NHS
Kent and Medway

Kent & Medway Guidance on Biosimilar Insulin Prescribing

Over the last few years, a variety of insulin preparations have become available, including biosimilar formulations. This guidance summarises the biosimilar insulins available currently in the UK and provides information to increase familiarity with biosimilar insulins; to support healthcare professionals within different healthcare settings who are engaged in the care of patients with diabetes/using insulin. The aim is to increase the uptake of prescribing of biosimilar insulins and to ensure that prescribing of biosimilar insulins is safe and appropriate.

When a patent expires on an originator insulin (biological medicine), opportunity arises for manufacturers to replicate them and make a biosimilar insulin (copy of the original approved insulin molecule/biological medicine). Biosimilar insulins, which have been approved for use in the UK, have been shown to be equivalent/have no clinically meaningful difference (safety, quality, and immunogenicity) to the originator insulins they are based on. The use of biosimilar insulins, which are becoming increasingly available and are typically cheaper, could enable cost savings.

The NICE guidelines for Type 1 diabetes in adults (NG17) and Type 2 diabetes in adults (NG28) recognise the use of biosimilar insulins. When starting an insulin for which a biosimilar is available, NICE recommends using the product with the lowest acquisition cost (see section below for biosimilar insulins available in the UK and costs compared to originator insulins). When patients are already using an insulin for which a lower cost biosimilar is available, NICE recommends discussing the possibility of switching to the biosimilar with the patient, discussing their preferences and making a shared decision. The decision to initiate a biosimilar insulin, or switch an insulin to its biosimilar version, should not be considered a routine procedure; it must be undertaken by a clinician with a special interest in diabetes, experienced and competent in prescribing insulins.

Kent and Medway Policy Recommendation and Guidance Committee (PRGC) Policy Recommendation: Switching between biosimilars

This document contains further information explaining what biological and biosimilar medicines are, and what National guidance (NICE and NHS England) says about biosimilars. The recommendations that the PRGC made in this policy, include:

- Switching from one biosimilar treatment to another biosimilar treatment can be appropriate so that the product of lowest acquisition cost is being used. The exception is where there are mitigating circumstances, or if the standard treatment course is less than 6 months.
- Biosimilars should be added to local formularies for their licensed indications at the time of their launch (or soon after) to maximise the financial savings available.

Summary of Prescribing Principles for Initiating Biosimilar Insulin

- All insulin prescriptions should include the brand name, the strength of insulin and the device to ensure continuity of supply of the insulin and associated administration devices.
- When a **new** insulin biosimilar has been added to the Local Formulary, prescribers are encouraged to follow a phased approach to its introduction:
    - **Phase 1** - Introduce the 1st line biosimilar insulin for new initiations of insulin, where there has been no previous use of the originator insulin (where clinically appropriate/appropriate for the individual patient). All patients requiring new initiations of insulin for type 1 and type 2 diabetes should be initiated on a biosimilar insulin.
    - **Phase 2** - Switch existing type 1 and type 2 patients from the originator brand to the 1st line biosimilar brand with appropriate counselling, where this is clinically appropriate. This is clinician decision based. If the patient's glycaemic control is not stable on the originator insulin, part of the discussion/management options should be to switch to the biosimilar brand.
- **The decision to initiate a biosimilar insulin, or switch an insulin to its biosimilar version, should not be considered a routine procedure; it must be undertaken by a clinician with a special interest in diabetes, experienced and competent in prescribing insulins.**
- Switching to and prescribing a biosimilar insulin should only be undertaken after discussion between clinician and patient, not given as substitution for the originator insulin at the point of dispensing.
- Patients switched to a biosimilar insulin must be fully informed and receive appropriate education. Consider potential differences between insulins in terms of device (e.g., cartridges or pens) and administration, and storage conditions and shelf life (check product Summaries of Product Characteristics).
- It is important that all healthcare professionals across all healthcare settings can access up-to-date records about patients' insulin, to accurately identify their current insulin products to ensure safe and effective transfer and continuity of care across healthcare sectors. When prescriptions of insulin are prescribed, dispensed, or administered, healthcare professionals should cross-reference available information to confirm the correct identity of insulin products.
- **Prescribers are reminded that whenever a patient's insulin is changed, their medication list, and their repeat prescription where necessary, should be updated on the clinical system, including stopping the previous insulin preparation.** This is to reduce the risk of inadvertent doubling of doses and to ensure patients are not prescribed duplicate prescriptions under different brand names. Their insulin passport/insulin safety card should be updated if they have one (as per the 2011 National Patient Safety Alert (NPSA) "The adult patient's passport to safer use of insulin").
- Patients switched to a biosimilar insulin should be advised to monitor their glucose readings more closely to identify any variability in glucose profile compared to the originator insulin.
- Biosimilar medicines, including insulins, have black triangle status in early years of use. Any issues or adverse effects should be reported to the MHRA using the Yellow Card system.

