Biosimilars aren’t new. In Europe, they’ve been used successfully for over a decade as an alternative to—or in lieu of—more expensive, originator biologic drugs. It’s no wonder they’re being given a close look at by Canadian employers seeking a reprieve from ever-increasing benefits plan costs. And biologic drugs are responsible for a lot of those costs; they constitute Canada’s fastest-growing segments in pharmaceutical spending.

Biosimilars are biologic drugs. As biologics, they are medications developed in living organisms and consist of large, structurally complex proteins. And being so similar, they have no clinically meaningful differences in terms of safety and effectiveness from the biologic they are compared to. The bottom line is that a biosimilar works in the same way as the reference product, effectively treating conditions such as rheumatoid arthritis, Crohn’s disease, ulcerative colitis and several other conditions. Also approved are Basaglar, a type of insulin, and Grastof, a drug that helps patients undergoing chemotherapy to fight infections. Most recently approved are Brenzys, also a TNF-a inhibitor, for use in the treatment of rheumatoid arthritis and ankylosing spondylitis, and Omnitrope (somatropine), a hormone used to treat growth hormone deficiency.

What’s most appealing to employers, in addition to the efficacy and safety profile of biosimilars, is that they can lower drug costs. That’s because, for patients starting a new treatment regimen, biosimilars are up to 47% lower in cost than the originator biologics. And this significant savings potential can be applied toward drug plan sustainability and affordability.

“[Biosimilars] are going to create some of the necessary room in [plan sponsors’] drug benefits plans” says Ned Pojskic, pharmacy strategy leader at Green Shield Canada. “We should embrace these cost-savings opportunities.”

Green Shield has certainly taken that stance, recently listing Inflectra as a preferred product over the originator biologic to treat rheumatoid arthritis, plaque psoriasis, psoriatic arthritis and ankylosing spondylitis. The provincial governments of Ontario, B.C., Alberta, Manitoba, and all Atlantic provinces also list this drug as first option over the originator.

Helen Stevenson, founder and CEO of Reformulary Inc., whose independent expert committee carefully reviews drugs before placing them on their formulary, has also taken a progressive stance on biosimilars. “We took a position that members would try one of two preferred biologics—Inflectra being one of them—before they go to another biologic. Where clinically appropriate, we are encouraging use of biosimilars as a first-line treatment.”

“Our committee believes the data is really strong and in some cases, [these drugs] are much more cost-effective. Our progressive view is well-grounded in evidence.”

Plan administrators like Jennifer Carson, CEO of Alberta School Employee Benefit Plan, are certainly receptive to the idea of biosimilars. “We are definitely exploring the opportunity,” says Carson. “We have had to look at our benefits plan to see where there is that opportunity to modify the plan design but not to put the member’s health at any risk,” she says. “There are very precious, finite dollars that flow into a benefits plan. But we believe there is still an opportunity to maintain a person’s optimal health.”
**What’s happening with biosimilars?**

Biosimilars, medications that enter the market subsequent to a version previously authorized, and with demonstrated similarity to an originator biologic drug, are relatively new to Canada, but they’re generating a lot of interest and activity among employers, pharmacy benefit managers and Canadian provincial governments. “Payers have a role to play in supporting a viable market for biosimilars,” says Ned Pojskic, pharmacy strategy leader at Green Shield Canada. “It’s a critical component if we’re going to maintain the future sustainability of drug plans.” Pojskic believes that biosimilars provide greater competition in the market by lowering drug prices, and allow for greater patient access to biologic treatment. Plus, they free up money in drug plans while maintaining access to critical medications for plan members.

**Why they’re important:**

**There’s a growing need for lower-cost drugs to treat conditions like arthritis.**

Over 4.6 million Canadian adults (one in six Canadians aged 15 years and older) report having a form of arthritis. By 2036, this number is expected to grow to an estimated 7.5 million Canadian adults (that’s one in five).

**Biosimilars are less expensive.**

In the case of Inflectra, it costs approximately 47% less than Remicade. For example, for the first year of treatment for a patient with rheumatoid arthritis, it might cost approximately $12,600 with a biosimilar versus $23,700 for the originator biologic (cost based on a 70 kg patient).

**Biologics are one of the fastest growing segments in pharmaceutical spending.**

In 2015, biologic medicines accounted for $6.3 billion in total sales in Canada. Biologic drug sales grew at a rate that was 50% more than total drug expenditures and represented 32% of total brand prescription drug sales in Canada. They are 4 out of the top 5 pharmaceutical brands. Almost all the savings associated with recent patent expiries and aggressive generic pricing restrictions have been offset by the increasing cost of biologics.

**Insurers are taking action.**

Green Shield Canada listed certain biosimilars, such as Inflectra, as preferred products over the originator biologics to treat rheumatoid arthritis, psoriasis, psoriatic arthritis and ankylosing spondylitis. “Evidence clearly indicated that both the safety and efficacy of the biosimilars were equal to the originators,” says Pojskic. “That satisfied us.”

