Measuring the Impact of the Substitution of Innovator Biologics With Biosimilars on Uptake and Costs Among Ontario Public Drug Benefit Recipients

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In Ontario, biologics have historically represented a small proportion of public drug claims but a large proportion of spending. Biosimilars, lower cost alternatives to biologics, offer a potential solution to the rising spending on biologics. From March 2023 to January 2024, the Ontario Ministry of Health required public drug program beneficiaries on eight innovator biologics to transition to biosimilars. Clinicians were reimbursed for supporting patients who transitioned. To evaluate the impact of this biosimilar switch policy, we conducted a repeated cross-sectional study using administrative data from April 2019 to June 2024. For the biologics (innovator and biosimilar) included in the policy, we reported the biosimilar market share, public drug program spending, and clinician support fees. We used interrupted time series analyses to evaluate the policy's impact, and forecasting to estimate drug cost savings. From March 2023 to June 2024, the percentage of affected individuals on biosimilars increased from 21.7% to 96.5%. Drug cost savings were $65.2 million between April 2023 to June 2024, with most savings attributed to non-insulin biosimilars. We estimated savings of $46.6 million in Year 1 (April 2023 to March 2024) and $95.9 million in Year 2 (April 2024 to March 2025). Clinician support fees totaled $3.4 million across the study period. Ontario's biosimilar policy achieved high biosimilar uptake and substantial cost savings. Future research should examine the impact of this policy on clinical outcomes to assess its broader implications for patient care and long-term sustainability.

Study Highlights

WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?

☑ Mandatory biosimilar switch policies have been implemented in most Canadian jurisdictions. Following their switch policy beginning in 2019, British Columbia reported substantial biosimilar uptake and cost savings. Ontario implemented its switch policy between March 31, 2023, and January 30, 2024, requiring public drug program beneficiaries on selected innovator biologics to transition to biosimilars, with limited exceptions.

WHAT QUESTION DID THIS STUDY ADDRESS?

☑ Our objective was to evaluate uptake and costs associated with Ontario's biosimilar policy among public drug program beneficiaries. Innovator biologics that were part of this transition were adalimumab, etanercept, glatiramer acetate, infliximab, insulin aspart, insulin glargine, insulin lispro, and rituximab.

WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?

☑ Our study quantifies the trends in uptake and drug program spending associated with Ontario's biosimilar policy, supporting policy evaluation and cross-jurisdictional comparisons. The transition to biosimilars was nearly complete across all drug categories 5 months after the transition period. Since the policy was launched, we estimated drug cost savings of $46.6 million in Year 1 and $95.9 million in Year 2, largely driven by non-insulin biosimilars. Clinician support fees totaled $3.4 million across the study period and declined rapidly post-transition.

HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?

☑ Our findings demonstrate that a biosimilar switch policy can substantially increase drug uptake and generate cost savings. Considering existing evidence showed no compromise to patient safety or effectiveness, our findings support the implementation of biosimilar switch policies and inform the adoption of similar policies in other jurisdictions.

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Biologic medications are high-cost therapies derived from living organisms that can treat conditions, such as diabetes, rheumatic diseases, and inflammatory bowel disease.[1] In 2023, biologics accounted for 29.6% of total public program spending in Canada (CAD $4.7 billion), while representing only 2.4% of claims.[2] When the patents for innovator biologics expire, biosimilars can enter the market. Compared with innovators, biosimilars do not have clinically meaningful differences in efficacy, safety, and immunogenicity, yet generally cost less.

Mandatory nonmedical switching is a policy that can increase biosimilar uptake and contain rising biologic spending. In this policy, formulary coverage for biologics is limited to biosimilars, requiring patients on innovator products to transition to maintain coverage. This has been implemented in Australia (for bevacizumab in metastatic bowel cancer), Canada, and Denmark.[3] As of August 1, 2024, nearly, all Canadian jurisdictions had implemented biosimilar switch policies, with several reporting substantial cost savings.[4,5] For example, since implementing its policy in 2019, British Columbia transitioned more than 40,000 individuals from innovators to biosimilars, saving $732 million over 5 years.[5] These savings were reinvested into the provincial drug program to expand coverage for drugs and medical devices.[5]

In 2023, the Canadian province of Ontario introduced its biosimilar switch policy for adalimumab, etanercept, glatiramer acetate, infliximab, insulin aspart, insulin glargine (100 U/mL), insulin lispro, and rituximab.[6] These biologics treat a range of conditions, most commonly diabetes, Crohn's disease, ulcerative colitis, rheumatoid arthritis, and psoriasis. Public drug program beneficiaries using these innovator biologics were given a 9-month transition period, from March 31 to December 28, 2023, to contact their prescriber and switch to a biosimilar. New users were required to initiate therapy with biosimilars. An update allowed pharmacists to dispense a one-time supply of innovator products until January 30, 2024, to ensure treatment access over the holidays.[7] After that date, public coverage for these innovator biologics ended. Patients who were pregnant or receiving palliative care were exempted during the transition period. Patients with medical reasons, such as adverse reactions to two or more biosimilars, are exempt. To support patients transitioning to biosimilars, Ontario reimbursed clinicians through support fees. Physicians received $61.20 and pharmacists $15 for the counseling and administrative tasks required to transition each public drug program beneficiary, per biologic.[8,9]

With Ontario's biosimilar switch policy now complete, it is important to assess its impact on biosimilar market share and associated cost savings. Therefore, we evaluated biosimilar uptake and public drug program savings associated with this policy in Ontario.

METHODS

Setting and study population

We conducted a repeated cross-sectional study of all Ontarians dispensed a biologic included in the switch policy that was reimbursed by the public drug program (Ontario Drug Benefit, ODB) between April 1, 2019, and June 30, 2024. The ODB program provides public drug coverage to Ontarians aged 65 and above, aged 24 and below without private insurance, those who receive income or disability support, require catastrophic drug coverage, or live in long-term care or other supportive housing.[10] There were eight biologics included in the policy: adalimumab, etanercept, glatiramer acetate, infliximab, insulin aspart, insulin glargine, insulin lispro, and rituximab. Strictly speaking, glatiramer acetate is a nonbiologic complex drug; however, the policy applied to its funding, so we considered it a biologic. The full list of products is provided in **Table S1**.

