Insulin aspart Frequently Asked Questions

1. What is the difference between Trurapi and NovoRapid?

Trurapi and NovoRapid are both Insulin aspart products. Insulin aspart is an anti-diabetic medicine for the treatment of patients with diabetes. Trurapi is approved by Health Canada as a biosimilar to NovoRapid. Trurapi and NovoRapid are manufactured and marketed by different companies.

2. What is the funding status of Trurapi (insulin aspart)?

Trurapi is listed on the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary) as a General Benefit.

3. What is the funding status of NovoRapid (insulin aspart)?

Effective with the February 2022 formulary update (effective **February 28, 2022**), there will be changes to the funding status of the following NovoRapid products:

Table 1

DIN	Brand Name	Generic Name	Strength & Dosage Form	MFR
02244353	NovoRapid Penfill	insulin aspart	100U/mL Inj Sol-5x3mL Pk	Novo Nordisk Canada Inc.
02377209	NovoRapid FlexTouch	insulin aspart	100U/mL Inj Sol-Prefil 5X3mL Pk Disposable Pen	Novo Nordisk Canada Inc.

Changes will be as follows:

- Affected NovoRapid products will be listed on the Formulary as a Limited Use (LU) benefit for the following indication:

  - Reason for Use (RFU) Code 628: For the treatment of diabetes mellitus for only those patients currently established on NovoRapid (insulin aspart) therapy.
  - LU authorization period: indefinite.

- New starts for affected NovoRapid products will not be accepted. However, patients who have been established on NovoRapid can continue to receive NovoRapid.

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

Trurapi was approved by Health Canada as a biosimilar to NovoRapid. These changes are aligned with the funding of other biosimilars under the Ontario Drug Benefit program's new starts policy. 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 February 2022 Formulary update (effective **February 28, 2022**), ODB-eligible patients will receive Trurapi when starting treatment with insulin aspart.

Patients who have been established on NovoRapid can continue to receive NovoRapid. However, beginning with the February 2022 Formulary update, prescriptions for NovoRapid will require RFU Code 628 to indicate that the patient has been established on NovoRapid.

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

The dispensing pharmacist should notify the prescriber and the patient that an RFU/LU code and criteria are required. If the prescription cannot be clarified to the new LU code (LU code 628), a temporary transition code RFU/LU 279 may be submitted to allow for continuity of care and for the claim to be processed in

HNS. The transition code will be activated for the affected NovoRapid DINs to transition patients to the new LU code and criteria for a period of three (3) months after the change. It is expected that after three (3) months all patients with a prescription for the correct LU Code and meet the new criteria. The transition code for the affected NovoRapid products will be deactivated with the May 2022 Formulary update.

7. How will these changes impact prescribers?

NovoRapid and Trurapi are not interchangeable products. As of the February 2022 Formulary update (effective **February 28, 2022**), new ODB-eligible patients starting treatment on insulin aspart will be required to be started on Trurapi. Prescribers should also note the RFU Code for patients established on NovoRapid and should notify their patients of the change.

8. How will these changes impact pharmacies/pharmacists?

NovoRapid and Trurapi are not interchangeable products. As of the February 2022 Formulary update (effective **February 28, 2022**), new ODB-eligible patients starting treatment on Insulin aspart are required to be started on Trurapi. Pharmacies/pharmacists can continue to submit claims for NovoRapid (insulin aspart), where applicable, and starting from the February 2022 Formulary update, with the appropriate RFU code 628 or temporary transition code (RFU/LU 279).

When a prescription for insulin aspart is received, pharmacists should verify whether the prescription is for Trurapi. Pharmacies should submit claims using the applicable drug identification number (DIN):

Table 2

DIN	Brand Name	Generic Name	Strength & Dosage Form	MFR
02506564	Trurapi	insulin aspart	100U/mL Inj Sol-5x3mL Cart Pk	Sanofi-Aventis Canada Inc.

02506572	Trurapi	insulin aspart	100U/mL Inj Sol-5x3mL 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 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.

10. Is the Ministry requiring patients to use biosimilars if they are on the innovator?

Patients currently using NovoRapid may continue to do so and are not required to change to Trurapi at this time.

Please refer to Health Canada's Biosimilar biologic drugs in Canada: Fact Sheet for more information.

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