



Biosimilars in Canada: Policies to Promote Switching and What It Means for Payers

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NPDUIS, Policy and Economic Analysis Branch, Patented Medicine Prices Review Board Disclosure: I have no actual or potential conflict of interest in relation to this topic or presentation.

Background and Objectives

- In Canada, sales of biologics topped \$11 billion in 2021, placing Canada among the top-ranked countries in the Organization for Economic Co-operation and Development (OECD) in terms of per capita spending
- ➤ Given the strength of this market, biosimilars offer a significant opportunity for cost savings for Canadian payers

➤ This presentation compares the emerging Canadian market for biosimilars with our international counterparts

The analysis delves more deeply into the market dynamics of biosimilars in Canada and assesses the impact of recent biosimilar switching initiatives, highlighting the potential for cost savings

Approach and Data Sources

> This study is part of the PMPRB's broader reporting in the *Biologics in Canada* chartbook series

Data sources:

- IQVIA's MIDAS® Database as of 2021 was used to compare the availability, uptake, and sales of biosimilars in Canada to the Organization for Economic Co-operation and Development (OECD) countries
- The market dynamics of biosimilars in Canada up to 2022 and the potential for cost savings were drawn from IQVIA's Canadian Drugstore and Hospital Purchases Audit (CDH)

> Limitations:

• IQVIA CDH data sourced from purchases made directly from the manufacturer or through a wholesaler and may include mark-ups. While MIDAS data is reported at various levels in the distribution chain, NPDUIS reporting is typically based on manufacturer ex-factory list prices. Cash discounts are not captured in these databases.

Overview



Biologics market trends in Canada and international comparisons



Biosimilar availability and uptake in Canada vs. other OECD countries



Biosimilar uptake challenges and current policies



Cost-saving opportunities from biosimilars



Biologic medicine sales nearly tripled over the last decade

- Biologic medicine sales in Canada nearly tripled over the last 10 years, rising from \$3.8B in 2012 to \$11.2B in 2021
- This represents a 10-year compound annual growth rate of 12.5%, with a 11.2% increase in the last year
- Sales of biologic medicines accounted for more than 1/3 of pharmaceutical spending in Canada in 2021 and sales per capita reached \$290

Sales of biologic medicines in Canada, 2012 to 2021



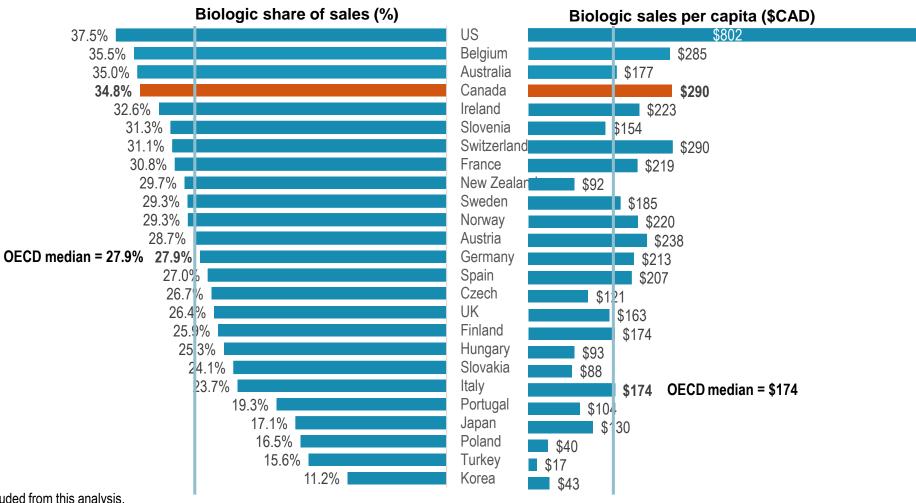
capita



Canada placed among the top-ranked countries in the OECD for biologics spending

Biologic share of total sales and sales per capita, OECD*, 2021

- In 2021, biologics accounted for 34.8% of pharmaceutical sales in Canada, the 4th-highest share in the OECD and exceeding the median of 27.9%
- Canada spends more on biologics per capita than most industrialized countries, with an average of \$290 per person in 2021, well above the international median of \$174



^{*} Countries with limited sales data were excluded from this analysis.

Note: Includes all prescription biologics as per Health Canada's Drug Product Database (DPD) Schedule D and Prescription lists, as well as insulin biologics in Canada as of 2020. **Data source:** MIDAS® Database, prescription retail and hospital markets, IQVIA. All rights reserved.