Two people with lived experience using biologics participated on the study team. The study team met with them throughout the research process to integrate their insight into the study design, interpretation of results, and manuscript content. Both are listed as co-authors on this manuscript.

Data sources

We used Ontario administrative health data linked through unique encoded identifiers and analyzed at ICES.[11] Specifically, we linked the Registered Persons Database (sociodemographic data; used to exclude individuals with missing age, missing sex, or invalid identifiers), ODB Claims (community pharmacy drug claims and pharmacy services, including pharmacist support fees), Ontario Health Insurance Plan Claims Database (diagnosis codes to identify indications for biologic use, and physician services, including physician support fees (fee code K900)), and Canadian Institute for Health Information (CIHI) Discharge Abstract Database (inpatient hospitalization diagnoses and procedures). We also used two validated derived databases, the Ontario Crohn's and Colitis Cohort dataset (sensitivity 77%, specificity 96%)[12] and the Ontario Rheumatoid Arthritis Database (sensitivity 78%, specificity 100%),[13] to identify indications for biologic use. The use of these data is authorized under Section 45 of Ontario's Personal Health Information Protection Act (PHIPA), which does not require Research Ethics Board review.

Indicators

We examined three indicators for the eight study biologics: (i) the monthly number and market share of individuals dispensed a biosimilar, (ii) the monthly number and market share of biosimilar claims, and (iii) the total monthly drug costs to the public drug program. Market share was defined as the number of patients dispensed a biosimilar affected by the policy divided by the total number of patients dispensed the biologic (biosimilar or innovator). Drug costs were calculated as the total paid by ODB (drug ingredient cost, markup, and dispensing fee) plus copayments and deductibles paid by the patient. We also assessed monthly physician and pharmacist support fees, beginning in March 2023 when they were first available. Analyses were conducted in Canadian dollars.

Descriptive analyses

For indicator (i), we computed the monthly number and market share of individuals dispensed a biosimilar—overall and stratified by indication. Indications were defined hierarchically to create mutually

exclusive categories: diabetes, Crohn's disease or ulcerative colitis, rheumatoid arthritis, and psoriasis, diagnosed prior to the last day of the month of interest (complete definitions are in **Table S2**). Individuals not classified into these categories were grouped under "Other or unknown indication."

For indicator (ii), we computed the monthly number and market share of biosimilar claims, while for indicator (iii), we computed monthly total drug costs—overall and stratified by biologic type. Biologic type was defined as insulin (aspart, glargine, or lispro) or non-insulin (adalimumab, etanercept, glatiramer acetate, infliximab, or rituximab). This stratification is important because insulins and non-insulins have different clinical indications, pricing, and public funding pathways. Insulins are used for diabetes, cost roughly 10 times less than non-insulins,[14–16] and have less stringent eligibility criteria for public coverage than non-insulins.[9]

Time series analyses

We used interventional autoregressive integrated moving average (ARIMA) models to evaluate the impact of Ontario's biosimilar switch policy on the overall market share of individuals (indicator (i)) and total drug costs (indicator (iii)). We tested for changes in the indicators using a ramp function from April 2023 to January 2024, as we expected biosimilar uptake to gradually increase across the transition period and then stabilize once formulary changes took full effect. For each ARIMA model, we assessed stationarity using augmented Dickey–Fuller tests. We removed non-stationarity and seasonality using differencing where necessary. We selected autoregressive and moving average parameters using autocorrelation, partial autocorrelation, and inverse correlation function correlograms. We used residual plots and Ljung-Box χ^2 tests to confirm that the residuals were not significantly autocorrelated.

To calculate realized cost savings across our observed study period, we took the difference between expected and actual costs from the start of the policy (April 2023) to June 2024. Expected costs, representing the scenario if the policy had not been implemented, were estimated by forecasting drug costs using ARIMA. In secondary analyses, we estimated annual cost savings up to 2 years post-policy; using 1-year timeframes facilitates comparisons with other studies. Therefore, we extended our forecast of expected drug costs to March 2025 and also forecasted actual drug costs from the last observed month (June 2024) to March 2025. We then estimated drug cost savings in Year 1 (April 2023 to March 2024) and Year 2 (April 2024 to March 2025). We reported cost savings both overall and stratified by insulin vs. non-insulin biologics.

Where appropriate, we explored data transformations to address issues in model residuals. Residual diagnostics indicated variance concerns for both the biosimilar market share model (skew and heteroscedasticity) and insulin cost models (mild heteroscedasticity), which could impact statistical inference, although estimates would remain unbiased. For the biosimilar market share outcome, a logit transformation was applied to account for bounded data; however, this did not meaningfully improve residual variance. Therefore, we retained the original scale for interpretability in our primary analysis and conducted a sensitivity analysis using an ARIMA model fit to log-transformed biosimilar recipient counts. For the insulin cost model, log-transformation did not improve the residual diagnostics, so we retained the original scale for interpretability and acknowledged this as a limitation. Analyses were performed using SAS Enterprise Guide Version 8.3 (SAS Institute, Cary, North Carolina) with a type 1 error rate of 0.05.

RESULTS

Biosimilar uptake

The percentage of individuals on a study biologic (innovator or biosimilar) who were dispensed a biosimilar increased from 2.3% (1,314 of 58,378 individuals) in April 2019 to 96.5% (51,382 of 53,247) in June 2024 (**Figure 1**). Although

