Ontario Health
Cancer Care Ontario

pCPA pan-Canadian Pharmaceutical Alliance

Switching Reference Biologics to Biosimilar Biologics

What health care professionals need to know

Biosimilars in Canada

Biosimilar biologics (or biosimilars) have been available in Canada for many years. Initially, there were a limited number of options, but over the last several years many biosimilars have been introduced for specialty conditions in rheumatology, gastroenterology, dermatology, neurology, endocrinology, oncology, and cardiology.[i] These biosimilars have been approved in Canada when they demonstrate there is no clinically meaningful differences between them and the reference biologic.[ii]

Biologics contribute a disproportionate amount to drug plan costs compared to their share of claims.[iii] There is also an increasing number of biologic agents to manage conditions that are leading to a growth in the number of biologics used. To address these costs, both government and private insurance companies have implemented programs that preferentially recommend the use of biosimilars when initiating these medications and actively switching patients from the reference biologic to their equivalent biosimilar.

As payers implement these policies, many health care professionals will be involved in discussing changes with patients, and to provide them the education and support to ensure these transitions are seamless. Biosimilars are not considered interchangeable with a reference biologic. Before a patient is switched to a biosimilar, their doctor must approve the change. This handout is designed to address the key questions regarding biosimilar switching to ensure each health care professional is best able to address these concerns.

Why switch from reference biologics to biosimilar biologics?

Many patients using reference biologics have been taking these medications for some time, are stabilized, and tolerating these therapies. The question posed by some health care professionals is:

- *'Why would we change to another product when my patient is doing well on their current medication?'*

To address this question, it is important to understand how biosimilars compare to reference biologics and the potential cost savings from these switching programs.

Reference biologic versus a biosimilar

When reference biologics are approved in Canada, they undergo a rigorous approval process that includes phase I, II, and III trials to ensure they are effective and have acceptable safety profiles for their indications. To support this research, Health Canada provides the manufacturer with a 20-year patent protection from the time of discovery of the biologic, where no other manufacturer can produce the same medication.

After the end of the patent, a manufacturer can apply to Health Canada for approval of a biosimilar. A biosimilar will only be approved in Canada if there are no expected clinically meaningful differences in efficacy and safety between a biosimilar and the reference biologic.[iv] Although the products are not identical, the differences are not expected to affect the efficacy and safety when compared to the reference biologic.

Bottom Line: Although the reference biologic and biosimilar are not identical, the biosimilar manufacturer must prove to Health Canada that any differences do not lead to meaningful differences in efficacy, safety, and immunogenicity to be approved in Canada.

Potential cost savings from a biosimilar switching program

Biologics have been transformational in the management of many different conditions. They have led to an improvement in outcomes and quality of life in many patients.[v] Unlike small molecule pharmaceuticals, they are made from living organisms, are structurally more complex and have substantially higher costs. In 2018, biologics represented only 1.5% of Canadian public drug plan claims, but accounted for 27.3% of public drug costs.

There has been incredible growth in biologic use over the last decade. In Canada, biologic medicine sales nearly tripled over 10 years, rising from $3.8B in 2012 to $11.2B in 2021.[vi] Biosimilars cost anywhere from 25% to 50% less than the reference biologics.[vii] Although less expensive, biosimilar utilization is significantly lower in Canada (8%) than many other jurisdictions in the world.

A study published in November 2021 evaluated the potential cost savings if biosimilar switching policies were implemented in Ontario.[viii] Some key findings of this study:

- In 2018, 14,089 individuals were prescribed a publicly funded biologic for inflammatory diseases. A mandatory nonmedical biosimilar switch would potentially have affected 7,209 patients and **saved $238.6 million from 2018 to 2020**. A new-user switch would have affected 757 patients and **saved $34.2 million.**
- Adalimumab switching program would lead to an additional 3-year **savings of $654.9 million**
- Insulin glargine switching program would lead to a **savings of $288.7 million**.

Bottom Line: Reference biologics and biosimilars have the same efficacy and safety. Many provinces and private insurance companies have implemented successful biosimilar switching programs. These programs are estimated to save hundreds of millions of dollars without affecting the care of the people using these medications.

What biosimilars are currently available?

