Ministry of Health
Drug Plan and Extended Benefits
2nd Floor, 3475 Albert Street
Regina, Canada S4S 6X6

September 25, 2023

Dear Health Care Providers:

RE: Saskatchewan Biosimilars Initiative Policy Notice: Humalog® (insulin lispro)

As you may be aware, the Saskatchewan Biosimilars Initiative was announced on October 20, 2022. Coverage for several reference biologics has already transitioned to biosimilar versions.

Effective October 1, 2023, the Saskatchewan Biosimilars Initiative transition period for Humalog® (insulin lispro) will continue.

- The transition was announced last year and was paused in December 2022.
- Supply of the biosimilar (Admelog®) has now stabilized, and patients can access the biosimilar.

Coverage of **Humalog® 100 units/mL** products will be available on the Saskatchewan Formulary until **March 31, 2024.** Patients will need to use a biosimilar version in order to maintain Saskatchewan Drug Plan coverage of their treatment after this date.

The table below shows the available biosimilar insulin formats:

Insulin	Reference Biologic Brand and Formats	Biosimilar Insulin Brand and Formats	End of Transition Period
Insulin lispro 100 units/mL	**HUMALOG** - Cartridge - Pre-filled pen - Vial	**ADMELOG** - Cartridge - Pre-filled pen - Vial	**March 31, 2024**

See the enclosed medSask insulin comparison chart for more details.
*Please note: Coverage of **Humalog® 200 units/mL** will continue to be available for patients who need a higher concentration formula, as there is no equivalent biosimilar format at this time.*

The biosimilar (Admelog®) is compatible with various insulin pump models from Insulet (Omnipod), Medtronic, Tandem, and Ypsomed. Health care providers and patients with questions about insulin compatibility with specific insulin pump models are encouraged to contact the insulin pump manufacturer.

Please visit www.saskatchewan.ca/biosimilars for the most up-to-date information on the Saskatchewan Biosimilars Initiative, including the current policy exceptions for other affected insulins (NovoRapid® and Lantus®). The webpage will be updated to reflect the Humalog® transition details on September 29, 2023.

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Patient Letters:

- The week of October 2, 2023, patients who recently filled a prescription claim for Humalog® 100 units/mL will be sent a letter from the Saskatchewan Drug Plan.
- This letter will notify them of the Saskatchewan Biosimilars Initiative policy.
- The letter directs patients to do the following before March 31, 2024:
    - Continue using their insulin according to their prescriber's instructions.
    - To start using a biosimilar insulin:
        - Ask the health care provider who normally prescribes their insulin; or
        - Ask their pharmacist if they can help them transition to a biosimilar insulin.
    - Discuss their questions about biosimilars with their doctor, nurse, or pharmacist.
- The letter also includes supporting information and handouts explaining how to transition to a biosimilar insulin.

General Reminders:

- **We encourage you to prepare patients to transition to biosimilars prior to the end of the transition period.** This ensures there is enough time to address patient concerns and update the patient's prescription with the biosimilar.
- Prescriptions must clearly indicate the biosimilar brand to be dispensed by the pharmacy. Biosimilars are not listed as interchangeable with the reference biologic on the Saskatchewan Formulary.
- Patients can receive a prescription for a biosimilar insulin from their usual prescriber.
- Pharmacists can also support patients to transition to a biosimilar insulin without a prescription from a primary care or specialist prescriber.

Patient Lists:

- Prescribers can request a list of patients who may need to start using a biosimilar to maintain Drug Plan coverage. The list will include patients who have received a recent prescription claim for Humalog® 100 units/mL.
- The Patient List Request Form is available on our webpage under *Prescriber Forms*.

Exemptions:

- The Saskatchewan Biosimilars Initiative includes a provision for exemptions to the policy where patients must remain on the reference biologic for medical reasons.
- Please consider all contributing factors prior to requesting an exemption. The medSask tool to assess unexpected responses to biosimilars may be helpful (enclosed).
- The Exemption Request Form is available on our webpage under *Prescriber Forms*.

Questions and Support:

For support with the Saskatchewan Biosimilars Initiative policy and drug coverage:

- Visit www.saskatchewan.ca/biosimilars
- Email sk.biosimilars@health.gov.sk.ca
- Call the Saskatchewan Drug Plan: 1-800-667-7581 (306-787-3317 in Regina)

For clinical support from medSask:

- **Health care providers:**
  - Visit medsask.usask.ca/professional-practice/biosimilars-in-Saskatchewan
  - Email druginfo@usask.ca
  - Call 1-800-667-3425 (306-966-6340 in Saskatoon)
- **Patients:**
  - Visit medsask.usask.ca/general-public/biosimilars-in-saskatchewan
  - Email med.sask@usask.ca
  - Call 1-800-665-3784 (306-966-6378 in Saskatoon)

Drug Plan and Extended Benefits

Enclosures

INSULIN LISPRO

Comparison Chart for Individuals Switching to Biosimilar Insulin

Rapid acting insulin analogue, bolus/prandial and for use in subcutaneous pump system

- **Use same dose (unit to unit) when transitioning to biosimilar.**
- **No clinical differences in onset, peak, or duration of action.**
- **No expected differences in adverse effects.**