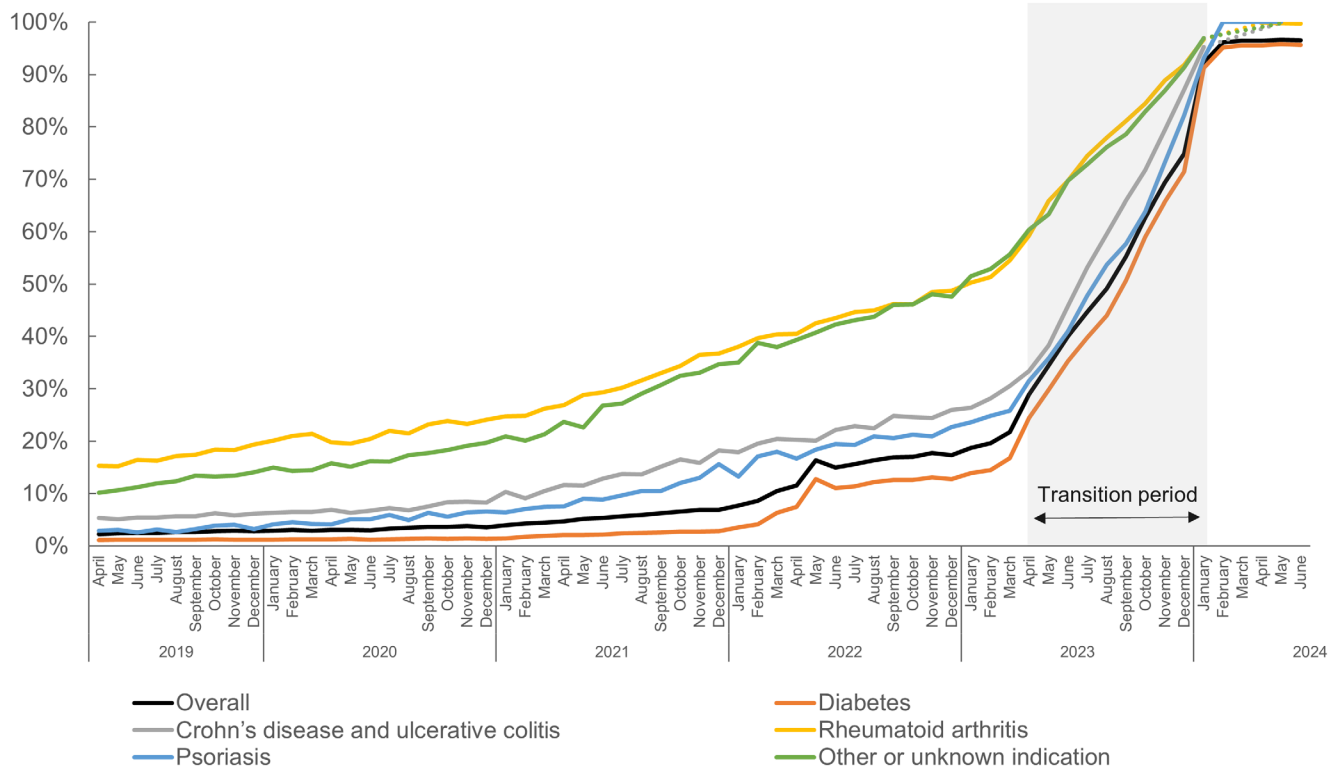

Figure 1 Market share of individuals dispensed a biosimilar in Ontario, April 2019 to June 2024. Denominator: Any biologic (innovator or biosimilar). Dotted lines indicate cell suppression, in accordance with data provider policies to prevent the identification of counts < six.

biosimilar market share was already increasing before the transition period in March 2023, uptake was limited, with less than one-third of patients receiving biosimilars indicated for diabetes (16.8%), Crohn's disease and ulcerative colitis (30.6%), and psoriasis (25.8%). By contrast, biosimilar market share was higher for rheumatoid arthritis (54.5%) and other unspecified indications (55.6%) (**Table 1**).

During the transition period, the total number of individuals dispensed a study biologic was stable overall and across diabetes and non-diabetes indications (**Figure S1**). The percentage of individuals dispensed a biosimilar increased across all indications (**Table 1**). Overall biosimilar market share of individuals increased 7.2% per month during the transition period (95% CI: 5.8%–8.6%, $P < 0.001$). This was consistent with our sensitivity analysis using log-transformed biosimilar recipient counts, which showed a significant monthly increase ($P < 0.001$; **Table S3**, **Figure S2**). By the end of the transition period in January 2024, 92.2% of patients were on a biosimilar (**Table 1**). Biosimilar market share plateaued thereafter. By June 2024, more than 95% of individuals dispensed a study biologic were on a biosimilar.

Costs

Trends. The total monthly cost of claims for all study biologics (innovator or biosimilar) was relatively stable before the transition period, ranging from $31.3 to $38.7 million (**Figure 2**). During the

Table 1 Individuals dispensed biosimilars in Ontario throughout the policy transition period and at the end of the study period

Indication for biosimilar	Month before the transition March 2023	Last month of transition December 2023	1 month holiday extension January 2024	End of study period June 2024
Overall	11,924 (21.7%)	40,940 (74.8%)	49,557 (92.2%)	51,382 (96.5%)
Diabetes	7,541 (16.8%)	31,733 (71.4%)	39,205 (91.2%)	40,635 (95.7%)
Crohn's disease and ulcerative colitis	1,043 (30.6%)	2,806 (87.1%)	3,333 (95.3%)	≥3,313 (≥99.8%)
Rheumatoid arthritis	2,076 (54.5%)	3,790 (91.8%)	4,130 (96.7%)	4,182 (99.7%)
Psoriasis	203 (25.8%)	645 (82.2%)	671 (93.1%)	≥751 (≥99.5%)
Other or unknown indications	1,061 (55.6%)	1,966 (91.3%)	2,218 (96.9%)	≥2,496 (≥99.8%)

The table above reports the number (*N*) of individuals dispensed a biosimilar and the percent (market share) of individuals dispensed a biosimilar for the specified indication (out of those dispensed any biologic – innovator or biosimilar). Indications were defined hierarchically in the order they appear above to ensure mutual exclusivity.