As many biologics have reached or are reaching the end of their patent, new biosimilars will be introduced to the Canadian market. The table below provides a list of some of the biosimilars available in Canada by area of specialty.

Specialty	Biosimilars available
Cardiology	Enoxaparin
Dermatology	Adalimumab, etanercept, infliximab, rituximab, and teriparatide
Endocrinology	Adalimumab, etanercept, infliximab, rituximab, teriparatide, insulin glargine, insulin aspart, insulin lispro, and somatropin
Gastroenterology	Adalimumab, etanercept, infliximab, rituximab, and teriparatide
Hematology	Enoxaparin
Neurology	Glatiramer*
Oncology	Pegfilgrastim, filgrastim, rituximab, bevacizumab, and trastuzumab
Rheumatology	Adalimumab, etanercept, infliximab, rituximab, and teriparatide
Vascular medicine	Adalimumab, etanercept, infliximab, rituximab, and teriparatide

* Glatiramer is a complex non-biologic drug but has been included in many provincial and territorial biosimilar policies.

Note: the biosimilars currently available in Canada will likely continue to grow and this list is not designed to be comprehensive but to demonstrate some of the currently available biosimilars.

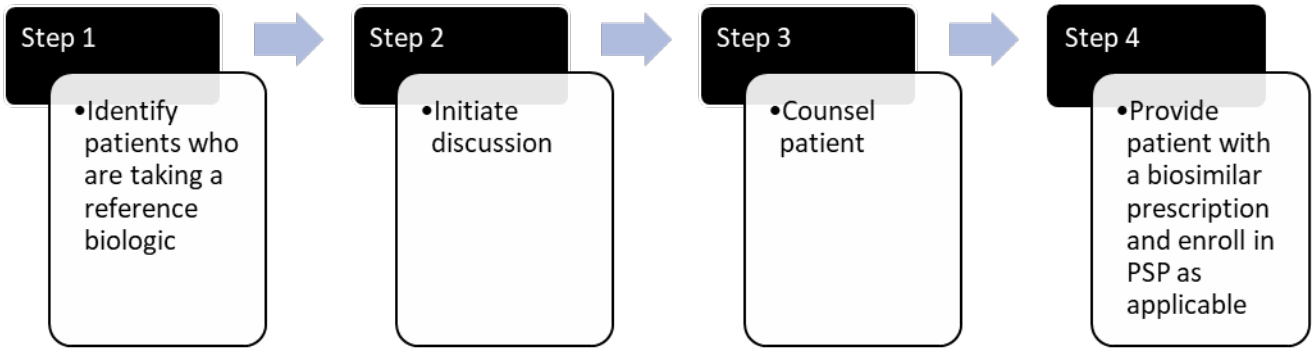
Have biosimilar switching programs been done before?

In many regions of Europe, biosimilar substitution programs have been implemented for many years. In Canada, British Columbia was the first province to implement a biosimilar switching program. Since its introduction, the province has increased the number of biosimilars in the program, as they have become available. Other provinces (Alberta, Ontario, New Brunswick, Nova Scotia, Saskatchewan, Quebec) and territories (Northwest Territories) have implemented biosimilar switching programs.

Bottom Line: Many countries and Canadian provinces have successfully implemented biosimilar switching policies. This has led to significant cost savings, while providing these patients with a medication with the same efficacy and safety as what they were taking before.

The process of switching to a biosimilar

Successfully switching patients from a reference biologic to a biosimilar involves several steps. The figure below reviews the different steps of transitioning to a biosimilar.



Step 1 – Identify patients who are taking a reference biologic

Switching programs implemented across the country have typically provided patients and health care professionals with time between a switching program announcement and fully implementing the program. When a switching program is being implemented, health care professionals who have patients taking a relevant reference biologic are strongly encouraged to initiate a discussion with patients regarding the potential changes to a biosimilar.

Step 2 – Initiate discussion

Once a patient who may be impacted by a biosimilar switching program has been identified, it is important to engage and initiate the discussion as early as possible. This allows the patient time to be provided with educational material and be part of the decision process.

