THE BENEFITS ALLIANCE GROUP
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GROUP BENEFITS ROUNDTABLE

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Kirk Davis
Davis Benefits & Pensions

UPFRONT

Biosimilars face barriers in Canada

Confusing, complicated, disconcerting—these are some of the words that advisors participating in The Benefits Alliance Group's recent roundtable discussion use to describe the market for biologic drugs in Canada today (see page 6 for the names of participants).

While no one disputes the value of these life-changing drugs, which use living cells to treat serious conditions, their cost relative to traditional, chemical drugs has been a challenge from day one. Seven out of the 10 top-selling drugs in Canada are biologics, used to treat less than two percent of the population.

"We get many complaints about the cost of biologic drugs, and their effect on stop-loss plans. Now we're hearing about the biosimilars. They cost less, but are they saving money for plan sponsors? It doesn't seem to be happening," notes Mike Skube, Principal at mls Financial Services in Thunder Bay, Ontario.

"There is an awful lot of confusion out there, especially when it comes to pricing strategies with carriers," adds Brian Brophy, Principal at Navigo Financial Solutions Inc. in Oakville, Ontario.

Biosimilar biologics began entering the market a few years ago, as patents expired for originator biologics. They are typically priced 30 to 35 percent lower than the originator, sometimes lower, as negotiated by the pan-Canadian Pharmaceutical Alliance. Currently there are 12 biosimilars in

Canada, and another seven may come over the next few years—if manufacturers choose to stick around.

"A big concern here is that manufacturers will stop coming to Canada with their biosimilars," says Kirk Davis, Principal at Davis Benefits & Pensions in Vancouver, B.C.

Why? Because the uptake of biosimilars in Canada is well behind that of European countries, despite growing clinical evidence showing that they are as safe and effective as originators (see sidebar). Canada's complex system for reimbursement, comprised of multiple public drug plans and multiple, competitive private insurers, is part of the problem. While this system works well enough for traditional drugs, it struggles to adequately address higher-cost specialty drugs.

In the past year, provincial drug plans have adopted policies that require or facilitate starting new patients on biosimilars; however, Canada's top three private insurers have not followed suit. Instead, they've opted to negotiate lower prices for Remicade, an originator biologic that is the top-selling drug in Canada, and some have implemented policies that reimburse an originator biologic up to the price of its biosimilar. For patients taking the originator who can't afford to pay the difference, financial assistance is likely available through the originator's patient support program (PSP).

"This may sound okay in the short run, because we're getting the lower prices for the originators, but it doesn't support a market economy. And it's not transparent," says Davis. Steve Hesketh, Principal at CapriCMW in Kelowna, B.C., agrees: "Manufacturers and carriers might be messing with economics to the point where they disincent future biosimilars coming to market. And if biosimilars leave Canada, how will insurers negotiate savings with the originators if they can't leverage biosimilar pricing?"

WHAT THE EVIDENCE SAYS

Studies from Europe, where the market is about eight years ahead of Canada when it comes to biologics, show no significant differences in terms of safety or efficacy between patients who have switched to a biosimilar and those who remained on the originator. Two studies that are frequently cited are the NOR-SWITCH study from Norway and the DANBIO study out of Denmark, both funded by government.[1,2]

A 2018 systematic review of 90 switching studies concluded that "the act of switching from a reference medicine to a biosimilar is not inherently dangerous, and that patients, healthcare professionals, and the public should not assume it is problematic."[3] Another review in 2017 similarly concluded that "efficacy and safety data generally showed no differences between patients who switched treatments versus those who did not."[4]

The 2017 paper, however, also recommended that switching "should remain a clinical decision made by the treating physician," and should consider "patient willingness to switch." The latter point acknowledges the nocebo effect, which occurs when a patient's negative expectations lead to negative results. 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 had not changed.[5]

One final point worth noting when it comes to the research on switching: the time to switch is when patients are doing well on the originator. If a person's condition is *not* well controlled, then transitioning to a biosimilar of that originator would likely be of no benefit since both drugs use the same active ingredient.

Insurers' current practices also raise questions about current pooling charges, when one considers that the lower negotiated prices have been in place for several years now. "Why are we not seeing some relief in pooling costs today? Perhaps we should be pushing harder to get answers on that," suggests Doug Calow, Principal at Calow Benefits Group in Barrie, Ontario.