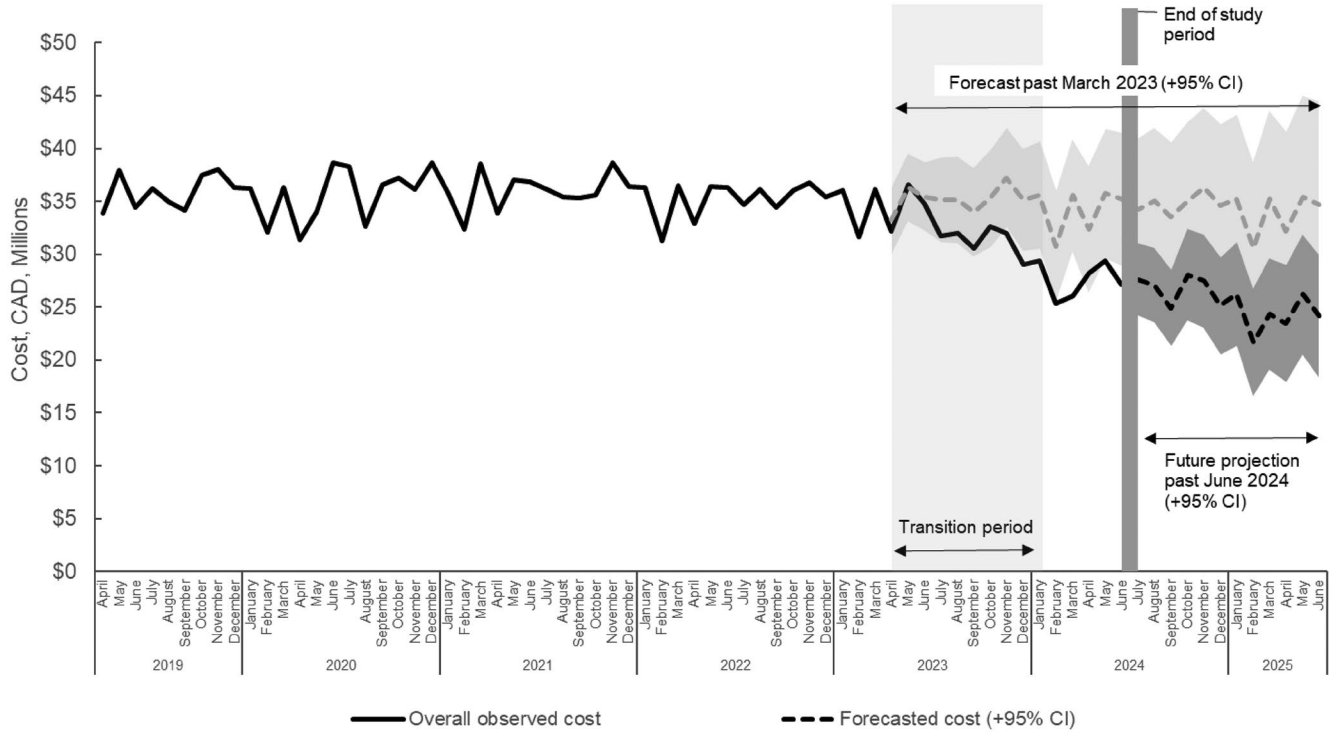

Figure 2 Actual and projected costs of biologics in Ontario, April 2019 to June 2025. The figure reports the total cost of claims dispensed for any biologic (innovator or biosimilar). Insulins include aspart, glargine, and lispro. Non-insulins include adalimumab, etanercept, glatiramer acetate, infliximab, and rituximab. CAD, Canadian dollar.

Table 2 Claims and total costs of biologics in Ontario throughout the policy transition period and at the end of the study period

Biologic category	Month before the transition March 2023	Last month of transition December 2023	1 month holiday extension January 2024	End of study period June 2024
Overall				
Claims for biosimilars	13,576 (20.6%)	47,948 (73.2%)	59,194 (91.5%)	59,904 (96.3%)
Claims for any biologic[a]	65,919	65,471	64,675	62,184
Total cost of biologics[a]	$36,163,496	$29,041,487	$29,387,974	$27,133,434
Insulins[b]				
Claims for biosimilars	8,565 (15.7%)	37,768 (69.9%)	47,548 (90.5%)	48,223 (95.5%)
Claims for any biologic[a]	54,717	54,015	52,536	50,480
Total cost of biologics[a]	$7,342,949	$6,109,782	$5,401,691	$5,221,020
Non-insulins[c]				
Claims for biosimilars	5,011 (44.7%)	10,180 (88.9%)	11,646 (95.9%)	11,681 (99.8%)
Claims for any biologic[a]	11,202	11,456	12,139	11,704
Total cost of biologics[a]	$28,820,547	$22,931,704	$23,986,283	$21,912,414
Total cost of support fees				
Pharmacist support fee	$495	$73,875	$38,705	$705
Physician support fee	$8,017	$275,767	$161,629	$21,175

The table above reports the number of claims for biosimilars and the percent (market share) of claims dispensed for a biosimilar (out of those dispensed for any biologic – innovator or biosimilar). Costs are in Canadian dollars. [a]Biologics include innovator biologics and biosimilars. [b]Insulins aspart, glargine, and lispro. [c]Adalimumab, etanercept, glatiramer acetate, infliximab, and rituximab.

transition period, monthly costs declined significantly (−$660,255 per month, 95% CI: −$1,029,869 to −$290,640, $P < 0.001$, **Table S3**), resulting in an 18.7% reduction in monthly costs, from $36.2 million in March 2023 (just before the transition period) to $29.4 million in January 2024 (end of the transition period; **Table 2**). By June 2024, monthly costs for biologics were $27.1 million per month (**Table 2**).

In stratified analyses of non-insulin and insulin biologic costs, we also observed significant declines. Monthly non-insulin biologic costs were stable before the transition period but decreased thereafter, from $28.8 million in March 2023 to $21.9 million in June 2024 (**Table 2**, **Figure 3**), with a significant monthly decline during the transition period (−$532,827 per month, 95% CI: −$779,821 to −$285,834, $P < 0.001$, **Table S3**). By contrast, monthly insulin costs were already declining before the transition period, decreasing from $9,656,989 in April 2019 to $7,342,949 in March 2023 (**Figure 4**). A further significant decline was observed during the transition period (−$104,337 per month, 95% CI: −$192,322 to −$16,352, $P = 0.02$, **Table S3**).

In total, $3.4 million was spent on physician ($3.0 million) and pharmacist ($433,290) support fees for biosimilars after they became available in March 2023. Physician support fees had two peaks: a large peak in the first 3 months of the transition period (highest at $396,331 in May 2023) and a smaller peak near the end of the transition period ($298,350 to $275,767 from October to December 2023, **Figure S3**). Monthly costs then rapidly declined, reaching $21,175 by June 2024. Pharmacist support fees were consistently lower than physician support fees (**Figure S3**). We observed one peak at the end of the transition period ($73,875 in December 2023), followed by a rapid decline, reaching $705 by June 2024.

Cost savings. Total realized public drug program spending on study biologics from the start of the transition period to the end of our study (April 2023 to June 2024) was $457.0 million. By comparison, we estimated counterfactual cumulative costs of $522.2 million in the absence of the policy, reflecting $65.2 million in cost savings (**Table 3**). When stratified by year since policy launch, we estimated savings of $46.6 million in Year 1 (April 2023 to March 2024) and $95.9 million in Year 2 (April 2024 to March 2025). Most cost savings came from non-insulin biologics, at $40.1 million in Year 1 and $86.8 million in Year 2. Cost savings for insulins were $4.2 million in Year 1 and $14.3 million in Year 2 (**Table 3**).