**Provincial governments are giving preferential access to biosimilars.**

The provincial governments of Ontario, B.C., Alberta, Manitoba, and all provinces in Atlantic Canada now list Inflectra as the first-option over the originator product. In February 2016, Ontario gave preferential access to Inflectra on its formulary.

**Biosimilars are being adopted and supported abroad.**

In Europe, where biosimilars have been used for over a decade, biosimilar penetration in 2013 for filgrastim was nearly 100% in Croatia, Czech Republic, Hungary and Romania,
according to IMS. In fact, data on biosimilars led the French National Agency for Medicines and Health Products Safety in 2016 to state: “The evolution of knowledge and the continuous analysis of efficacy and safety data for biosimilars in the European Union show that a position formally excluding any form of interchangeability during treatment no longer appears justified.”

Under physician care, transitioning existing patients from the originator biologics to biosimilars may be cost-effective.

As real-world evidence accumulates, plan sponsors and drug benefit administrators should consider implementing policies to transition treatment-experienced patients receiving originator drugs to biosimilars in order to create additional savings.

The long-awaited results of the independent, entirely publicly funded NOR-SWITCH study were recently presented and showed that transitioning patients from the originator biologic Remicade to the biosimilar version Inflectra is safe and effective. NOR-SWITCH was a one-year study, which involved 481 patients.

### Costs of top 2 biosimilars used in Canada—vs. their originators

<table>
<thead>
<tr>
<th>Originator Product</th>
<th>Cost</th>
<th>Biosimilar Product</th>
<th>Cost</th>
<th>Tx Cost Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>$23,701.44</td>
<td>Inflectra</td>
<td>$12,600.00</td>
<td>1st year of Tx, based on a 70 kg patient weight*</td>
</tr>
<tr>
<td>Lantus</td>
<td>$677.81</td>
<td>Basaglar</td>
<td>$575.97</td>
<td>Based on a stable dose of 30 units per day</td>
</tr>
</tbody>
</table>


More and more provinces are giving preferential listing to the biosimilar option. Pharmacy benefit managers like Green Shield Canada have also given this preferential status to biosimilar drugs like Inflectra. Given the majority of provincial plans have taken this stance concerning Inflectra, there are strong signals to private payers about the opportunity to follow suit.

But waiting for change isn’t advised. Unlike generics, biosimilars cannot be automatically substituted at the pharmacy. Instead, it’s up to public and private payers to adapt reimbursement policies to encourage biosimilars and to provide viable and sustainable conditions for their continued use.

In order to capitalize on the opportunity for cost savings, benefit providers and plan sponsors must design their plans to have biosimilars placed in preferred reimbursement positions for use in place of more expensive originator products.

Transitioning stable patients from the originator biologic to a biosimilar is another option private payers should consider. Transitioning could generate additional savings for plan sponsors and private payers. It could also mean the difference between a heavily restricted plan that offers little benefit to plan members—and one that delivers critical medications to those who need them.

“I’m hoping the direction is that we fully embrace these products,” says Ned Pojskic, pharmacy strategy leader at Green Shield Canada. “We want to look five or 10 years down the road from today and have a healthy, vibrant biosimilar market that allows us to achieve cost savings and the ability to buy new drugs through our formularies.”
Points to ponder:

Does your drug plan have a mechanism to prefer the use of biosimilars over the originator biologics and take advantage of cost savings?

Remember:

There are significant cost savings with biosimilars.

Given today’s pressures of drug plan affordability and sustainability, once they are listed as preferred, biosimilars offer a great opportunity to deliver savings to both plan sponsors and plan members. Plus, they free up room in the benefits plan by reducing the amount of former spending on costlier biologics.

They’re not new.

Biosimilars have been around—and used with great success—in many European countries for over a decade. “Just because they’re new here doesn’t mean they’re new everywhere. It’s happening across the world,” says Pojskic.

They’re safe.

When Health Canada approves a biosimilar drug for certain indications and uses, patients can be confident the safety and efficacy are comparable to the originator biologic. Plus, European studies demonstrate that safety—health authorities are increasingly finding that objections to interchangeability are unfounded. A study in the journal Annals of Internal Medicine in August 2016 found that biosimilar TNF-a inhibitors have very similar safety and effectiveness to their reference biologics.

The time is now.

Employers and plan members stand to benefit the sooner action is taken—from health, productivity and cost-savings standpoints.

If you’re a plan sponsor or advisor interested in increasing the uptake of biosimilars, ask your benefits carriers about their options for accommodating them.

Have you discussed the potential for biosimilars in bringing savings to your plan with your advisor or benefits provider?

Consider educating your plan members on the opportunity for them to get the treatment they need while saving money with the biosimilar option.

References


This report was commissioned and supported by Merck in Canada. The opinions and information contained herein are those of the author(s) and do not necessarily reflect the views or opinions of Merck in Canada.