Should I switch a patient to a biosimilar?

Biosimilars in Canada

The first biosimilar biologic (or "biosimilar") Omnitrope was approved in Europe in 2006 and then in Canada in 2009.[1] Since that time, many other biosimilars have been launched to help manage a number of medical conditions. Health Canada will only approve a biosimilar if the manufacturer can demonstrate there is no clinically meaningful differences between it and the reference biologic.[2]

Biologics contribute a disproportionate amount to drug plan costs compared to their share of claims.[3,4] Biosimilars are associated with lower cost, but their uptake is lower in Canada than in many other countries.[4] To improve the utilization of biosimilars, some provincial and public payers have implemented or are considering switching policies. These programs will switch patients from the reference biologic to the biosimilar, if one is available.

Are biosimilars just generic biologics?

Biosimilars are not the same as generic drugs.[2] Generic drugs are chemically synthesized and thus contain the identical medicinal ingredient as the reference product.[2] Biosimilars are produced from living organisms or their cells. They tend to be large, complex and naturally variable.[2] A biosimilar is highly similar to the reference biologic but not identical.[2] A biosimilar is a biologic, the difference is it is designed to be highly similar to a medication already available in Canada.

Although not identical, a biosimilar is only approved in Canada if it is equivalent in terms of efficacy and safety to the reference biologic.[2]

Are biosimilars interchangeable with the reference biologic?

A drug is interchangeable in Canada if a pharmacist can change to another equivalent drug without the intervention of the clinician who wrote the prescription.[2] Biosimilars are not currently interchangeable with reference biologics.

Why are payers implementing a biosimilar switching program?

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.[2] By implementing a switching program, payers can reduce the cost of biologic medications while maintaining the same outcomes in patients.

The province of British Columbia was the first province to implement a biosimilar switching program. It will lead to over $100 million in savings that can be invested to improve coverage for other medications.[5]

What is the data to supporting switching to a biosimilar?

A systematic review of 178 studies reviewed the evidence surrounding switching patients from reference biologics to biosimilars.[6] This included switching studies with somatropin, filgrastim, insulin, anti-TNFs and monoclonal antibodies used in oncology (rituximab, trastuzumab).[6] The majority of the studies consisted of a single switch (from reference biologic to biosimilar) where some included multiple switches (alternating back and forth between the reference biologic and biosimilar).[6] Based on the review of these studies, the authors concluded:[6]

There are no robust data that indicate that switching from a reference biological to a biosimilar is related to any major efficacy, safety, or immunogenicity issues.

Do I have to increase monitoring for a patient switching to a biosimilar?

A biosimilar is expected to have the same efficacy and safety as the reference biologic. Switching is not expected to lead to any clinically meaningful changes. No changes in routine monitoring are recommended when switching to a biosimilar.

What if a patient does not want to switch to a biosimilar?

Some patients who are stabilized on a reference biologic may not want to switch to a biosimilar. Many times, this can be addressed through proper education by the healthcare professional. Simply explaining that there are no differences in efficacy and safety between the biologic and biosimilar may be all that is required. The information below can help with patient education.

If the patient still refuses to switch, they could stay on their reference biologic. The fundamental issue is that the payer may reduce or eliminate the coverage and payment for their current medication depending on the local policy. This would normally translate to a large increase in the out-of-pocket cost for the patient.

Most patients will switch to a biosimilar, with education and reassurance that the change will not cause any change in efficacy and safety.

What education should I provide to a patient who is switching to a biosimilar?

When a patient is being switched to a biosimilar, they should be educated by healthcare professionals on the new therapy. The following table reviews some of the key questions that patients may have regarding the switch.

Patient education regarding biosimilar switches

Patient question	How to respond
What is a biosimilar?	• A biosimilar is a medication that is very similar to what you are currently taking. • It works just as well and is just as safe as the medication you are currently taking.
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 more people get access to funding for other medications.
Have other people had to switch to a biosimilar?	• Biosimilar switching programs have been in Canada for years. • This program has 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.
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 reference biologic. • There should be no change in how well the biosimilar works for you.
Are there any changes in side effects?	• The biosimilar is just as safe and has the same side effects as the medication you are taking.
Are there anything different with this medication?	• When you change to a biosimilar it will have a different brand name than your current medication, but it is the same. • 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.
Who is going to help me with the change?	• I am here to support you and answer any questions you may have regarding this change.

References

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