Q&A Biosimilars – Health Professionals

1. **What are biologic drugs?**

   Biologic drugs, commonly referred to as “Biologics”, are made using living organisms or their cells. They are usually larger and more complex molecules than chemically produced drugs.

2. **What is an originator biologic drug?**

   An originator biologic drug is the first biologic brand marketed for a particular drug. For example, for the biologic drug adalimumab, Humira is the originator biologic. Originator biologics may also be referred to as the reference biologic drug.

3. **What are biosimilars?**

   Biosimilars, are highly similar versions of originator biologic drugs. They are introduced to market when the patent expires on the originator biologic drug.

4. **Are biosimilars identical to their originator biologic drug?**

   No, they are highly similar but not identical. There are natural variations in biosimilars due to the use of living cells in the manufacturing process. In fact, natural variations also occur when comparing batches of the originator drug.

5. **Are biosimilars considered generics?**

   No, biosimilars are not the same as generic drugs. Generic drugs are small molecules that are chemically synthesized and contain identical medicinal ingredients to their reference products.

6. **Are biosimilars safe and effective compared to the originator biologic drug?**

   Yes. For a biosimilar drug to be approved by Health Canada, the manufacturer must demonstrate that there are no meaningful differences in safety and effectiveness compared to the originator version. Patients should expect no difference when transitioning from an originator biologic to a biosimilar for treatment of their medical condition.

7. **Are biosimilars less costly than originator biologics?**

   Yes. Biosimilar drugs cost less since the foundation of research and development has already been completed by the manufacturer of the originator biologic. The originator biologic drug is protected by a patent for several years, which allows its manufacturer to recoup research and development costs. Once the patent expires, manufacturers can produce and market biosimilars at a lower cost.

8. What is the NLPDP Biosimilars Initiative?

The NLPDP Biosimilars Initiative is a biosimilars transition policy where beneficiaries using certain originator biologics will transition to a biosimilar version to maintain coverage.

9. Does transitioning to a biosimilar impact patient outcomes?

Health Canada indicates that patients and health care providers can be confident that biosimilars are effective and safe for each of their authorized indications, and that no differences in efficacy and safety are expected following a change in routine use between an originator biologic and its biosimilar in an authorized indication. There are many research studies which show little to no clinical differences between biosimilars and their originators, either when used with new patients, or for patients transitioning to a biosimilar.

10. Is Immunogenicity a concern with transitioning to a biosimilar?

No. Health Canada requires an assessment of immunogenicity, prior to biosimilar authorization to rule out clinically meaningful differences with respect to the risk and impact of immunogenicity. Ongoing assessment by the manufacturer post-market is also required. Analyses of transitioning and interchangeability over the past 10 years in the European Union have shown that immunogenicity is not affected by transitioning between products.

11. My patient is pregnant. Can I delay the transition to biosimilar until after delivery?

Yes. Please advise NLPDP in writing by faxing a request to 709-729-2851 and include the patient's name, MCP and delivery date. NLPDP will extend originator coverage accordingly.

12. My patient is using an insulin pump that has not been shown to be compatible with biosimilar insulins. Can funding be maintained for originator insulin?

NLPDP understands that studies are underway to confirm compatibility of certain biosimilar insulins with certain insulin pumps. NLPDP will continue to fund the originator for patients using select pumps until studies confirm biosimilar compatibility. Please advise NLPDP in writing by faxing a request to 709-729-2851 and include the patient's name, MCP and insulin pump used. NLPDP will extend originator coverage if compatibility has not yet been confirmed.

13. What originator biologics are included in the NLPDP Biosimilars Initiative and what are the biosimilar alternatives?

The biologics in the table below were included at the start of the initiative. As the first biosimilar(s) comes to market for an originator biologic, a 12-month transition period will apply. At the end of the 12-month transition period, funding and/or special authorizations for the originator biologic will end.