Increased utilization of biosimilars, on the other hand, should have a more direct, positive impact on pooling costs. Not only are the prices of biosimilars transparent, but they are far more likely to fall under most plan sponsors' thresholds for pooling.

The key to uptake for biosimilars, ultimately, lies in switching or transitioning patients already on an originator to a biosimilar. These patients account for about 80% of the potential market for biosimilars. It should be noted that switching is not to be confused with automatic substitution, which can occur at the pharmacy without the need for a doctor's prescription (as is the case when brand-name traditional drugs are automatically substituted with generic drugs).

While regulatory bodies around the world were understandably cautious about switching in the early years, numerous studies have since shown that it is safe and does not change health outcomes (see sidebar). As a result, regulatory bodies and governments in Europe have taken steps to publicly endorse, encourage or enforce switching.

In Canada, public plans have yet to endorse or require the switching of patients already on an originator to a biosimilar, and it's highly unlikely that

any of the large private insurers will make the first move.

Advisors at the roundtable agree that the ball is mainly in the public payer's court when it comes to jump-starting switches from originator biologics to biosimilar biologics, as well as bringing transparency to the market. "The issues around liability, accessibility, interchangeability and prescribing behaviour—the sense is that private plans are looking to the public side to take leadership, and then they can follow," summarizes Hesketh.

Where does that leave advisors and plan sponsors today? In somewhat of a holding pattern, with an onus on advisors to keep on top of the situation. "Right now, most clients really don't know the floor from the ceiling in this whole area, so we need to have enough of a dialogue to help prepare them for such a complex issue. Then when we're ready to make a recommendation, it's not the first time they're hearing about it," says Hesketh.

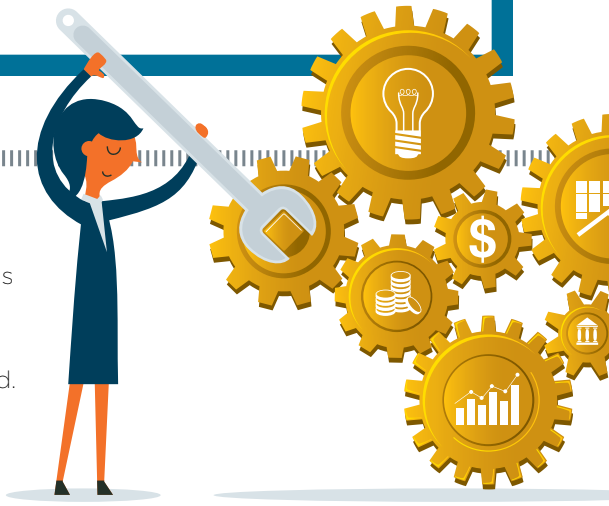
PATIENTS AND PRESCRIBERS: OPINIONS DIVIDED

The Ontario Rheumatology Association (ORA) recently became the first prescriber group in Canada to support the possibility of switching patients using an originator biologic to a biosimilar (also referred to as "policy transitioning," "administrative switching" or "non-medical switching"). Its position paper, released in June 2018, states: "The ORA recognizes that non-medical switching from innovator to biosimilar biologic medications with approved indications for patients with rheumatic disease is safe and has the potential to save healthcare system resources."

Meanwhile, the Canadian Rheumatology Association is reviewing its position on biosimilars. Its current position paper, dated May 2017, states that "administrative switch/interchangeability for patients on established therapy is not supported at the present time."

Differences in opinion can also be found among patient groups. Arthritis Consumer Experts (ACE) actively advocates for improved policies to support transitioning, in part to free funding so that more patients can have access to biologics. In its Biosim*Exchange microsite, launched in 2016, ACE states that "policy transition is appropriate if the prescribing physician and their patient have the education and information tools they need to support the patient."

Meanwhile, organizations such as Crohn's and Colitis Canada and the Gastrointestinal Society consistently state they do not support switching to biosimilars for non-medical reasons, citing the concerns of patients and prescribers.



