



Forced-Switching and the IBD Patient

Forced-switching, also known as non-medical switching, occurs when a patient is moved from their therapy without authorization by either the patient or the physician and done so for reasons other than the patient's health and safety.

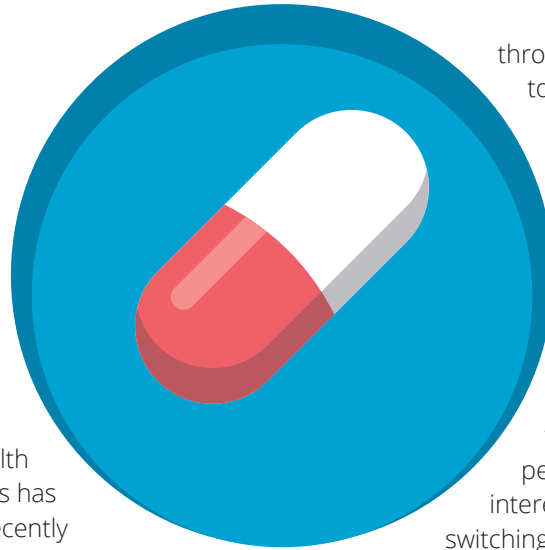
The decision to switch is mostly made for financial reasons, so private or public health insurance providers can save money. This has drawn much attention in the IBD world recently because of the entry of biosimilar anti-TNF medications in Canada.

What is the difference between a biologic and biosimilar?

A biologic, commonly referred to as an innovator drug, is a type of drug treatment produced from living cells, created to target specific parts of the immune system and treat chronic diseases such as IBD. The most common biologics used to treat IBD are:

- **Remicade (infliximab)**
- **Humira (adalimumab)**
- **Stelara (ustekinumab)**
- **Entyvio (vedolizumab)**

When the patent on a biologic drug has expired, a version of the biologic (innovator) can be made. This is called a biosimilar. Biosimilars are not the same as "generic" drugs, a generic is an identical copy of a chemical drug. A biosimilar will be similar in safety and efficacy to the original biologic, but the differences in how the drug is manufactured can result in structural differences and differences in impurities. These differences can lead to changes in how the drug moves



through the body and how the body responds to the drug (immunogenicity). So, the drug is similar but not identical.

Although saving the health care system money sounds appealing, there are things to consider that are important to both patients and their care providers.

The first population affected by forced-switching will be adult patients, but pediatrics won't be far behind. This in itself is interesting. If there were no concerns around switching, you would imagine the policy would be no different for adult or pediatric patients; however, forced-switching currently applies to adult patients only.

Some commonly asked question surrounding forced-switching are:

Will switching a patient put them at risk for triggering a flare?

This is a primary concern surrounding forced switching, taking patients who are stable on a medication and switching them to another. Although studies suggest that doing this type of switch is safe, it's still too early to know for sure.

It is important to note, not all provinces have adopted forced-switching. Currently the provinces of: xxx have adopted this policy with xxx to yet make a forced-switching policy determination.

Canada is not the first country to adopt forced-switching, Europe and the United Kingdom have adopted this practice, which has resulted in savings that has allowed investment back into the care of IBD patients in some areas.

For pediatric patients currently on a biologic, will their prescription change when they transition?

Yes the prescription would change. It's important for children and their families to understand what drug treatment they are receiving. For example, Remicade is the name of the innovator drug and Inflectra is the biosimilar name. Both Remicade and Inflectra are classified infliximab, as they are both antibodies created to target TNF-alpha in the body. They share a classification (infliximab) but are not equally the same drug, which is why it's important to know the difference and the name of the drug you are taking. As more biosimilars come to market, knowing the name of the innovator or biosimilar you are taking will ensure you consistently receive the same drug you have coverage for.

How can forced-switching impact patients

One overlooked aspect of the forced-switching conversation is the psychological impact on a patient and/or their family. It is important to remember, to be prescribed a biologic means the patients has significant enough disease to warrant using a biologic. The patients who will be targeted for forced switching are those who have responded to a biologic and are stable. What a wonderful journey from going from being sick to being well, then forced to switch to another "unknown" medication. This will likely have a psychological impact that may affect the person's quality of life.

Does the physician have a say when it comes to forced switch?

Unfortunately, force-switching policies will provide very little say for the physician and/or patient. Therefore, this policy removes a physician's autonomy; the freedom and ability to make care decisions aimed at promoting a patient's health and well-being.

If forced to switch, will a patient receive the same level of support from the biosimilar company?

An important aspect of being on a biologic therapy is the patient support program behind the drug. In many instances, patients develop meaningful therapeutic relationships with the support program co-coordinators, trainers, and nurses. Not all programs are created equal. Forced switching would mean losing the support a patient has grown accustomed to and having to engage in a new experience. This does not mean that it will be bad, but it will be different.

Does forced-switching only apply to those receiving public health care assistance?

The thought is that it will happen at the level of the public payer first, but it is likely private insurance companies will soon follow suit.

To learn more about forced-switching and how it may affect you or someone you care for, speak to your gastroenterologist.

To learn more about biologics and biosimilars, visit our website at: bit.ly/RRBio-Similars

If you would like to speak out for "patient and doctor rights" and send a letter to your local MPP/MLA and Minister of Health, visit: bit.ly/CCCForcedSwitching

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