| Government of Saskatchewan<br><br>**Saskatchewan Ministry of Health Drug Plan and Extended Benefits Branch Policy** | **Section:**<br><br>*Pharmacy Professional Services* | **Reference**<br>DP-PPS-18<br><br>**Date of Issue**<br>February 27, 2023<br>Update September 25, 2023 |
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**BIOSIMILAR INSULIN TRANSITION FEE**

Policy and Billing Procedure for Pharmacies

## BACKGROUND

- Effective February 27, 2023, the Drug Plan and Extended Benefits Branch (DPEBB) will pay community pharmacies a Biosimilar Insulin Transition Fee (BITF) to support the transition from a reference biologic insulin to a biosimilar version.
- The Saskatchewan Biosimilars Initiative was announced on October 20, 2022, to increase the use of more cost-effective biosimilar drugs:
    - Established patients already receiving a reference biologic drug with an available biosimilar version will be required to use a biosimilar version in order to maintain coverage under the Saskatchewan Drug Plan.
    - After the end of the announced transition period, coverage of the reference biologic will no longer be provided.
- The BITF will be paid when a pharmacist:
    - Provides a Schedule II biosimilar insulin to replace a reference biologic insulin when a patient does not have a prescription for the biosimilar from a primary care or specialist prescriber; and
    - Completes a patient assessment, biosimilar insulin selection, counselling, and notification using the medSask Administrative Pharmacist Assessment Record (A-PAR). Patient follow-up must also be completed (or attempted) in an appropriate timeframe after providing the biosimilar insulin, and also documented on the A-PAR form at that time.
- For clarity:
    - A BITF will be paid only for the **first** transition from a reference biologic insulin to a biosimilar version; and
    - One BITF can be claimed **for each** eligible insulin (insulin aspart, insulin glargine, and/or insulin lispro) transitioned from a reference biologic to a biosimilar version. See Table 2 for a list of eligible biosimilar insulin options listed on the Saskatchewan Formulary.

- **Important Notes:**

  **Insulin Pump Users:**
  - NOVORAPID patients: Coverage of NOVORAPID will continue to be available for patients who use insulin pumps while the biosimilars undergo insulin pump certification.
  - HUMALOG patients: ADMELOG biosimilar (insulin lispro) is compatible with various insulin pump models from Insulet (Omnipod), Medtronic, Tandem, and Ypsomed.

  **New Patients:**
  - Pharmacists can claim a BITF for transitioning a patient presenting with their first prescription for an impacted reference biologic insulin (NOVORAPID, LANTUS, or HUMALOG) to provide a biosimilar version instead.
  - For example: a hospital discharge or initiating therapy with a prescription written for the reference biologic brand.

  **Vial formats:**
  - Pharmacists can claim a BITF when transitioning patients from a NOVORAPID or LANTUS vial to a biosimilar cartridge or pre-filled pen, where this is appropriate for the patient.
  - NOVORAPID and LANTUS vials will remain covered until biosimilar(s) in a vial format are listed on the Saskatchewan Formulary.
  - If a patient uses a vial with an insulin pump, see the note above for **Insulin Pump Users.**

- A BITF is not eligible when (*this list is not exhaustive*):
  - The patient has not been previously prescribed or established on a reference biologic insulin impacted by the Saskatchewan Biosimilars Initiative;
  - The patient already has a prescription for a biosimilar insulin from a physician or nurse practitioner;
  - The pharmacist assessment determines that a biosimilar insulin is not appropriate for the patient;
  - The medSask A-PAR is not completed to guide the transition; or
  - Subsequent transitions are made to a different biosimilar insulin brand, or back-and-forth from the reference biologic to a biosimilar.
- The cost of the insulin is subject to the eligible patient's usual medication coverage.

**PURPOSE**

- Insulin can be sold as a Schedule II drug, and pharmacists can support patients to transition to a lower-cost biosimilar version of their insulin without the need for a prescription from a primary care physician, nurse practitioner, or specialist.
- The need to transition to biosimilar insulins is expected to be time-limited based on the Saskatchewan Biosimilar Initiative transition periods. Therefore, the BITF is also anticipated to be a time-limited fee and will be stopped at the discretion of the DPEBB.

- As other biosimilar options are implemented in the Saskatchewan Biosimilars Initiative, a BITF may be reinstated at the discretion of the DPEBB.