To initiate these discussions, consider using a statement such as one of the following:

- *"Has anyone discussed a potential change in your medication to a biosimilar?"*
- *"Have you been informed of a change in the drug plan regarding your medication?"*
- *"There may be a change in the coverage of your medication, do you have a couple of minutes to discuss this today?"*

Step 3 – Counsel patient

The next step is to counsel the patient about the biosimilar. The following table reviews some key educational points that should be discussed when counselling your patient.

Topic	Discussion
Change in brand name	• Each biosimilar will have a different brand name than the reference biologic.
Change in packaging and device	• The packaging and device may look different than the reference biologic • It is important to ensure the patient is trained and educated on the new device – training is often provided by the patient's pharmacy or the Patient Support Program.
Efficacy and safety	• Health Canada has approved the biosimilar because its efficacy and safety is the same as the reference biologic they are currently taking.
Change in patient support program	• Many of the reference biologics have patient support programs (PSPs) • The biosimilar manufacturers have PSPs for their product to which the patient can register (usually enrolled by their health care provider).
Reason for the change	• The main reason for the change is to offer the same benefits from the medication that the patient is currently receiving at a fraction of the cost.
Switching programs have been implemented successfully in other regions	• Many people are concerned that these types of programs have not been tried before. • It is important to remind patients that these programs have been implemented in other countries and provinces for years and have been shown to be safe and effective.
Follow-up	• There are no expected changes in efficacy and safety when switching from a reference biologic to a biosimilar. • No increase in follow-up is required based on these changes, unless more frequent follow-up is needed for a specific patient, based on the health care professional's judgement.

Step 4 – Provide patient with a new biosimilar prescription and facilitate enrollment of patient in a patient support program for the biosimilar as applicable

- A new prescription will be required to dispense the biosimilar version of a biologic.
- Some biosimilars will require enrollment into the patient support program associated with the biosimilar. The patient support programs may provide services for administration, monitoring, access, and general information about the drug product. Many biologics require specialized administration, therapeutic drug monitoring, or dose optimization support. In these cases, the patient support programs are part of the patient's care team.

Helping patients who are resistant to change

Whenever a new program is implemented, patients may express concerns about the change. This can many times be mitigated by initiating the discussions early, providing them with education and material to read. There are several potential patient concerns with these changes and the following table provides answers to many common patient concerns.

Addressing common patient concerns regarding biosimilar switches:

Patient question	How to respond
Why do I need to switch my medication?	• Biosimilar medications work just as well as your current medication, but they are much less expensive. • This change should have no impact on your condition but can help to ensure the drug plan's costs are sustainable and potentially increase funding for new medications introduced in Canada.
Have other people had to switch to a biosimilar?	• Biosimilar switching programs have been implemented in Canada for several years. • These programs have been very successful. • British Columbia has had a switching program for a few years. They estimate this program is going to save over $100 million over the next few years. In this time, most of Canada has implemented a switching program.
Does the biosimilar work as well as my medication?	• Health Canada will only approve a biosimilar in Canada if it works as well as the original biologic medication. • There should be no change in how well the biosimilar works for you.

Patient question	How to respond
Are there any changes in side effects?	• The biosimilar is just as safe as the medication you are taking. You should not experience any new or different side effects from the biosimilar.
Are there any differences with this medication?	• When you change to a biosimilar it will have a different trade name than your current medication, but it is the same medication. • If you inject your medication, the pen that you use to inject may look a little different. Your doctor, nurse or pharmacists can help to train you how to use the new pen. • The patient support program may also be different than your current program.
What if I refuse to change?	• You may be able to continue on the reference biologic, however it may not be covered by the drug plan. We may have to seek an exception or alternative funding sources. • If receiving treatment at the hospital: we may not have the ability to accommodate the request at this hospital if the reference biologic is no longer on the hospital formulary.
Who is going to help me with the change?	• Myself and the rest of the medical team are here to answer any questions you have regarding this change.

Patient Resources

Patient and clinician education is important aspect of increasing trust and acceptance. Ontario Health and the pan-Canadian Pharmaceutical Alliance have developed a number of tools to help clinicians and their patients to learn more about biosimilars. These tools can be accessed at: cancercareontario.ca/en/cancer-care-ontario/programs/provincial-drug-reimbursement/biosimilars-initiatives/health-care.

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