Insulin Lispro Frequently Asked Questions

1. What is the difference between Admelog® and Humalog®?

Admelog and Humalog are both insulin lispro products. Insulin lispro is an anti-diabetic medicine for the treatment of patients with diabetes. Admelog (insulin lispro) is approved by Health Canada as a biosimilar to Humalog. Admelog (insulin lispro) and Humalog (insulin lispro) are manufactured and marketed by different companies.

2. What is the funding status of Admelog (insulin lispro)?

Admelog (insulin lispro) has been listed on the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary) as a General Benefit with the December 2020 update (effective December 18, 2020).

3. What is the funding status of Humalog (insulin lispro)?

Effective with the January 2021 Formulary update (effective January 29, 2021), there will be changes to the funding status of the following Humalog products:

DIN	Brand Name	Generic Name	Strength & Dosage Form	MFR
02229704	Humalog®	Insulin Lispro	100U/mL Inj Sol-10mL Pk	Eli Lilly Canada Inc.
09853715	Humalog®	Insulin Lispro	100U/mL Inj Sol-5 x 3mL Pk	Eli Lilly Canada Inc.
02403412	Humalog® KwikPen®	Insulin Lispro	100U/mL Inj Sol-5 x 3mL Pk	Eli Lilly Canada Inc.

02470152	Humalog® Junior KwikPen®	Insulin Lispro	100U/mL Inj Sol-Pref Pen 5 x 3mL Pk	Eli Lilly Canada Inc.

The changes will be as follows:

- The above Humalog products will no longer be listed on the Formulary as a General Benefit (GB).

- The above Humalog products will be listed on the Formulary as a Limited Use (LU) benefit ONLY for the following indication:

  RFU Code 599: For the treatment of diabetes mellitus for only those patients currently established on Humalog therapy.

  (LU authorization period: Indefinite)

- New starts for the above affected Humalog products will not be accepted. However, the above Humalog products will continue to be funded for ODB eligible patients who have been established on Humalog.

4. What is the rationale behind changing the funding status for insulin lispro?

Admelog (insulin lispro) was approved by Health Canada as a biosimilar to Humalog (insulin lispro). Biosimilars have similar efficacy and safety as originator biologics and present an opportunity to achieve better value for money for biologic drugs that will help to support long-term sustainability and accessibility of Ontario's public drug programs.

5. How will these changes impact patients?

As of the December 2020 Formulary update, ODB eligible patients should receive Admelog when starting treatment with insulin lispro.

Patients who have been established on Humalog can continue to receive Humalog. However, beginning with the January 2021 Formulary update, prescriptions for Humalog will require RFU Code 599 to indicate that the patient has been established on Humalog.

6. What happens if an ODB eligible patient presents a prescription for an affected Humalog product without an RFU code?

The dispensing pharmacist should notify the prescriber and the patient that an RFU code is required and confirm that the patient is eligible under the new LU criteria. If the prescription cannot be clarified to the new RFU code (RFU code 599), a temporary transition code RFU 279 may be submitted to allow for continuity of care and for the claim to be processed in the Health Network System (HNS). The transition code will be activated for the affected Humalog DINs to help transition current patients on Humalog to the new RFU code and criteria for a period of three months after the change. It is expected that after three months, prescriptions will have the correct RFU Code to confirm that the patient meets the new criteria. The transition code for the affected Humalog products will be deactivated with the April 2021 Formulary update.

7. How will these changes impact prescribers?

Humalog and Admelog are not interchangeable products. As of the December 2020 Formulary update, ODB eligible patients starting treatment on insulin lispro should be started on Admelog in order to be eligible for funding under the ODB program. Prescribers should notify their patients of the change. Prescribers should also note the RFU Code for patients established on Humalog.

8. How will these changes impact pharmacies/pharmacists?

Humalog and Admelog are not interchangeable products. As of the December 2020 Formulary update, ODB eligible patients starting treatment on insulin lispro should be started on Admelog in order to be eligible for funding under the ODB program. Pharmacies/pharmacists can continue to submit claims for Humalog (where applicable), and starting from the January 2021 Formulary

update, with the appropriate RFU code or temporary transition code (where applicable).

When a prescription for insulin lispro is received, pharmacists should verify whether the prescription is for Admelog (insulin lispro). If the prescription is for Admelog, pharmacies must use the applicable drug identification number when submitting a claim for Admelog:

DIN	Brand Name	Generic Name	Strength & Dosage Form	MFR
02469901	Admelog	Insulin Lispro	100U/mL Inj Sol-10mL Pk	Sanofi-Aventis Canada Inc.
02469898	Admelog	Insulin Lispro	100U/mL Inj Sol-5 x 3mL Pk	Sanofi-Aventis Canada Inc.
02469871	Admelog	Insulin Lispro	100U/mL Inj Sol-5 x 3mL SoloSTAR Pref Pen Pk	Sanofi-Aventis Canada Inc.

9. What are biosimilars?

Biosimilars also referred to as subsequent entry biologics or follow-on biologics, are biologics that are similar to, and would enter the market after the patent or data protection rights for an innovator biologic has expired. They are similar to generic drugs. However, unlike generic drugs, biosimilars are not deemed bioequivalent to, nor interchangeable with, their reference drugs. Health Canada evaluates all the information provided to confirm that the

biosimilar and the reference biologic drug are similar and that there are no clinically meaningful differences in safety and efficacy between them.

Please refer to Health Canada's fact sheet on biosimilars for more information:

https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

Additional information:

For pharmacies:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other health care providers and the public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559.
In Toronto, TTY 416-327-4282