



Crohn's and
Colitis Canada
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Crohn's and Colitis Canada's Biosimilar Position Statement: Updated September 2019

Biosimilars are a safe and effective treatment for people with Crohn's disease and ulcerative colitis (the two main forms of inflammatory bowel disease).

The decision to switch a patient from a biologic drug to its biosimilar should be based on patient/doctor choice.

Non-medical switching from a biologic drug to its biosimilar is not in the best interest of patients.

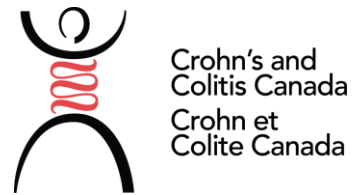
*In the event of implementation of a **non-medical** switching policy, Crohn's and Colitis Canada offers the following:*

Cross-Canada specialist experts indicate that a one-time switch from a biologic drug to its biosimilar may be safe and effective for **some** adult patients with inflammatory bowel disease (IBD). Multiple switching (i.e. switching from a biologic to one of its biosimilars, then switching back, or to its other biosimilar(s)) is **not** supported by these experts due to lack of scientific evidence that this strategy is safe.

Crohn's and Colitis Canada understands the fiscal pressures on the Canadian health care system and are aware that a non-medical switching policy is proposed to take advantage of the significantly lower cost of biosimilar treatment as compared with biologic treatment. Reinvestment of the savings into the care of patients with Crohn's and colitis should be strongly considered. It must also be noted that should the price differential between biologics and biosimilars be eliminated, a mandatory non-medical switch should **not** be considered by policy-makers.

Crohn's and Colitis Canada emphasizes that the drug cost is not the only factor important to patients and health care providers. Any non-medical switching policy must be accompanied by quality patient support programs adapted for specific patient populations together with guidelines for extraordinary monitoring protocols to ensure effective transition and continuity of care for patients. Additional burden on current health care support teams must not be a consequence of policy change.

Crohn's and Colitis Canada supports the careful consideration of appropriate, individual medical exemption by IBD specialists. In particular, Crohn's and Colitis Canada supports exemption for pediatric, pregnant or breast-feeding patients. As evidence in select patient populations becomes available, more precise information for exemptions should be incorporated.



Crohn's and Colitis Canada supports our patient population who have strongly expressed their concerns about losing their hard-earned treatment stability, their unwillingness to risk losing this stability, their fear of running out of therapeutic options, and the lack of consultation with their specialists regarding decisions to change their treatment plan. Patient concerns must be addressed **fully** prior to implementing policy change including significant communication, education and follow up.

Should a mandatory non-medical switch policy be implemented, Crohn's and Colitis Canada is positioned to support patients affected by this policy. The care of patients with Crohn's disease and/or ulcerative colitis remains our paramount concern. Patient/doctor choice remains the best option.

Crohn's and Colitis Canada considers this an area of ongoing research and will continue to monitor emerging evidence, consult Canadian scientific and clinical IBD experts, and update our position as warranted.