Q&A Biosimilars – NLPDP Beneficiaries

1. **What are biologic drugs?**

   Biologic drugs, commonly referred to as "Biologics", are made using living organisms or their cells. Biologics are used to treat various medical conditions.

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

   An originator biologic drug, is the first brand marketed for a particular biologic drug.

3. **What are biosimilars?**

   Biosimilars, are highly similar versions of originator biologic drugs. They are produced 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 the manufacturing process of biologic drugs due to the use of living cells. In fact, due to this manufacturing process, variations also occur between batches of the originator drug.

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

   Yes, before a biosimilar drug is approved by Health Canada, the manufacturer must show 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 its biosimilar version.

6. **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 highly similar biosimilars at a lower cost.

7. **What is the NLPDP Biosimilar Initiative?**

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

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

   The biologics in the table below are included at the start of the initiative. On a go forward basis, when the first biosimilar(s) come 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	April 1, 2024
glatiramer	Copaxone	Glatect	April 1, 2024
infliximab	Remicade	Avsola, Inflectra, Renflexis	April 1, 2024
rituximab	Rituxan	Riximyo, Ruxience, Truxima	April 1, 2024
ranibizumab	Lucentis	Byooviz	December 1, 2024
ustekinumab	Stelara	Wezlana, Jamteki	May 1, 2025
Insulin			
Insulin aspart	NovoRapid	Kirsty, Trurapi	April 1, 2024
Insulin glargine	Lantus	Basaglar, Semglee	April 1, 2024
Insulin lispro	Humalog	Admelog	April 1, 2024

9. Why is the NLPDP Biosimilars Initiative necessary?

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

10. How do I get my prescription changed to a biosimilar? Do I need a new Special Authorization?

<u>If you use **Insulin** included in the Biosimilars Initiative:</u>

- Your pharmacist may be able to complete your transition to a biosimilar insulin and write your new prescription
- Biosimilar insulins are open benefits of NLPDP therefore a special authorization is not required

- If your pharmacist is unable to assist, you will need to make an appointment with your physician or nurse practitioner prior to the end of your transition period to have the prescription for your biosimilar insulin written

<u>If you use a **non-insulin originator biologic** included in the Biosimilars Initiatve:</u>

- Your prescriber can assist you with transitioning to a biosimilar no later than your next special authorization reassessment and renewal appointment, if applicable, or at your next check-up
- If you require a special authorization, it will be approved for a biosimilar.
- Your prescriber can help answer your questions, explain the transition process and write your biosimilar prescription
- If you are not due to see your prescriber prior to the end of your transition period, you will need to make an appointment to discuss transitioning your medication to a biosimilar

11. Where can I get more information about this initiative?

NLPDP has developed a number of resources to support you in your transition to a biosimilar. Our biosimilars webpage (**www.gov.nl.ca/hcs/prescription/biosimilars**) contains a pamphlet, links to resources, and more.

If you still have questions, please feel free to contact NLPDP directly at 709-729-6507 or 1-888-222-0533.

12. Do patient support programs exist for biosimilars?

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