DISCUSSION

In this study on Ontario's switch policy, we observed high biosimilar uptake and substantial cost savings. In March 2023, the month before the transition period, study biosimilars comprised only 21.7% of market share. By June 2024, 5 months after the transition period, this had increased to 96.5% and exceeded 95% market share across all drug categories (diabetes, Crohn's disease and ulcerative colitis, rheumatoid arthritis, and psoriasis). We estimated drug cost savings of $46.6 million in Year 1 of the policy and $95.9 million in Year 2. The lower cost savings in Year 1 were expected as it reflected the 10-month transition period during which switching was not yet mandatory, and patients who were pregnant or receiving palliative care were exempt. Although significant savings were achieved for both insulin and non-insulin biologics, total savings were mostly driven by non-insulins. Physician and pharmacist support fees totaled $3.4 million—modest and short-lived compared with drug cost savings. Our findings suggest that Ontario's biosimilar policy achieved

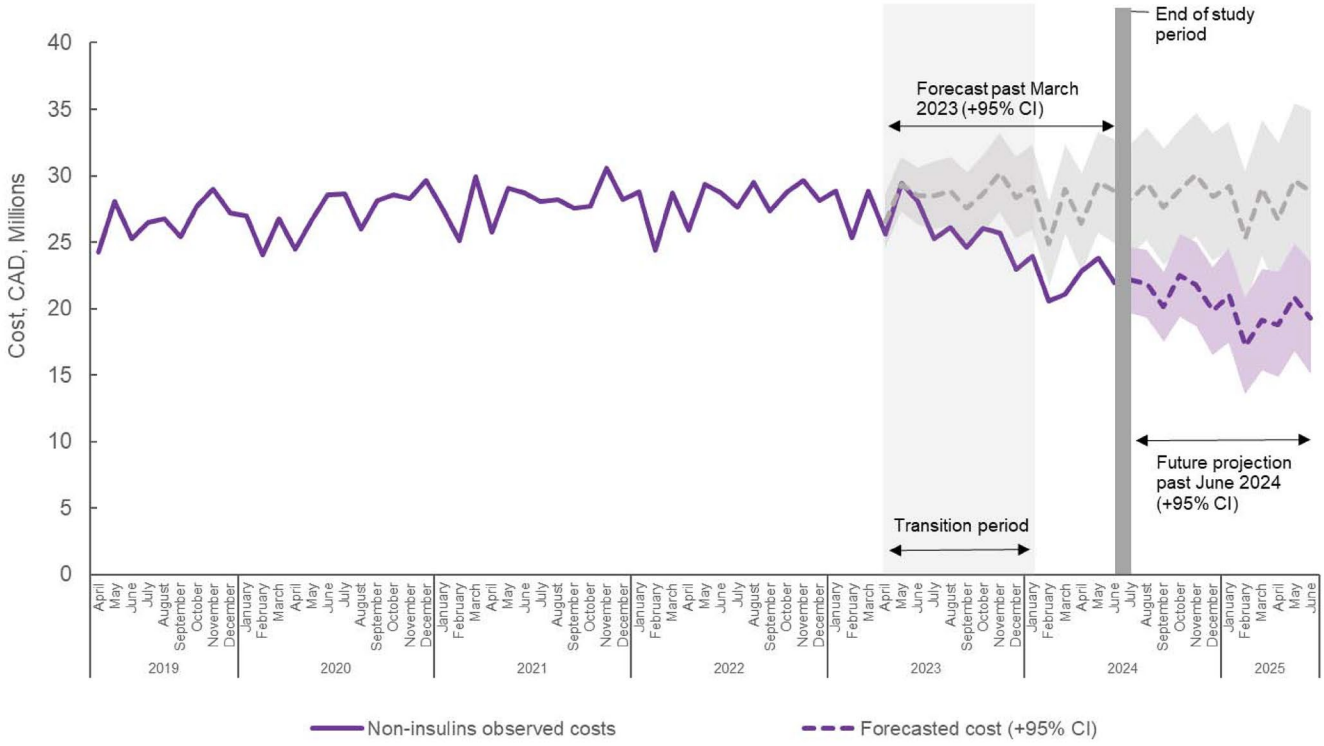

Figure 3 Actual and projected costs of non-insulin biologics in Ontario, April 2019 to June 2025. The figure reports total cost of claims dispensed for any biologic (innovator or biosimilar). Non-insulins include adalimumab, etanercept, glatiramer acetate, infliximab, and rituximab. CAD, Canadian dollar.

