

Drug Info Update: More on the newly active ODB biosimilar policy

In December 2022, the Ministry of Health <u>announced</u> indicating that they would require patients using certain biologics - Copaxone®, Enbrel®, Humalog®, Humira®, Lantus®, NovoRapid®, Remicade®, and Rituxan® to transition to biosimilar products. This switch is expected to have major cost savings implications for the publicly funded plan. Claims analysis and modeling has suggested that a biosimilar substitution policy will save the system tens of millions of dollars annually¹.

- The transition period began March 31, 2023, and patients are expected to be transitioned by December 29, 2023 –
 ODB suggests the patient meets with their care team to select a biosimilar product, have it prescribed (these products are NOT directly interchangeable like generics and should be prescribed by name), and develop a plan for monitoring
 - There is a K900A support payment of \$61.20 available to physicians for facilitating the transition to biosimilars for patients receiving ODB benefits – details about the payment can be found here
 - We are working on practice tools (stamps, macros) in the EMRs to help support documentation of plans
 - See also page 2 for a refresher on biologic drugs, from The Dose Winter 2022, and suggested talking points
- TVFHT Pharmacists can also help run EMR queries to identify affected patients
- o Patients have been mailed information letters from the ministry if they have recently filled an affected medication
- Exemptions for staying on originator products will be considered on a case-by-case basis, through EAP application –
 note that patients will have had to try and fail on two different biosimilars before receiving an exemption
- Similar policies are already in place in 8 other Canadian provinces/territories
- This change only applies to ODB currently, but private plans are expected to make similar formulary changes. Making
 the switch to lower cost products for cash or private paying patients can result in lower out of pocket costs
 (deductibles/plan maximums)

See chart below for a summary of relevant information related to the affected products and switching logistics

Originator Biologic	Chemical Name	ODB Funded Biosimilars	Format	Comparative Cost Between Biosimilars^	Details	Clinical Notes
NovoRapid	Insulin aspart	Kirsty ^^ Trurapi ^^	Pen Pen, cartridge	\$42.71/box \$45/box	General benefit	Dose converted 1:1 Close monitoring w/ HCP Recommend that patient self-monitors blood glucose more frequently during and for a period after switch
Humalog 100u/mL*	Insulin lispro	Admelog **	Pen, cartridge, or vial	\$45/box \$22.70/vial	General benefit	
Lantus	Insulin glargine	Semglee Basaglar	Pen Pen, cartridge	\$63.80/box \$72.43/box	General benefit	
Humira	Adalimumab	Abrilada Amgevita Hadlima Hulio Hyrimoz Idacio Simlandi Yuflyma		Same price for all biosimilar products, differing by dose	LU	Most are prescribed by specialists outside of primary care
Enbrel	Etanercept	Brenzys Erelzi		same for both \$241/box	LU	
Remicade	Infliximab	Avsola Renflexis Inflectra		\$493/box \$493/box \$525/box	LU	
Copaxone	Glatiramer acetate	Glatect		\$35/syr	LU	
Rituxan	Rituximab	Riximyo Ruxience Truxima		Same \$29.70/mL	LU	

[^] Cost is listed as per box ODB List price, subject to pharmacy markup and fee; if referring to this chart for non-ODB patients, cost after fees will be higher

^{^^} Not available in 10mL vials - for insulin pump users continue to use NovoRapid

^{*}Humalog 200u/mL is excluded as there is no biosimilar available

^{**}Admelog is back-ordered, availability expected July 2023. You can still write a prescription for the pharmacy to fill when available, as long as the patient also has an active prescription for Humalog to fill now.



A 5-point Refresher on Biosimilars – From The Dose Newsletter Winter 2022

Biosimilars differ from generic drugs in that the reference innovator biologic drug is often large and complex and is synthesized from living cells rather than chemicals. Because of this complexity, biosimilars are not identical to their reference product, as in the case of generic drugs, but rather are considered highly similar.

While not directly interchangeable in Ontario (meaning, being able to be freely switched without prescriber intervention), the level of evidence submitted to Health Canada for a biosimilar product would suggest that there would not be an expected difference in efficacy or safety between routine use of a reference product and an approved biosimilar product.

Biosimilars enter the market upon expiration of the reference biologic drug's original patent. Special standards exist for approval of biosimilars, which are more rigorous than for generic chemicals, and includes demonstration through clinical and nonclinical trials of similarity in terms of structure, function, efficacy, and safety to the innovator product.

Biosimilars share the same nonproprietary name as the innovator product (e.g. adalimumab, innovator product - Humira®) and are given a different trade name (e.g. Hulio®, Idacio®, Amgevida®, etc) Manufacturing facilities and processes are regulated by Health Canada for biosimilars in the same manner as innovator products, including a mandatory Risk Monitoring Plan for post-marketing surveillance. In over 10 years of use in the European Union, no unexpected safety signals have been identified among biosimilars.

Talking points for patients regarding biosimilar products

Biosimilars,

- Are safe and effective;
- Work the same way as their current medication;
- Add no increased risk of adverse reactions;
- Don't involve major changes to their routines or dosing;
- May have additional services provided by a patient support program;
- Are available at nearby infusion centres, though it may be a different infusion centre than they currently attend (applies to infliximab and rituximab); and
- Are well-studied and transition programs have been successful around the world

References and Supplemental Links

¹Gomes 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. 2021 Nov 23;9(4):E1055-E1062. doi: 10.9778/cmajo.20210091. PMID: 34815261; PMCID: PMC8612652.

https://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/fq_exec_office_pharm_20230310.pdf '

MOH News Release December 20, 2022: 2022 News

Health Canada fact sheet on Biosimilar biologic drugs: Fact Sheet

MOH Executive Officer policy notice March 10, 2023: Executive Officer Notice Mar23

MOH Q & A document for pharmacists: Biosimilar QA

ODB Formulary Summary of Changes March 2023, at Formulary Downloads

Thank you to Sharon Emmanuel at Byward FHT for her work summarizing these changes, some of which was used in the preparation of this document