Biosimilar Switching Frequently Asked Questions (FAQ)

What is a biosimilar drug?

A **biosimilar** drug, or **biosimilar**, is a medicine that is very close in structure, function, safety, and efficacy to an existing biologic drug (also known as the *reference* or *originator* drug). Once the patent of a reference drug expires, other manufacturers may produce biosimilars. Health Canada authorizes biosimilars for sale using the same strict standards for quality, effectiveness and safety as for all other biologic drugs. In some cases, biosimilar drugs can cost up to 50% less than the reference biologic drug.

An increasing number of biosimilar drugs will be entering the market in the coming years. It is important for patients to learn about this type of drug so that they can participate actively in discussions about biologics and biosimilars with their doctor and be aware of their treatment options.

Are biosimilar drugs as effective as reference biologic drugs?

Health Canada monitors the safety of all drugs on the market, including biosimilars. Biosimilars are only approved for sale after demonstrating that there are no meaningful differences in effectiveness and safety compared to the reference biologic drug.

Is it safe to transition from a reference biologic drug to its biosimilar version?

Biosimilars must meet strict regulations and testing requirements at Health Canada to prove they are as safe and effective as the originator biologic. Regarding the safety of biosimilars, Health Canada has clearly stated that its rigorous standards for approval mean that patients and health care providers can have the same confidence in the quality, safety and effectiveness of a biosimilar as the originator biologic.

Many plans in European countries have required patients taking reference biologics to switch to biosimilars for years. There are now more than 150 research studies across various medical conditions in rheumatology, gastroenterology, and dermatology that collectively show no meaningful clinical differences when patients are switched from a reference biologic to a biosimilar version.

Based on that experience and research, the provincial drug plan in British Columbia became the first in Canada to require biosimilar switching in 2019. Ontario is now the eighth province or territory to expand the use of biosimilar medications, following British Columbia, Alberta, New Brunswick, Quebec, Northwest Territories, Nova Scotia, and Saskatchewan.

Why do biosimilars cost less than reference biologics?

Biologic manufacturers spend years studying a new drug before it can be authorized for sale. The manufacturer then holds a patent on that drug that prevents other manufacturers from selling their own version of it. This allows the reference biologic manufacturer to earn back the money invested in researching and bringing the drug to market. When the patent of a reference biologic expires, other manufacturers can then produce biosimilar versions, which does not carry the same upfront research and development costs of a brand new reference biologic.

Are there any exemptions to the biosimilar switch requirement?

Individuals in the following situations do not have to transition to a biosimilar equivalent:

- Pregnant women are excluded from the initial transition but must make the transition to the biosimilar within 6 months following delivery.
- Pediatric patients are excluded from the initial transition but must make the transition within 6 months following their 18th birthday.

If you fall into one of the two exempted groups, please ensure your specialist has completed **Part 3: Biosimilar Transition Exemptions of the Biosimilar Switch Form**.

What biologic products are being transitioned?

This change will impact you if you are taking any of the following reference biologics:

ORIGINATOR BIOLOGIC	PREFERRED BIOSIMILAR DRUG(S)
Remicade® (infliximab)	**Renflexis®**
Humira® (adalimumab)	**Idacio®**
Enbrel® (etanercept)	**Brenzys®**
Copaxone® (glatiramer acetate)	**Glactect®** **Teva-Glatiramer Acetate®**
Rituxan® (rituximab)	**Riabni®** **Riximyo®** **Ruxience®** **Truxima®**

If you are taking any of the medications mentioned above, you will require a new prescription to continue to receive coverage for your medication(s). This new prescription would allow you to transition from the originator biologic drug that you are currently on to a biosimilar version. We encourage you to speak to your healthcare professional to discuss this transition.

I am taking one of Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab). Why do I need to switch to a specific biosimilar version, when there are multiple biosimilars available on the market?

All biosimilars that have been approved by Health Canada have been shown to provide the same effectiveness and safety as their reference biologic.

The Plan has established preferred biosimilar listings for specific biologic drugs. This means that rather than covering all of the biosimilar versions that are available for a given originator biologic drug, the Plan has chosen one as its preferred biosimilar, which allows for this biosimilar to be priced lower than other options available. **Savings from biosimilar switching and preferred biosimilar listings help to ensure the long-term sustainability of the Plan while Plan members continue to receive safe and effective specialty drug therapy.**

If I transition to a biosimilar, do I have to go to a different infusion centre?

If you are taking Remicade® or Rituxan®, as part of the biosimilar transition you may have to go to a new infusion centre to receive your infliximab or rituximab infusion.

We encourage you to speak to your healthcare professional for more information.

What do I need to do next?

If you have received a letter regarding the biosimilar switch plan design change, and are receiving one of Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Rituxan® (rituximab) or Copaxone® (glatiramer), you will need to:

1. Fill out and sign the enclosed form titled Biosimilar Switch to provide consent to the FACET Program Clinical Team to participate in the process.
2. Schedule an appointment or contact your doctor or pharmacist to discuss the switch if you have any questions or concerns. Have your doctor complete and sign the form.
3. Submit the completed form by fax to 1-844-446-1575 or email a scanned copy to claims@facetprogram.ca.
4. If you have any questions regarding this process, please email the FACET Prior Authorization Program at claims@facetprogram.ca or call 1-844-492-9105.

What is the FACET program?

Cubic Health's FACET program is a team of independent, clinical pharmacists and nurses that provide ongoing specialty claims management and clinical support for plans across the country. The Plan has partnered with FACET to provide members with safe, effective, and appropriate specialty drug therapy. If you have questions surrounding the transition to biosimilars, the FACET pharmacy team can provide you with objective, evidence-based clinical recommendations and advice.