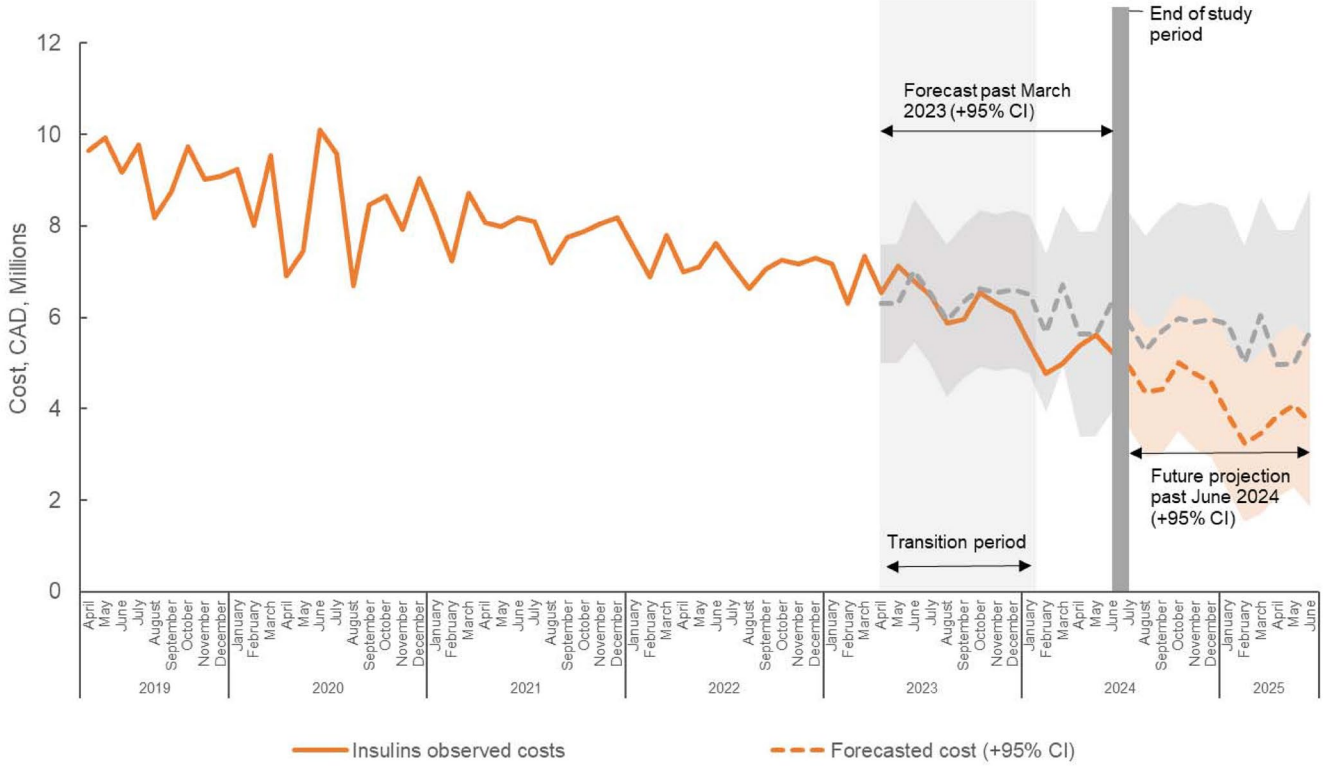

Figure 4 Actual and projected costs of insulin biologics in Ontario, April 2019 to June 2025. The figure reports the total cost of claims dispensed for any biologic (innovator or biosimilar). Insulins include aspart, glargine, and lispro. CAD, Canadian dollar.

Table 3 Projected cost savings for biologics in Ontario after policy implementation

	Start of transition until end of study period[a] April 2023 to June 2024	Year 1[a] April 2023 to March 2024	Year 2[a] April 2024 to March 2025
Overall			
Realized costs	$456,998,553	$372,264,245	$317,253,791
Expected costs	$522,227,881	$418,882,526	$413,138,099
Cost savings	$65,229,328	$46,618,281	$95,884,308
Insulins[b]			
Realized costs	$89,101,085	$72,891,500	$54,839,585
Expected costs	$94,698,225	$77,060,786	$69,185,251
Cost savings	$5,597,140	$4,169,286	$14,345,667
Non-insulins[c]			
Realized costs	$367,897,468	$299,372,745	$254,271,964
Expected costs	$424,287,332	$339,513,724	$341,101,578
Cost savings	$56,389,864	$40,140,979	$86,829,613

The table above reports the difference between realized and expected costs. Biologics include innovator biologics and biosimilars. [a]While realized costs in Year 1 reflect actual observed data as they do not extend past the study period, realized costs in Year 2 include both observed and forecasted data. [b]Insulins aspart, glargine, and lispro. [c]Adalimumab, etanercept, glatiramer acetate, infliximab, and rituximab.

meaningful drug cost reductions that were not offset by clinician support fees.

Although considerable, the cost savings in our study were less than previously projected. An earlier Ontario study using data up to 2019 estimated that a mandatory nonmedical switch policy for infliximab, etanercept, and adalimumab would result in up to $122.2 million of cost savings in Year 2.[17] By contrast, our analysis of non-insulin biologics—using realized data and including two additional biologics (glatiramer acetate and rituximab)—estimated cost savings of $86.8 million in Year 2. One contributing factor was the continued, though limited, access to innovator biologics through exemptions (< 4% of patients and claims by the end of the study period). Another likely contributing factor was that the first adalimumab biosimilar was only approved in Canada in February 2021, and therefore was not captured in the data used for the previous study. Therefore, the counterfactual costs in that study may have been overestimated as they could not account for the gradual uptake of adalimumab biosimilars that helped contain rising costs between February 2021 and March 2023.

Our findings in Ontario are generally consistent with trends in other jurisdictions that have implemented mandatory nonmedical biosimilar switch policies. We observed rapid biosimilar uptake following policy implementation, reaching 96.3% of claims 5 months post-policy. In British Columbia, uptake was also strong, reaching more than 94% of claims for adalimumab, etanercept, infliximab, insulin glargine, and rituximab within 2 years of their switch policies.[5] However, in this timeframe, uptake of biosimilar insulin aspart and lispro was slower, at 56% and 62%, respectively.[5] In Ontario, we also observed slower biosimilar uptake for insulins than non-insulins, though only slightly (95.5% vs. 99.8% at 5 months post-policy). Possible reasons include insulin pump incompatibility with some biosimilars,[18] a temporary insulin lispro biosimilar shortage (March to September 2023),[19] and relatively limited patient support programs for insulin biosimilars.[6] Internationally, Denmark's adalimumab biosimilar switch policy also produced rapid uptake, with biosimilars reaching 95% of pen sales within 2 months and an associated 83% decrease in costs.[20] As more jurisdictions evaluate their biosimilar policies, cross-jurisdictional comparisons will be valuable for guiding future policy implementation and modifications.

Most realized drug cost savings that we observed were attributable to non-insulin biologics. Cost savings are influenced by the number of claims. Before the policy, claims for non-insulins were trending upwards, whereas claims for insulins (aspart, lispro, and glargine 100 U/mL) were already trending downwards. Insulin is a family of products where innovator companies have incrementally introduced products with improved pharmacokinetics (e.g., faster onset or longer duration) and delivery (from vials to pens). For example, since the approval of glargine 100 U/mL in Canada in 2008, four other long-acting insulins have been approved: detemir (2009), glargine 300 U/mL (2018), degludec (2018), and icodec (2024).[21] The first three are funded by ODB, and none have biosimilars.[21,22] As uptake of newer insulins increases, the market size for older insulins may shrink, explaining the pre-policy decline in claims for aspart, lispro, and glargine. Therefore, costs for these insulins would likely have declined even without the policy, resulting in less dramatic cost savings than non-insulins. Cost savings are also influenced by the price per claim. Annual costs for non-insulins are roughly 10 times higher than for insulins,[14–16] offsetting the fact that only one-quarter as many patients used non-insulins. Prices can be further reduced by biosimilar competition,[23] which progressed more slowly for insulins than non-insulins pre-policy. Taken together, the trends in the number of claims and price per claim can explain the larger cost savings for non-insulins than insulins.