Biologic	Originator Biologic	Funded Biosimilar(s)	Date originator funding ends
Non-insulin Biologics			
adalimumab	Humira	Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma	April 1, 2024
enoxaparin	Lovenox	Inclunox, Noromby, Redesca, Elonox	April 1, 2024
etanercept	Enbrel	Brenzys, Erelzi; Rymti	April 1, 2024
glatiramer	Copaxone	Glatect	April 1, 2024
infliximab	Remicade	Avsola, Ixifi, Renflexis, Remandry, Remsima	April 1, 2024
rituximab	Rituxan	Riximyo, Ruxience, Truxima	April 1, 2024
ranibizumab	Lucentis	Ranopto	December 1, 2024
ustekinumab	Stelara	Wezlana, Jamteki; Steqeyma	May 1, 2025
denosumab	Prolia	Jubbonti; Stoboclo	September 1, 2025
denosumab	Xgeva	Wyost; Osenvelt	September 1, 2025
tocilizumab	Actemra	Tyenne	June 1, 2026
aflibercept (2 mg/0.05 ML)	Eylea	Aflivu, Yesafili	November 1, 2026
Omalizumab	Xolair	Omlyclo	December 15, 2026
Insulin			
Insulin aspart	NovoRapid	Kirsty, Trurapi	April 1, 2024
Insulin glargine	Lantus	Basaglar, Semglee	April 1, 2024
Insulin lispro	Humalog	Admelog	April 1, 2024

14. Do I have to transition my patients to a biosimilar?

For NLPDP beneficiaries to maintain coverage under the drug program, they must be transitioned from originator biologic to a biosimilar.

15. What is the nocebo effect and how can I minimize its effects for my patients?

Perceptions and fears about biosimilars not performing to the same level as reference biologic drugs can lead to a nocebo effect. This is when the patient's beliefs and attitudes about biosimilars can result in a negative expectation for the effectiveness of the drug and adversely affect the outcomes of treatment. It stems from a patient's negative expectations and not the pharmacologic action of the treatment itself.

You can minimize the nocebo effect by reassuring the patient that no clinically meaningful differences in safety and effectiveness is expected by transitioning to a biosimilar and Health Canada uses the same rigorous standards when authorizing both the biosimilar and originator.

16. Why is the NLPDP Biosimilars Initiative necessary?

It is necessary to get the most value from the medications covered under the drug program. Savings from the NLPDP Biosimilars Initiative will be reinvested to fund new drug therapies and expand access to other drug therapies.

17. Do I need to write a new prescription and special authorization for a biosimilar?

For patients using an **Insulin** included in the Biosimilars Initiative:

- **Community pharmacists** may be able to complete the transition to a biosimilar insulin and write the new prescription.
- Biosimilar insulins are open benefits of NLPDP therefore a **special authorization is not required**.
- If the pharmacist is unable to assist, the patient may contact their physician or nurse practitioner to have a prescription for biosimilar insulin written.

For patients using **non-insulin originator biologics** included in the Biosimilars Initiative**:**

- It is expected that prescribers (mostly specialists) will assist patients with transitioning to a biosimilar no later than their next special authorization reassessment and renewal appointment, if applicable. If a patient has a long term approval for the originator biologic, they must transition to a biosimilar prior to the end of the transition period.
- Patient lists, including special authorization expiry dates, where applicable, were circulated to each prescriber.
- There is no need to specify a preferred biosimilar product on the special authorization form.
- Patients **will require a new prescription** for their biosimilar.

18. Can I transition my patients to a biosimilar prior to their special authorization renewal time (if applicable)?

Yes, absolutely! You can transition your patients earlier by notifying a pharmacist at NLPDP. You can do this by faxing your patient list to NLPDP at 709-729-2851 or by contacting a pharmacist directly at 1-888-222-0533 or 709-729-6507 to discuss the transition method that works best for you.

19. What resources are available to me to help ease this transition for my patients?

NLPDP has developed a number of resources to make the transition easier. The NLPDP webpage (**www.gov.nl.ca/hcs/prescription/biosimilars/**) contains useful clinical resources, patient information, patient support program information, and more.

20. Do patient support programs exist for biosimilars?

Yes, manufacturers of biosimilars often provide patient support programs comparable to the originator biologics. For information regarding the various support programs, please visit the biosimilar webpage at (**www.gov.nl.ca/hcs/prescription/biosimilars/**).

21. Where can I go to get more information?

- Visit the NLPDP biosimilars webpage (**www.gov.nl.ca/hcs/prescription/biosimilars/**).
- Call a NLPDP representative directly at 709-729-6507 or 1-888-222-0533