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 1.800.667.2549 (306.787.8744 in Regina), option 3.
- medSask: email druginfo@usask.ca or call 1.800.667.3425 (306.966.6340 in Saskatoon)

medSask
YOUR MEDICATION INFORMATION SERVICE

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

30 APR 2023