THERAPEUTIC SUBSTITUTION – Biosimilar insulins		Effective Date: October 4, 2023 to September 30, 2024
Eligibility	**Description / Scope / Documentation / Notification**	**Reimbursement rate**
1. Patient must be enrolled in the a. Diabetes Drug Program 2. Both medications must be benefits of the Pharmacare program for which the patient is enrolled. **<u>Exception</u>**: The therapeutic substitution fee will be eligible to be claimed in the 3 months following the delisting of the originator insulin (until Sept 30, 2024).	A "Therapeutic Substitution" is when the pharmacist substitutes the drug prescribed with a different drug that is expected to have an equivalent therapeutic effect, as long as that drug is from within the same therapeutic class. When making a therapeutic drug substitution, the pharmacist must be satisfied that the dose and the dosing regimen of the new drug selected will have an equivalent therapeutic effect. **The pharmacist must be satisfied that the following conditions are met when making a "Therapeutic Substitution" decision** 1. The decision: a. Addresses the health needs of that patient, b. Maintains or enhances the safety or effectiveness of drug therapy, c. Does not place the patient at increased risk, d. Considers formulary or payer restrictions and other patient-related information, and e. Ensures the drug is approved for the intended indication by Health Canada or strong evidence supports using the drug for the intended indication (e.g., clinical practice guidelines); 2. Professional independence has been maintained and the pharmacist avoids conflict of interest. If a decision is made based on economic benefit to the pharmacist or pharmacy, this will be considered professional misconduct; 3. The pharmacist has considered all relevant information about the patient, the condition and the drug, and the pharmacist has effectively communicated this to the patient to ensure they agree with the decision; and 4. The pharmacist takes full responsibility for their decision. PEI Pharmacare will reimburse for "Therapeutic Substitution" where a drug from the "Non-Reference Drugs" list within a class/category is substituted for a drug from the "Reference Drugs" list within the same class/category. **Biosimilar insulins are considered for reimbursement of this service through PEI Pharmacare Programs:** **Bolus insulins:** **Insulin aspart (100 units/mL)** <u>Reference Drugs</u> — <u>Non-Reference Drugs</u> Kirsty™ — NovoRapid® Trurapi® **Insulin lispro (100 units/mL)** <u>Reference Drugs</u> — <u>Non-Reference Drugs</u> Admelog® — Humalog®	1.3 x Dispensing Fee The dispensing fee refers to the maximum dispensing fee allowed as identified in the Pharmacy Services Agreement.

	Basal insulin: **Insulin glargine (100 units/mL)** Reference Drugs — Non-Reference Drugs Basaglar® — Lantus® Semglee®	
	Notes: • Pharmacies are able to submit one fee for basal insulin switch and one fee for bolus insulin switch per patient. This fee should be claimed on the first dispense of a biosimilar insulin prescribed. • Each fee may be claimed **once for each eligible originator insulin** switched to a biosimilar per patient (i.e., one fee for basal insulin and one fee for bolus insulin) during the identified switching period. • **The fee is reflective of the pharmacist:** o Explaining the biosimilar initiative to the patient o Providing reassurance of the quality, safety, and effectiveness of their biosimilar insulin o Conducting a therapeutic substitution from an originator insulin to a biosimilar insulin o Answering questions and provide written materials if needed • **To claim the fee:** o The pharmacist must be the prescriber **AND** o The patient must be enrolled in the PEI Diabetes Drug Program • **The fee cannot be claimed if:** o The prescription for the biosimilar insulin is written by another primary care provider o Subsequent transitions are made to a different biosimilar insulin brand, or back-and-forth from the originator insulin to a biosimilar. • Until June 30, 2024, Pharmacies can continue to bill PEI Pharmacare programs for the drugs on both the "Reference Drugs" list and the "Non-Reference Drugs" list and reimbursement will occur as it does now. The only change, at this time, is if the pharmacist makes a substitution of a drug from the 'Non-Reference Drug" list with a drug from the "Reference Drug" list in the same class/category the pharmacist is eligible to bill a fee for "Therapeutic Substitution". After June 30, 2024, the originator insulins will no longer be covered by PEI pharmacare. The decision to provide a "Therapeutic Substitution" of a prescription is at the discretion of the individual pharmacist. However, once a pharmacist undertakes the "Therapeutic Substitution" of a prescription, they take full responsibility for and assume liability for that prescription. For further guidance please refer to the Process To Follow/Consider When Providing Professional Pharmacy Services in the PROFESSIONAL SERVICE REIMBURSEMENT FRAMEWORK document.	
	Adjudication steps: • Submit the prescription that has been therapeutically substituted identifying the pharmacist as the prescriber. After the above step is completed:	

- Submit a claim for “Therapeutic Substitution”, using the appropriate PDIN (see below) to the eligible PEI Pharmacare Program (Diabetes Drug Program).

Reference Drugs	Non-reference drugs	Therapeutic Substitution PDIN
Basal biosimilar insulin	Basal originator insulin	93899739
Bolus biosimilar insulin	Bolus originator insulin	93899740

- Process as per a regular claim with the following consideration;
  - Quantity of one (1)
  - Days supply of one (1)
  - The “sig” field must contain, in the following order;
    - Prescription number of the prescription that has been therapeutically substituted
    - DIN then name of the original drug
    - DIN then name of the substituted drug
  - Claimed amount for the service is to be submitted in the drug cost field
  - Identify the pharmacist as the prescriber

Note:

- Missing or incomplete information in the “sig” field will result in the reversal of the claim for “Therapeutic Substitution”. If the “sig” field is blank, the claim will be reversed, and the pharmacy will see the reversal on their Pharmacy Claims Detail Report. If the information is incomplete the pharmacy would be contacted/consulted prior to any reversal.

Documentation:

The pharmacist must document in the patient’s record any adaptation/therapeutic substitution of the prescription, the rationale for the decision, and any appropriate follow-up plan. The documentation must always relate back to the original prescription and include (if applicable) reference to any and all previous adaptation/therapeutic substitution.

- Documentation must include:
  a) Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
  b) Original prescription information (including prescribers name and contact information)
  c) A description of the adaptation/therapeutic substitution (including all relevant prescription details)
  d) The rationale for the decision to adapt/therapeutically substitute the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
  e) Acknowledgment of informed consent
  f) The date and name of practitioner(s) notified

Notification of Other Health Professionals:

- The pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing) and this must be recorded in the patient’s record or directly on the prescription hard copy.