**LEGISLATIVE AUTHORITY**

- *The Pharmacy and Pharmacy Disciplines Act*
- *The Prescription Drugs Act (Saskatchewan)*
- *The Drug Schedules Regulations, 1997 Amendment Regulations*
- *The Health Administration Act*

**ELIGIBLE PATIENTS**

- An eligible patient must be a beneficiary under the DPEBB. A beneficiary is a Saskatchewan resident with an active Health Services Number (HSN) and **not covered** under Workers Compensation, SGI, Non-Insured Health Benefits (NIHB), Veteran Affairs and Armed Forces.**

**Exclusion: Residents of Long Term Care facilities are not eligible for the BITF.

**ELIGIBLE PRODUCTS**

- Biosimilar insulin products eligible for a BITF are listed in Table 2.

**PROCEDURES**

*The Pharmacist will*:
1. Adhere to the *Regulatory Bylaws of the Saskatchewan College of Pharmacy Professionals*.
2. Adhere to the *medSask Biosimilar Insulin Administrative Pharmacist Assessment Record (A-PAR)* to determine appropriate action in the sale of a Schedule II biosimilar insulin (e.g., recommend and select appropriate biosimilar insulin(s) and device(s), make a referral to a physician, nurse practitioner, or Certified Diabetes Educator when indicated).
3. Fully complete all sections of the medSask Biosimilar Insulin A-PAR and fax the Prescriber Notification Form to the patient's primary care practitioner for continuity of care (unless the patient does not have a primary care provider).

*The Pharmacy will:*
1. Submit the drug claim for the Schedule II biosimilar insulin electronically for adjudication before the BITF claim (**paper claims will not be accepted**).
2. Submit the BITF on the same day as the drug claim.
3. Match the prescriber in the BITF claim to the prescriber submitted for the biosimilar insulin claim.
4. Ensure the dispensed prescription is captured on the Pharmaceutical Information Program (PIP).

5. Retain copies of the A-PAR for a period of two years for the purpose of a DPEBB review of adherence to the Biosimilar Insulin Transition Fee policy and billing procedure. *There may be additional requirements to retain the A-PAR documentation as specified by the Saskatchewan College of Pharmacy Professionals.*
6. Provide copies of the A-PAR upon DPEBB's request as part of its review of adherence to the Biosimilar Insulin Transition Fee policy and billing procedure.

*The Drug Plan and Extended Benefits Branch will:*

1. Provide pharmacies with the Biosimilar Insulin Transition Fee policy and billing procedure.
2. Pay pharmacies the BITF upon receipt of the electronic claim.
3. Update the list of Drug Identification Numbers (DINs) for eligible biosimilar insulins.
4. Request and review the A-PAR to confirm pharmacists and pharmacies have adhered to the Biosimilar Insulin Transition Fee policy and billing procedure.
5. Recover the BITF if DPEBB determines, based on its review, that there was non-adherence to the Biosimilar Insulin Transition Fee policy and billing procedure.
6. Notify pharmacies of updates to the BITF policy and billing procedure.

*The Saskatchewan College of Pharmacy Professionals will:*

1. Maintain and update the guidelines as appropriate.

## PHARMACY INFORMATION BULLETINS

Information on the application and operation of the Biosimilar Insulin Transition Fee may be found in Pharmacy Information Bulletins issued by DPEBB on an "as required" basis.

## RESOURCES

- Saskatchewan Drug Plan Formulary website: https://formulary.drugplan.ehealthsask.ca/SearchFormulary
- Saskatchewan Biosimilars Initiative webpage: www.saskatchewan.ca/biosimilars
- medSask Biosimilar Insulin A-PAR: https://medsask.usask.ca/professional-practice/biosimilars-in-saskatchewan#toc-biosimilar-cc_XdXXC
- Biosimilars in Saskatchewan Webinar from medSask and the Saskatchewan Drug Plan and Extended Benefits Branch: https://pharmacy-nutrition.usask.ca/cpdpp/continuing-education-/biosimilars-in-saskatchewan-webinar.php

**BILLING PROCEDURE:**

- Steps for pharmacists when selling a Schedule II biosimilar insulin to replace a reference biologic insulin:
  1. Dispense the eligible biosimilar insulin and submit the claim for adjudication electronically via the DPEBB on-line claim system.
  2. Adjudicate the BITF using the appropriate pseudoDIN to the DPEBB.
  - Billing shall occur on a real-time basis.