CHRONIC DISEASE

More tools to manage diabetes

When it comes to better managing a benefit plan's spend for chronic conditions, diabetes could be a good place to start, agree advisors at the roundtable discussion. "Diabetes is a part of conversation we have with a lot of clients. Nine times out of 10 we'll see that diabetes meds are in the top 10 and continuing to grow," says Richard Dobing, Associate at Strategic Benefits & Insurance Services Ltd., in Kingston, Ontario. "On top of that, many people with diabetes also submit claims for drugs to treat cholesterol and blood pressure, and lately we're seeing drugs for weight loss as well."

Claims data from Great-West Life Assurance Company confirm the trend. Diabetes drugs ranked second on its 2017 top-10 list for paid amounts, at 9% of total spend, after biologics for autoimmune diseases (10%). This is up from the fourth spot (7%) in 2010. Among claimants aged 60 to 64, diabetes drugs are the number-one spend (12%). Moreover, the average covered amount per claimant with diabetes was $2,900 in 2017 (including claims for other drugs), compared to $1,100 per claimant for Great-West Life's overall book of business.

"The larger number of patients coupled with numerous and more costly drugs inevitably places upward pressure on drug plans," summarizes Barb Martinez, Practice Leader, Benefits Solutions, at Great-West Life, and guest speaker at the roundtable. As a result, "you will see more programs coming out from insurers around managing diabetes."

For example, Great-West Life will be unveiling an automated step therapy program for diabetes drugs in 2019. The program will check that new claimants for diabetes drugs have tried the lower-cost first line of therapy first, as recommended by clinical guidelines,

before coverage is authorized for a second line of therapy. According to the TELUS Health 2018 Drug Data Trends report, about a third of new diabetes patients submit claims for a second-line therapy without having prior claims for the first-line therapy.[6]

"Doing prior authorization on high-volume drug categories like diabetes drugs requires a lot of manual labour. Fortunately, we're at a point where technology can do it for us. This takes prior authorization to the next level," says Martinez.

"Automated step therapy is a positive, absolutely," notes Davis. "That should be something we see in place for all the big chronic disease categories."

But plan member education is key, cautions Dobing. "Step therapy will work well if the individual understands the reason behind it. If not, something like this could lead them to think it's just an opportunity to decline payment. Step therapy must be carefully communicated."

Benefits advisors should also be aware of the increasingly sophisticated blood glucose monitoring devices and insulin pumps that are available to people with diabetes who require insulin, and who may be the biggest cost drivers to a plan because of their challenges with disease management. Continuous glucose monitors (CGMs) automatically measure glucose every five minutes to give people more insightful, actionable information about their blood sugar levels. CGMs combined with self-adjusting insulin delivery pumps (which adjust insulin delivery as required every five minutes based on the CGM readings) are the latest technology, just approved in Canada. These combination monitors-and-pumps "are transforming care for people with diabetes," says Ruth Pichora, Director of Reimbursement and Value-Based Healthcare at Medtronic, and a guest speaker at the roundtable.

CGM and CGM glucose sensors cost about $3,000 to $5,000 annually, and the first steps for benefits advisors are to ensure their clients' plans currently include coverage, then find out the levels of coverage. Some insurers manage CGM and insulin pumps on an opt-in basis. "New devices don't automatically get added on. Even today I'm finding coverage is not always there for pumps, which have been around for a while," notes Dobing.

Some plans cover insulin pumps, but not CGM and CGM sensors or vice versa. Members often need both to manage their type 1 diabetes well. "This is an area where we can advocate for clients," he adds. "On the one hand insurers are telling us that diabetes costs are getting really bad, but on the other hand the coverage is not there for these devices, or it's not enough. Let's change the plans if need be to prevent disability costs down the road."

PREVENTION IN THE DIGITAL AGE

An ounce of prevention can definitely make a difference for conditions like type 1 and type 2 diabetes. Research has found that losing just five percent of body weight, for example, can dramatically reduce the incidence of the disease, and with it the associated risk for cardiovascular disease.

Workplaces that offer wellness programs, such as lunch-and-learns with dietitians, onsite weight-loss programs and fitness classes, are on the right track. Yet participation rates can be less than optimal, and the programs may not appeal to those who need it most (and for whom privacy may be a concern).

That's where digital technology can come in.