Product	Humalog® (reference biologic)			Admelog® (biosimiliar)	
Strength	100 units/mL#			100 units/mL	
Manufacturer	Eli Lilly			Sanofi-Aventis	
DIN	**02229705**	**02403412**	**02470152**	**02469898**	**02469871**
Supplied As	Cartridge—for use with HumaPen Savvio® or HumaPen Luxura® HD reusable pen (discontinued)	Prefilled pen—KwikPen®	Prefilled pen—Junior KwikPen®	Cartridge—for use with AllStar® Pro or JuniorSTAR® reusable pen	Prefilled pen—SoloSTAR®
Pen colour, injection button colour	HumaPen Savvio®: graphite or red pen HumaPen Luxura® HD: green pen	Dark blue pen, burgundy dose knob	Dark blue pen, blue dose knob	AllStar® Pro, JuniorSTAR®: blue or silver pen	Yellow pen, burgundy button
Administration	Remind individuals that the 'feel' of delivery devices may be different, but the basic mechanics of dialing a dose and subcutaneously injecting the insulin with a pen remain the same.				
Dosing Increments	HumaPen Savvio®: 1-60 units in 1 unit increments HumaPen Luxura® HD: ½-30 units in ½ unit increments	1-60 units in 1 unit increments	½-30 units in ½ unit increments	AllStar® Pro: 1-80 units in 1 unit increments JuniorSTAR®: 1-30 units in ½ unit increments	1-80 units in 1 unit increments
"Clicks" as dose delivered	✓	X	X	AllStar® Pro: ✓ JuniorSTAR®: ✓	✓
End of dose "click"	X	X	X	X	X
Prevents dialing of more units than remain	HumaPen Savvio®: ✓ HumaPen Luxura® HD: X	✓	✓	AllStar® Pro: ✓ JuniorSTAR®: X	✓
Needle Compatibility	All pen devices are compatible with BD Pro Ultra-fine™, Insupen®, NovoFine® and Unifine ® pen needles.				
Storage: unopened	Refrigerated (2-8 °C) until expiration date. Keep away from direct heat and light. Do not freeze.				
Storage: in use	Room temperature^ (max. 30 °C) for up to 28 days. Keep away from direct heat and light. Do not freeze.				
Ok to return to fridge when in use?	X	X	X	X	X

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Updated March 31, 2023. Refer to the Saskatchewan Drug Plan Formulary prior to dispensing to confirm formulary listings.

Humalog® 200 units/mL KwikPen® available (DIN: 02439611) but transition not required as biosimilar version not available.

^ Room temperature generally refers to temperatures from 15 °C to up to 25 °C– 30 °C. Product specific instructions may have slight variation in room temperature. Refer to product monograph or product insert for detailed storage information .

References available at www.medsask.usask.ca

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Transitioning To A Biosimilar: Assessment Of Unexpected Response

- **Biosimilars are demonstrated to be as effective and safe as the reference biologic. The unexpected response may not be related to the use of a biosimilar.**
- **When assessing an unexpected response: acknowledge and address patient concerns, use objective measures in addition to subjective information, and consider all potential factors.**

FACTORS	CONSIDERATIONS FOR REVIEW
Drug Storage **Deviations from manufacturer recommended storage may compromise efficacy.**	• Storage conditions ✓ Not exposed to temperature extremes (including during transport) ✓ Storage time at room temperature not exceeded ✓ Drug not expired
Drug Regimen **Non-adherence may lead to treatment failure resulting in unnecessary changes to or escalation of treatment.**	• Adherence ✓ Original reference biologic discontinued by patient ✓ Administered dose is the same as the reference biologic ✓ Dose given on time and as scheduled (i.e., no interruption of therapy)
Drug Administration **Improper use of the device could result in delivery of subtherapeutic dose.**	• Site of administration ✓ Appropriate and different from last site of administration • Dose delivery (as applicable) ✓ Plunger of prefilled syringe completely depressed ✓ Viewing window indicates complete drug delivery ✓ Autoinjector held in place at least 10 seconds ✓ Dose not accidently discharged (i.e., autoinjector button pressed too soon)
Drug Interactions **Concomitant medications or supplements may:** • **reduce efficacy of the biosimilar;** • **increase side effects; or** • **have side effects that mimic a disease flare.**	• New use of: • Prescription medications • Over-the-counter medications • Supplements • Samples • Products ordered on the internet or purchased outside of Canada
Clinical Status Of Condition Being Treated	• Natural disease progression • Possibility of disease flare

FACTORS	CONSIDERATIONS FOR REVIEW

Other Therapies Used To Manage Condition	• Adherence or recent changes to:
	  • Concomitant medications
	  • Nonpharmacologic management (e.g. physical therapy, psychotherapy, diet, exercise, sleep/rest, etc.)

Overall Health Status	• Change in physical health including comorbid conditions, injury, or new diagnosis • Change in mental, emotional, social health (e.g. financial instability, work stress, access to care, etc.)
Nocebo Effect **Negative expectations may influence treatment outcomes.**	• Patient knowledge about biosimilars and sources of information • Patient anxiety about transitioning to the biosimilar • Health care provider confidence in the quality, safety, and efficacy of biosimilars

Managing Injection Site Pain

The transition to a different product may result in a change to how the injection feels. Consider:

- Product formulation factors: excipients, pH, volume, temperature, viscosity
- Device features: needle length and gauge
- Injection technique: injection speed and movement during injection
- Patient factors: low body weight, female sex, mental health status, disease severity, expectations of pain

Unexpected and severe adverse effects should be reported to Health Canada:

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

Who to contact with questions or concerns:

- Saskatchewan Biosimilars Initiative: email sk.biosimilars@health.gov.sk.ca or call 1.800.667.7581 (306.787.3317 in Regina)
- medSask: email druginfo@usask.ca or call 1.800.667.3425 (306.966.6340 in Saskatoon)

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REFERENCES AVAILABLE AT https://medsask.usask.ca/index.php

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