Since the policy's launch, six additional biologics have been added to the expanded switch list, including high-cost biologics, such as ustekinumab, ranibizumab, and denosumab.[6] Notably, ranibizumab was the second-highest cost biologic in Ontario in 2018, accounting for 17.4% ($188.3 million) of total biologic

spending.[24] Thus, we anticipate that the fiscal impact of this policy will continue to grow, with important implications for public drug program budgets. Importantly, these savings can be reinvested to improve access to new and effective high-cost therapies as they become available.

Although cost savings support the sustainability of public drug programs, it is also important to consider the impact of mandatory nonmedical biosimilar switch policies on patient outcomes. Potential concerns include adverse events, destabilization, and loss of patient choice.[25,26] However, Canadian and international evidence has been reassuring. Experimental studies indicate no differences in safety or immunogenicity when switching from innovators to biosimilars.[27] Real-world studies from Canada and Denmark following their mandatory nonmedical switching policies reinforce these findings. For example, studies from British Columbia on insulin glargine, infliximab, and etanercept found only marginal and expected differences in healthcare utilization, with no signals of reduced safety or effectiveness.[28–30] Similarly, Danish studies on infliximab and etanercept reported no clinically meaningful differences in disease activity or healthcare utilization.[31–33] Building on this evidence, our findings support that biosimilar switching can generate meaningful cost savings, which can be reinvested into the healthcare system without compromising safety and effectiveness. While the clinical findings above are reassuring, future work is needed for other outcomes (e.g., morbidity, quality of life), to identify vulnerable subgroups, and to confirm their generalizability to the Ontario context.

A major strength of our study is the use of real-world dispensing data on publicly funded biologics. However, several limitations require discussion. First, drug pricing information was based on claims submitted by community pharmacies to the Ontario government. This does not reflect actual costs paid by the government from confidential listing agreements with manufacturers, and thus the cost savings may be overestimated. Second, we relied on administrative databases to assess indications for biologic use. Although these databases and definitions are validated and have high sensitivity and specificity, some misclassification is possible. Third, our study focused on ODB beneficiaries dispensed biologics affected by the policy. This excluded: (i) patients ineligible for ODB, (ii) patients eligible for ODB but who used innovators post-policy through private coverage or out-of-pocket payment, and (iii) patients eligible for ODB but switched to therapeutically equivalent biologics without biosimilars (e.g., innovator insulin glargine to degludec). For example, by the end of the transition period in the province of Alberta, 15% of patients on innovator insulin glargine discontinued public drug coverage and more than 40% switched to a different biologic, with similar patterns observed for infliximab.[34] Six months after the transition period in British Columbia, 13% of patients on innovator glargine continued to use it through private coverage or out-of-pocket payment, and 2% switched to a different long-acting insulin.[28] We expect minimal impact from (ii) and (iii), given the stable number of affected individuals in Ontario during the transition period (**Figure S1**). Lastly, statistical inference for the biosimilar market share and insulin cost models may have been affected by unexplained variation not fully captured by the ARIMA models. Nonetheless, the findings from our sensitivity analysis were consistent with the main analysis, and there was no extreme or systematic pattern in the spread of the residuals in the untransformed insulin cost model; we expect any impact on statistical inference to be minor and unlikely to alter conclusions.

CONCLUSION

Ontario's biosimilar policy successfully shifted prescribing patterns and generated substantial cost savings, with significant spending reductions overall and across both insulin and non-insulin biologics. Although insulin biosimilars had slightly lower uptake than non-insulin biosimilars, the transition to biosimilars was nearly complete for all drug categories within 5 months of the transition period. Most cost savings were driven by non-insulin biosimilars. Additional cost savings are expected in the future as the policy expands to additional biologics. While Canadian and international evidence suggests that these policies do not compromise patient safety or effectiveness, future research is needed for other outcomes (e.g., function, quality of life) and to confirm the generalizability to the Ontario context. In conclusion, our findings demonstrate that Ontario's mandatory nonmedical biosimilar switch policy effectively promoted biosimilar uptake and achieved meaningful cost savings.

SUPPORTING INFORMATION

Supplementary information accompanies this paper on the *Clinical Pharmacology & Therapeutics* website (www.cpt-journal.com).

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CONFLICTS OF INTEREST

The authors declared no competing interests for this work.

AUTHOR CONTRIBUTIONS

A.I. and M.K.H.H. wrote the manuscript; all authors designed the research; all authors performed the research; J.Y. analyzed the data.