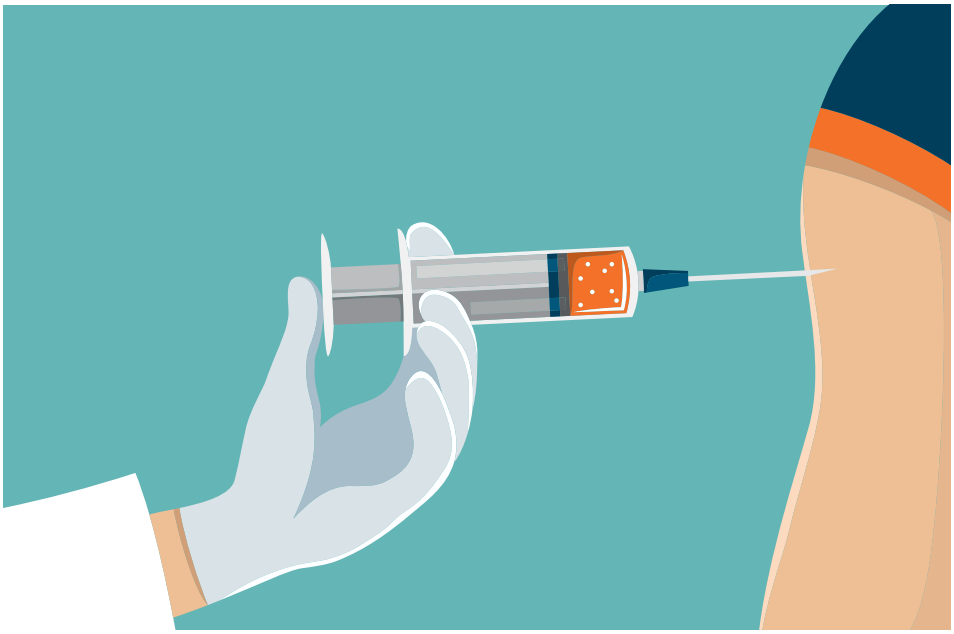
Medtronic, for example, is developing digital support tools, and recently acquired Nutrino, a provider of nutrition-related data services, analytics and technologies. "Using artificial intelligence to predict how a person's glucose will respond to different types of foods and to create personalized insights will simplify and improve daily diabetes management," says Pichora.

What could be especially appealing for plan sponsors is that the payment for some of the programs may be value-based: "If we don't deliver on the desired outcomes that were set, we will pay back the cost for that individual," states Pichora.

"Digital tools are really exciting, and the cost is likely reasonable when you consider the costs that would be minimized in prescription drug benefits year after year," says Andrea Hansen, Principal at Sutton Financial Group in Saskatoon, Saskatchewan. She adds that it could also be an offering for members already diagnosed with type 2 diabetes, to help them make lifestyle changes that could reduce or eliminate prescription drug usage. "There is a real interest among employers to educate and support their employees, and it would be great to be able to offer something proactive like this."

Adding value to benefit plans: adult vaccinations & chronic pain management

For advisors looking to differentiate themselves even further in the market, two areas in particular may be worth bringing to the attention of clients: coverage for adult vaccinations, and a new option to support plan members with chronic pain. Both can avert potentially significant benefits costs down the road, including long-term disability leaves.



Tapping into vaccinations

Coverage for adult vaccinations is a relatively easy way to inject value into benefit plans for both plan sponsors and plan members, agreed advisors at The Benefits Alliance Group roundtable discussion after hearing a presentation by Dr. Darin Cherniwchan, Medical Director of the Fraser Valley Travel Clinic in B.C.

"When we talk about why employers invest in group benefits, one of the primary objectives is to protect the health of employees to maintain productivity. That's why vaccination really makes sense. It's better to pay a little more now to prevent something that can cost a whole lot more later," says Hansen, adding that she's begun bringing adult vaccines to clients' attention since it's not a standard offering in benefit plans. "It's part of our reviews now and we're making the business case for it."

Another key factor to keep in mind is that vaccinations, for adults, are as much about attenuating—or lessening the impact—of an illness as they are about prevention. For people at high risk, such as those with existing respiratory or inflammatory diseases, an infectious disease can trigger a cascade of negative health outcomes that can persist long after the infectious disease has gone. "The risk of heart attack and stroke, for example, is much higher after an episode of influenza or pneumonia. Shingles can cause chronic neuropathic pain," says Dr. Cherniwchan.

