate on behalf of clients. To help achieve this objective, The Benefits Alliance Group is partnering with pharmaceutical manufacturers to learn more about emerging trends in pharmaceuticals and their implications for private benefit plans. A sincere thank you to the members of The Benefits Alliance Group who contributed their insights and calls to action as participants in the *Advisors Forum* roundtable discussion hosted by The Benefits Alliance Group in June 2019, at its Toronto office.

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The Benefits Alliance Group is comprised of 30 independent member firms with more than 175 advisors. Collectively they administer more than 7,500 group benefit plans with $1.4 billion in group insurance premiums, and 1,500 group retirement plans with $3.5 billion in retirement plan assets.

This event was funded in full by Janssen Inc. All authors including Janssen Inc. reviewed the article and approved the final version of the manuscript. Christopher Fearman is an employee of Janssen Inc.