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1. Health Canada. Guidance document: information and Submission Requirements for Biosimilar Biologic Drugs <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/brgtherap/applic-demande/guides/seb-pbu/seb-pbu-2016-eng.pdf> (2017).
2. Canadian Institute for Health Information. Prescribed drug spending in Canada, (2023).
3. Kim, J., Arias, J., Gavura, S. & Ontario Health Provincial Drug Reimbursement Programs. National and international policies on the use of biosimilars: an environmental scan. *Can. J. Health Technol.* **4**, 1–58 (2024). https://doi.org/10.51731/cjht.2024.927.
4. Government of Manitoba. Manitoba biosimilars initiative. <https://www.manitoba.ca/health/pharmacare/biosimilars.html>.
5. Government of British Columbia. B.C.'s biosimilars initiative: a report on patient and financial impact. <https://news.gov.bc.ca/files/BCBiosimilarsInitiativeAReportonPatientandFinancialImpact_June%202024.pdf>. Accessed March 24, 2025.
6. Government of Ontario. Biosimilars <https://www.ontario.ca/page/biosimilars>.
7. Ontario Ministry of Health: Health Programs and Delivery Division. Executive officer notice: update to biosimilar policy <https://www.ontario.ca/files/2023-12/moh-executive-officer-notice-en-2023-12-15.pdf>.
8. Negotiations Branch Ontario Health Insurance Plan Division. Bulletin 230302 — biosimilar support fee code K900A <https://www.ontario.ca/document/ohip-infobulletins-2023/bulletin-230302-biosimilar-support-fee-code-k900a>.
9. Ontario Ministry of Health: Health Programs and Delivery Division. Biosimilar Policy: Q&A for Pharmacists <https://files.ontario.ca/moh-questions-answers-executive-officer-notice-pharmacies-en-2023-03-13.pdf>.
10. Government of Ontario. Get coverage for prescription drugs. <https://www.ontario.ca/page/get-coverage-prescription-drugs>. Accessed March 30, 2025.
11. Schull, M.J., Azimaee, M., Marra, M. *et al*. ICES: data, discovery, better health. *Int. J. Popul. Data Sci.* **4**, 1135 (2020).
12. Benchimol, E.I. *et al*. Validation of international algorithms to identify adults with inflammatory bowel disease in health administrative data from Ontario, Canada. *J. Clin. Epidemiol.* **67**, 887–896 (2014).
13. Widdifield, J. *et al*. An administrative data validation study of the accuracy of algorithms for identifying rheumatoid arthritis: the influence of the reference standard on algorithm performance. *BMC Musculoskelet. Disord.* **15**, 216 (2014).
14. Health Canada. Universal access to diabetes medications, and diabetes device fund for devices and supplies. <https://www.canada.ca/en/health-canada/news/2024/02/universal-access-to-diabetes-medications-and-diabetes-device-fund-for-devices-and-supplies.html>. Accessed September 21, 2025.
15. Canadian Agency for Drugs and Technologies in Health. Table 4, CADTH cost comparison table of DMARDs; pharmacoeconomic review report: upadacitinib (Rinvoq): (AbbVie): indication: for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate <https://www.ncbi.nlm.nih.gov/books/NBK558495/table/pe.app1.tab1/> (2020).
16. Canadian Agency for Drugs and Technologies in Health. Table 8, CADTH cost comparisons for relapsing-remitting multiple sclerosis; pharmacoeconomic report: ofatumumab (Kesimpta): (Novartis Pharmaceuticals Canada Inc.): indication: multiple sclerosis, relapsing-remitting <https://www.ncbi.nlm.nih.gov/books/NBK572540/table/pe.app1.tab1/> (2021).
17. Gomes, T. *et al*. Projected impact of biosimilar substitution policies on drug use and costs in Ontario, Canada: a cross-sectional time series analysis. *CMAJ Open* **9**, e1055–e1062 (2021).
18. Health PEI. Biosimilar insulin resources <https://src.healthpei.ca/sites/src.healthpei.ca/files/Biosimilar%20Insulin%20Resources_0.pdf> (2024). Accessed March 22, 2025.
19. Government of Ontario. Executive officer notice: removal of temporary PINs for Humalog(R) (insulin lispro): shortage of the insulin lispro biosimilar (Admelog(R)) is resolved. <https://files.ontario.ca/moh-executive-officer-notice-en-2023-09-21.pdf> Accessed May 13, 2025.
20. Jensen, T.B., Kim, S.C., Jimenez-Solem, E., Bartels, D., Christensen, H.R. & Andersen, J.T. Shift from adalimumab originator to biosimilars in Denmark. *JAMA Intern. Med.* **180**, 902–903 (2020).
21. Health Canada. Drug product database online query <https://health-products.canada.ca/dpd-bdpp/>.
22. Government of Ontario. Ontario Drug Benefit Formulary Search. <https://www.formulary.health.gov.on.ca/formulary/> (March 31, 2025). Accessed April 8, 2025.
23. Samsung Bioepis. Biosimilar market report, Q3 2024 <https://www.samsungbioepis.com/en/newsroom/newsroomView.do?idx=409> (2024).
24. Tadrous, M., McCormack, D., Martins, D., Kitchen, S., Singh, S. & Gomes, T. Current and prospective utilization of innovator biologics and biosimilars in Ontario (2020) https://doi.org/10.31027/ODPRN.2020.01.
25. Murdoch, B. & Caulfield, T. The law and ethics of switching from biologic to biosimilar in Canada. *J. Can. Assoc. Gastroenterol.* **3**, 228–233 (2020).
26. Kaplan, G.G., Ma, C., Seow, C.H., Kroeker, K.I. & Panaccione, R. The argument against a biosimilar switch policy for infliximab in patients with inflammatory bowel disease living in Alberta. *J. Can. Assoc. Gastroenterol.* **3**, 234–242 (2020).
27. Herndon, T.M. *et al*. Safety outcomes when switching between biosimilars and reference biologics: a systematic review and meta-analysis. *PLoS One* **18**, e0292231 (2023).
28. Fisher, A., Kim, J.D. & Dormuth, C. The impact of mandatory nonmedical switching from originator to biosimilar insulin glargine. *Clin. Ther.* **44**, 957–970 (2022).
29. Hoang, T.T., Reid, J., Galorport, C., Bressler, B., Leung, Y. & Rosenfeld, G. Outcomes of a mandatory non-medical switch of infliximab to a biosimilar for inflammatory bowel disease in British Columbia, Canada. *J. Can. Assoc. Gastroenterol.* **7**, 299–305 (2024).
30. Fisher, A., Kim, J.D., Carney, G. & Dormuth, C. Rapid monitoring of health services use following a policy to switch patients from originator to biosimilar etanercept—a cohort study in British Columbia. *BMC Rheumatol.* **6**, 5 (2022).
31. Glintborg, B. *et al*. A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry. *Ann. Rheum. Dis.* **76**, 1426–1431 (2017).
32. Glintborg, B., Sørensen, J. & Hetland, M.L. Does a mandatory non-medical switch from originator to biosimilar infliximab lead to increased use of outpatient healthcare resources? A register-based study in patients with inflammatory arthritis. *RMD Open* **4**, e000710 (2018).
33. Glintborg, B., Ibsen, R., Bilbo, R.E.Q., Lund Hetland, M. & Kjellberg, J. Does a mandatory non-medical switch from originator to biosimilar etanercept lead to increase in healthcare use and costs? A Danish register-based study of patients with inflammatory arthritis. *RMD Open* **5**, e001016 (2019).
34. Hagen, T. Mandatory biosimilar switching pays off for Canada. *Am. J. Manag. Care* <https://www.ajmc.com/view/mandatory-biosimilar-switching-pays-off-for-canada> Accessed September 21, 2025.