Even in cases without complications, sick days and the spreading of infection can significantly impact productivity. The growing popularity of travel to tropical destinations increases the risk of unvaccinated employees spreading diseases such as hepatitis A upon their return.

The vaccinations cost between about $45 and $250, depending on the vaccine, and coverage typically includes vaccinations against pneumonia, shingles, HPV and common tropical diseases such as hepatitis. How does that translate for the plan sponsor? "It would add one to two percent to the health benefit rate. That's not insignificant, but that's the expected initial cost. However, it's goes back to the reason why you invest in insurance—when you consider the cost from that perspective, it is minimal. Especially when you factor in the positive message received by employees, that their employer is willing to pay for this," says Hansen.

Adds Kathleen O'Keefe, Senior Benefit Consultant at Owens MacFadyen Group (OMG) in Toronto, Ontario: "For both insured and ASO plans it should not have much impact, because we're not talking about a high percentage of people using the benefit. Advisors should be able to justify with the carrier that the incremental cost would be low."

Chronic pain, revisited

Advisors with clients concerned about their disability claims may find it worthwhile to dig a bit deeper into the claims data, to find out if chronic pain is a persistent factor. If so, a tailored pain management support program may be the best option to shorten the duration of disability leaves—not to mention ensure that the employee can return to work.

Chronic pain is a unique, complicated condition to treat, and research increasingly suggests that traditional private benefit plans (where therapies are better suited for acute pain) and long-term disability management processes are not adequately set up to address it. "The best option isn't even on the radar," states Geoff Buxton, Disability Management Professional at CompCall Ltd. in Sherwood Park, Alberta, and a guest speaker at the roundtable.

What is that option? A four- to six-week individualized pain management program, requiring about six hours per week of a member's time, during which doctors and specialists, including psychologists and occupational therapists, focus their attention of the plan member's unique experiences with pain. The program includes education and counselling on the psychology of pain.

"Pain can be as much a psychological injury as it is a physical injury, which means that the perception of pain is a strong indicating factor of its impact," says Buxton. "Pain can cause anxiety, anger and depression, which can increase the perception of pain. That can lead to something called catastrophizing. A person's entire existence comes to focus on their pain, which makes it worse, which makes them focus on it more, which makes it worse. They go into a downward spiral, and it usually happens in the first year of LTD."

Buxton adds that among claimants in traditional LTD programs who did

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

Brian Brophy
Navigo Financial Solutions

Lynn Brophy
Navigo Financial Solutions

Douglas Calow
Calow Benefits Group

Kirk Davis
Davis Benefits & Pensions

Richard Dobing
Strategic Benefits
& Insurance Services

Andrea Hansen
Sutton Financial Group

Steven Hesketh
CapriCMW

Gil McGowan
The Benefits Alliance Group

Kyle O'Brien
Benefits Associate

Kathleen O'Keefe
Owens MacFadyen Group

Michael Skube
mls Financial Services

Laurie Sobie
Bell Financial

not go back to work in 2017, 48% had some level of chronic pain, based on LTD claims handled by his firm.

In contrast, adoption of the personal pain management program by the Workplace Safety and Insurance Board (WSIB, also referred to as WCB) has resulted in far more employees with chronic pain returning to work, shares Buxton. In fact, less than 15% of those who complete the program continue to have chronic pain that prevents a return to work. "WCB does not accept that you can't work because of chronic pain. Everyone goes back to their job, or are retrained for something else they can do."

Why don't more employers in the private sector offer such a program? Lack of awareness is the first barrier, followed closely by concerns over cost. "Private disability providers do not have a defined process for assessing what happens to people with chronic pain, let alone recommend this type of a program to members. It's a bit of a black hole in disability management," says O'Keefe.

The pain management program costs between $4,000 and $10,000, depending on the member's individual needs. Yet that one-time cost will have a better return on investment than LTD leaves that persist for more than a year and have a 50-50 percent chance of the employee never returning, agree advisors at the roundtable.

Until traditional disability programs change, it's up to advisors to push for a closer look at disability claims, continues O'Keefe. "If there are troubling patterns to do with chronic pain, we can recommend bringing in an independent disability specialist to implement a pain management program."

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For more information please contact:
Gil McGowan, President
gil.mcgowan@benefitsalliance.ca

The Benefits Alliance Group is comprised of 32 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.

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