Availability of biosimilars in Canada has increased, without a major impact on overall costs

Number of medicines* with biosimilars approved in Europe, the US, or Canada, as of 2021

- Despite an increase in biosimilar approvals in Canada over recent years, Europe continues to lead with the highest in terms of the number of biosimilar approvals
- While the number of biosimilars has increased in Canada, their share of overall biologic sales remains modest, at 7.6% in 2021

Biologic Medicine	EMA (n=18)	FDA (n=12)	Health Canada (n=14)
Adalimumab	✓	✓	✓
Bevacizumab	✓	✓	✓
Enoxaparin Sodium	✓		✓
Epoetin Alfa	✓	✓	
Epoetin Zeta	✓		
Etanercept	✓	✓	✓
Filgrastim	✓	✓	✓
Follitropin Alfa	✓		
Infliximab	✓	✓	✓
Insulin Aspart	✓		✓
Insulin Glargine	✓	✓	✓
Insulin Lispro	✓		✓
Pegfilgrastim	✓	✓	✓
Ranibizumab	✓	✓	
Rituximab	✓	✓	✓
Somatropin	✓	✓	✓
Teriparatide	✓		✓
Trastuzumab	✓	✓	✓
% Biosimilar sales of overall biologics, 2021	15.1%	4.4%	7.6%

^{*} Multiple biosimilar trade names referencing the same originator biologic are counted as one biosimilar medicine.



Biosimilar uptake in Canada is moderate compared to other OECD markets for high-selling products

- Canada demonstrates growing use of biosimilars
- Infliximab, the highest-selling biologic and one of the earliest with a biosimilar available in Canada, had a 28% biosimilar share in Canada in 2021, well below the OECD median of 76%
- Adalimumab, the 2nd top-selling biologic medicine in Canada, achieved a sizable uptake of 22% by 2021, with a median uptake of 36% in the OECD

Biologic medicine	Sales in Canada, 2021 (\$million)	-2021					
Infliximab	\$1,262		28%			= 0E0	D mediar
Adalimumab	\$969		22%			■ Can	ada
Etanercept	\$264				49%		
Insulin Glargine	\$226		30%				
Rituximab	\$222			41%			
Epoetin alfa*	\$116	n/a					
Trastuzumab [‡]	\$110						89%
Filgrastim*	\$98						92%
Bevacizumab [‡]	\$98					8	6%
Pegfilgrastim*	\$98						98
Insulin Aspart	\$92	0%					
Insulin Lispro	\$80	6%					
Enoxaparin Sodium	\$63		16%				
Somatropin	\$45		20%				
Follitropin alfa*	\$20	n/a					
Teriparatide	\$11		17%				
	0	%	20%	40%	60%	80%	100

^{*}Generally used to treat acute conditions.

[‡] Mainly used for treatment of oncology indications and administrated in hospitals in Canada.

[†] Canada is excluded from the median.



Many Canadian public drug plans have undertaken or announced initiatives to increase biosimilar uptake as of 2022

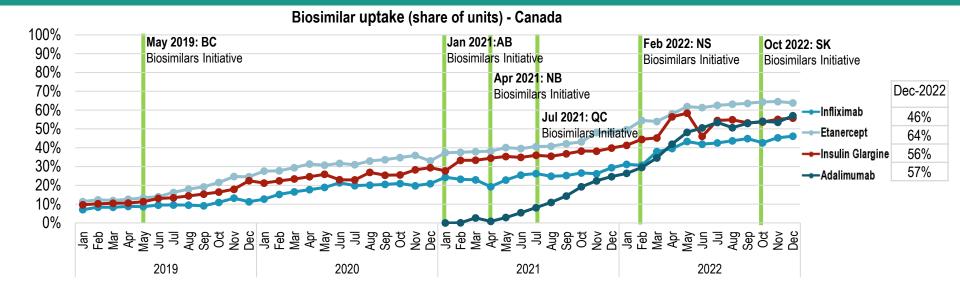
Patient switching is a key factor in biosimilar uptake and reflects the polices in the relevant jurisdiction

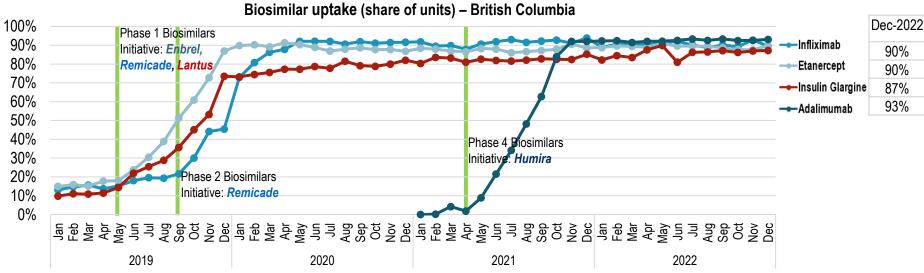
Initiative	
British Columbia	In May 2019, British Columbia became the first Canadian province to initiate a switch to biosimilar medicines for patients covered under the PharmaCare program. Under the Phase 1 & 2 policy initiatives, patients using Enbrel, Remicade, and Lantus for specific indications are required to switch to the biosimilar. The switching policy expanded to Phase 3 & 4 in 2020 and 2021 to include Rituxan and Humira .
Alberta	Effective Jan. 2021, Alberta announced that all patients taking Enbrel , Remicade , Lantus , Neupogen , Neulasta , Rituxan , and Copaxone for indications ranging from rheumatoid arthritis to diabetes and multiple sclerosis are required to switch to the biosimilar. This policy has since been expanded to include Humira , Lovenox , and Humalog .
Saskatchewan	Effective Oct. 2022, Saskatchewan started to implement mandatory biosimilars switching. The policy affects medications including Humira , Lovenox , Enbrel , Neupogen , Copaxone , Remicade , Rituxan , NovoRapid and Lantus . The list will grow as more biosimilars for reference biologics become available.
New Brunswick	Effective Apr. 2021, New Brunswick only reimburses biosimilar versions of approved indications of Humira , Enbrel , Remicade , Lantus , Humalog , Rituxan , Copaxone , and Lovenox .
Ontario	Ontario announced their biosimilars switching policy coming into effect from March 31, 2023. This policy affects the following biologics: Copaxone, Enbrel, Humira, Lantus, NovoRapid, Remicade and Rituxan. This list will expand as more biosimilars for originator biologics become available in Canada
Quebec	Effective Jul. 2021, the Quebec government announced a non-medical switching policy to require patients covered by the Quebec public drug plan who are treated with biologics drugs to switch to biosimilar versions where available and on an ongoing basis.
Nova Scotia	Effective Feb. 2022, Nova Scotia began a non-medical biosimilar switching policy. Medications that require switching to biosimilars: Humira, Enbrel, Remicade, Lantus, Humalog, NovoRapid and Rituxan . The policy will apply to other medications on the Formulary as new biosimilar medications are approved.
the Northwest Territories	Effective Dec. 2021, the Government of the Northwest Territories launched a Biosimilars Initiative, individuals on originator biologics must switch to a biosimilar to maintain public coverage.
MB, PEI, NL,YT, NIHB	Planning to implement biosimilar switching strategies.



