Projected Impact of Biosimilar Substitution Policies on Drug Use and Costs in Ontario

A cross-sectional time series analysis

ODPRN
Quality. Relevance. Timeliness.

Background

- Biologic drugs are compounds derived from living organisms that are important treatment options across a number of medical indications, including rheumatic conditions, inflammatory bowel disease (IBD), and diabetes.
- While their use has had measurable impact on patient outcomes, the cost of these medications is high, putting pressure on patients and public payers as healthcare expenditures grow.
- A biosimilar is a drug that is highly similar and has no clinically meaningful differences to an innovator biologic that has already been authorized for sale, but with a lower price.
- In the last few years, several provinces across Canada have announced new biosimilar reimbursement policies that vary in their approach and the specific indications and biologic drugs included.

What did we investigate?

The ODPRN used real-world data in Ontario to estimate the number of patients potentially impacted by different biosimilar policy options and the cost implications of these policies. Three people with lived experience using biologics participated on the study team.

Key findings

- **Uptake of biosimilars is low**: 85-90% of people prescribed biologics reimbursed by the Ontario government for rheumatic conditions or IBD are receiving innovator products.
- **Major cost**: In 2018, infliximab, etanercept and adalimumab cost the Ontario public drug programs $280.8 million. If nothing changes, it is estimated that these costs will total $925.3 million between 2018 and 2020.
- **Potential for large cost-savings:** Depending on the policy implemented, and negotiated biosimilar prices, the potential 3-year (2018-2020) cost implications of biosimilar reimbursement policies vary considerably. Annual savings are estimated to range between $34.2 million (new user switch for rheumatic conditions and IBD only; excluding adalimumab) and $645.9 million (mandatory switches, with biosimilars priced at 25% of innovator biologics).
- **Impact on patients varies**: Between 757 to 115,895 patients receiving innovator biologics could be impacted depending on the policy selected.

For more information

Gomes, T., McCormack, D., Kitchen, S., Paterson, M., Mamdani, M., Proulx, L., Bayliss, L., & Tadrous, M. (2021). Projected Impact of Biosimilar Substitution Policies on Drug Use and Costs in Ontario, Canada: A cross-sectional time series analysis. *CMAJ Open*.

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Potential policies for publicly funded biologics for rheumatic conditions or IBD

1. **Mandatory Switching**: Everyone previously prescribed a publicly-funded innovator biologic would be mandated to switch to a biosimilar for public drug reimbursement. This could also be interpreted as a policy of mandatory biosimilars for people starting therapy, and forced price reductions of innovator biologics to the same threshold as biosimilars for existing innovator biologic users.
2. **New User Biosimilar Requirement**: Biosimilars are mandatory for people newly starting therapy when a biosimilar is available. Existing innovator biologic users can continue treatment uninterrupted. *This is the current reimbursement policy for these products in Ontario.*
3. **Additional considerations:** 1) negotiating lower biosimilar prices (i.e. 25% or 50% of innovator price), 2) accounting for the recent introduction of biosimilars for adalimumab, and 3) considering biosimilars for insulin glargine (indicated for diabetes).

Important considerations

- Although clinicians generally believe that biosimilars are effective and safe, there is a concern by some that switching patients already stable on treatment could destabilize their condition, which could have major impacts on patients' quality of life and incur costs to the healthcare system. This concern appears to be greater for IBD patients.
- Some costs of patient care and medication administration (e.g. infusion clinics, lab tests, patient support) are covered by biologic drug manufacturers; therefore, any policies of mandatory changes should build in timelines that allow for scaling up of these services. Safeguards should be put in place to ensure patients retain the same standard of care and are not be responsible for paying out of pocket for these tests.
- Clinicians and patients both highlight the need to monitor whether patient outcomes change after switching from innovator biologics to biosimilars, including qualitative studies of patient experience.
- There is a perceived need for education for patients and physicians, particularly within the context of a non-medical switch, which could incur additional costs to the healthcare system.