**Step 1: Dispensing the Medication:**

- Use "SKCP" and your own pharmacist ID number in the Health Provider fields.
- Use "D" in front of your own pharmacist ID number.
- Ensure the following fields are:

| | |
|---|---|
| • **PATIENT IDENTIFIER** | = client nine-digit Health Services Number (HSN) |
| • **DISPENSING DATE** | = date of the activity (e.g., February 27, 2023) |
| • **RX NUMBER** | = enter the sequential RX# |
| • **HEALTH PROVIDER ORGANIZATION ID** | = SKCP |
| • **HEALTH PROVIDER ID** | = Pharmacist ID number (e.g. D1234) |
| • **PHARMACIST ORGANIZATION ID** | = SK |
| • **PHARMACIST ID** | = Pharmacist ID number (e.g. D1234) |
| • **DIN** | = enter the DIN of the biosimilar insulin provided to the patient ***must be an eligible insulin listed in Table 2** |
| • **COMPOUNDING FEE (CF)** | = $0.00 |
| • **COMPOUND NAME** | = blank |
| • **QUANTITY (QTY)** | = enter quantity dispensed |
| • **DAYS SUPPLY** | = enter days supply dispensed |
| • **ACQUISITION COST (AC)** | = enter actual acquisition cost |
| • **DISPENSING FEE (DF)** | = $0.00 |
| • **MARKUP** | = tiered as per pharmacy agreement |
| • **TOTAL RX COST** | = enter total cost |
| • **PATIENT PAID** | = as appropriate |
| • **ADJUDICATION FLAG** | = Y |

**Step 2: Submitting the Biosimilar Insulin Transition Fee (BITF):**

- Submit the BITF electronically via the DPEBB on-line claim system on the date the biosimilar insulin is provided to the patient (paper claims will not be accepted).*
- DBEBB pays 100% of the BITF to the pharmacy.
- Ensure the following fields are:
  - **PATIENT IDENTIFIER** = client nine-digit Health Services Number (HSN)
  - **DISPENSING DATE** = date of the activity (e.g., February 27, 2023) ***must be the same date as the prescription claim in step 1**
  - **RX NUMBER** = enter the sequential RX#
  - **HEALTH PROVIDER ORGANIZATION ID** = SKCP
  - **HEALTH PROVIDER ID** = Pharmacist ID number (e.g., D1234) ***must match the provider ID from the prescription claim in step 1**
  - **PHARMACIST ORGANIZATION ID** = SK
  - **PHARMACIST ID** = Pharmacist ID number (e.g., D1234)
  - **DIN** = 00951378
  - **COMPOUNDING FEE (CF)** = $0.00
  - **COMPOUND NAME** = blank
  - **QUANTITY (QTY)** = 1 (limitations are as noted in Table 1)
  - **DAYS SUPPLY** = enter days supply dispensed
  - **ACQUISITION COST (AC)** = $18.00
  - **DISPENSING FEE (DF)** = $0.00
  - **MARKUP** = 00 / 00 / 00
  - **TOTAL RX COST** = total fee
  - **PATIENT PAID** = $0.00
  - **ADJUDICATION FLAG** = Y

* Use the **WEB page https://www.drugplan.health.gov.sk.ca** if unable to bill the fees electronically through the pharmacy's Practice Management System. Contact the pharmacy's software vendor if unsure how to install the WEB certificate. Refer to the DPEBB Pharmacy Reference Manual, Section VI to use the WEB page.

The BITF will not appear on:

- PIP;
- the Formulary; and
- requested patient profiles.

**Table 1: Biosimilar Insulin Transition Fee Billing Code (Limitations)**

| Billing Code (pseudoDIN) | Billing Threshold/Limitation |
|---|---|
| 00951378 | • Maximum of ONE (1) claim per patient for each initial insulin product transitioned to a biosimilar<br>  ○ ONE (1) claim for insulin aspart<br>  ○ ONE (1) claim for insulin glargine<br>  ○ ONE (1) claim for insulin lispro<br>• Must be submitted as a Quantity of ONE (1) |

**Table 2: List of Eligible DINs**

| Insulin | Reference Biologic Brand | Biosimilar Insulin Brands | Format | DIN |
|---|---|---|---|---|
| Insulin aspart 100U/mL | NOVORAPID | KIRSTY | Pre-filled pen | 02520974 |
| | | TRURAPI | Cartridge | 02506564 |
| | | TRURAPI SOLOSTAR | Pre-filled pen | 02506572 |
| Insulin glargine 100U/mL | LANTUS | BASAGLAR | Cartridge | 02444844 |
| | | BASAGLAR KWIKPEN | Pre-filled pen | 02461528 |
| | | SEMGLEE | Pre-filled pen | 02526441 |
| Insulin lispro 100U/mL | HUMALOG | ADMELOG | Cartridge | 02469898 |
| | | ADMELOG SOLOSTAR | Pre-filled pen | 02469871 |
| | | ADMELOG | Vial | 02469901 |
| Pharmacists should refer to the Saskatchewan Formulary and the Saskatchewan Biosimilars Initiative policy details to confirm the most current transition requirements for each insulin/format. | | | | |