Implemented biosimilar initiatives show positive signs in terms of increased utilization

- Increase in uptake of biosimilars has been observed nationally, with gradual market penetration in recent years
- As ongoing biosimilar switching initiatives are implemented at the jurisdiction level and by payer, Canada offers a unique model to observe the impacts of variations in approach and timing of biosimilar uptake across jurisdictions
- In British Columbia, the first Canadian province to implement a biosimilar switching initiative, biosimilars now account for ~90% of these high-selling biologics markets

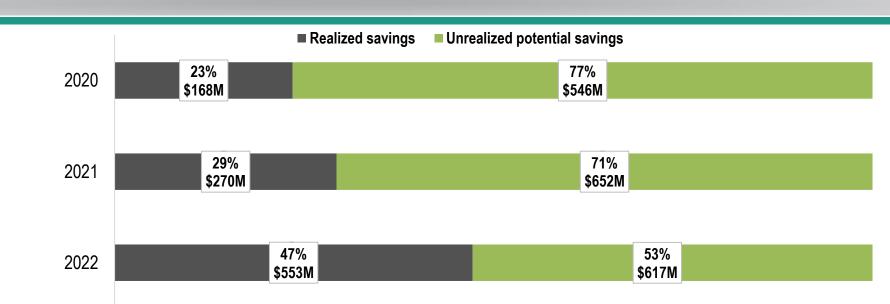






Canadians are realizing a growing fraction of the potential savings from biosimilars

- National market penetration in line with the results seen in British Columbia may have significant cost implications for Canadian payers
- Biosimilars of four high-selling biologics targeted by the Biosimilars Initiative (infliximab, etanercept, insulin glargine 100IU and adalimumab) saved Canadians an estimated \$990 million over 3 years (2020 2022)
- ➢ If national uptake for these biosimilars had followed the trends in British Columbia, additional savings of nearly \$1.8 billion would have been attained from 2020 to 2022



	Potential savings in 2020			Potential savings in 2021			Potential savings in 2022		
Biologic medicine	Estimated actual savings	Unrealized savings	Total	Estimated actual savings	Unrealized savings	Total	Estimated actual savings	Unrealized savings	Total
Infliximab	\$ 118.9M	\$ 452.2M	\$ 571.1M	\$ 169.5M	\$ 460.5M	\$ 630.0M	\$ 286.3M	\$ 370.2M	\$ 656.4M
Etanercept	\$ 33.4M	\$ 64.2M	\$ 97.6M	\$ 42.1M	\$ 51.7M	\$ 93.8M	\$ 55.2M	\$ 34.1M	\$ 89.3M
Insulin glargine	\$ 15.4M	\$ 29.5M	\$ 44.9M	\$ 20.2M	\$ 24.7M	\$ 44.9M	\$ 26.1M	\$ 15.7M	\$ 41.8M
Adalimumab	-	-	-	\$ 38.3M	\$ 115.5M	\$ 153.8M	\$ 185.1M	\$ 197.5M	\$ 382.5M
Savings	\$ 167.7M	\$ 545.9M	\$ 713.6M	\$ 270.0M	\$ 652.4M	\$ 922.4M	\$ 552.6M	\$ 617.4M	\$ 1,170.0M

Conclusions

- Biologics are a high-growth market segment in Canada, with sales tripling over the last decade
- > Availability of biosimilars in Canada has increased recently, without a major impact on overall costs
- ➤ Biosimilars uptake for high-selling products in Canada is moderate compared to other OECD markets
- > There are ongoing initiatives to encourage greater biosimilar uptake nationwide
- The potential savings offered by biosimilars are significant in Canada



National Prescription Drug Utilization Information System

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