For **further information and advice** for healthcare professionals when starting treatment with a biosimilar, the MHRA has guidance on minimising the risk of medication error with high-strength, fixed combination and biosimilar insulin products, which following ensures the risk of medication errors with insulins is minimised.

Originator Insulins and available Biosimilar Insulins

Insulin aspart (short-acting insulin)

Originator Insulin:

- **NovoRapid® - ON FORMULARY**
  - NovoRapid® (insulin aspart) is a rapid-acting insulin, which is available as 100 units/ml as a vial, a cartridge, or FlexPen® and FlexTouch® pens (prefilled pens).

Biosimilar Insulin:

- **Trurapi® - 1st LINE**
  - Trurapi® is a biosimilar aspart insulin. Trurapi® has been shown to be equivalent to NovoRapid® in its pharmacokinetic and pharmacodynamic properties.
  - It is available as 100 units/ml, as a vial, cartridge or SoloStar® pen (prefilled pen).

Originator insulin (insulin aspart 100 units/ml) and device(s)	Cost (NHSBSA dm+d April 2023)	Biosimilar insulin (insulin aspart 100 units/ml) and device(s)	Cost (NHSBSA dm+d April 2023)	Potential cost saving
NovoRapid® 5 x 3ml FlexPens	£30.60	Trurapi® 5 x 3ml SoloStar pens	£21.42	£9.18
NovoRapid® 5 x 3ml FlexTouch pens	£32.13			£10.71
NovoRapid® 5 x 3ml cartridges	£28.31	Trurapi® 5 x 3ml cartridges	£19.82	£8.49
NovoRapid® 1 x 10ml vial	£14.08	Trurapi® 1 x 10ml vial	£11.97	£2.11

Insulin lispro (short-acting insulin)

Originator Insulin:

- **Humalog® - ON FORMULARY**
  - Humalog® (insulin lispro) is a rapid-acting insulin, which is available as 100 units/ml and as a **high-strength** insulin as **200 units/ml.**
  - The 100 units/ml preparation is available as a vial, cartridge and KwikPen® (prefilled pen), whereas the 200 units/ml is only available as a KwikPen®.
  - The 100 units/ml and 200 units/ml preparations are bioequivalent, which means there is no dose conversion required when switching between different strength products, although patients should be counselled on the different strengths, devices, administration etc.
  - Care must be taken when prescribing, dispensing, and administering Humalog® as it is available in multiple strengths, all of which have the same name (as well as Humalog mixes/combination products existing).

Biosimilar Insulin:

- **Admelog® - 1st LINE**
  - Admelog® is a biosimilar lispro insulin. Admelog® has been shown to be equivalent to Humalog® in its pharmacokinetic and pharmacodynamic properties.
  - It is available as 100 units/ml, as a vial, cartridge or SoloStar® pen (prefilled pen)

Originator insulin (insulin lispro 100 units/ml) and device(s)	Cost (NHSBSA dm+d April 2023)	Biosimilar insulin (insulin lispro 100 units/ml) and device(s)	Cost (NHSBSA dm+d April 2023)	Potential cost saving
Humalog® 5 x 3ml KwikPens	£29.46	Admelog® 5 x 3ml SoloStar pens	£22.10	£7.36
Humalog® 5 x 3ml cartridges	£28.31	Admelog® 5 x 3ml cartridges	£21.23	£7.08
Humalog® 1 x 10ml vial	£16.61	Admelog® 1 x 10ml vial	£14.12	£2.49

Insulin glargine (long-acting insulin)

The Kent and Medway formulary status for insulin glargine (for the originator insulin glargine and the available biosimilar insulin glargines) will be updated when the formularies across Kent and Medway are reviewed and aligned in due course. Below is an overview of the available insulin glargine products and their cost.

Originator Insulin:

- **Lantus® -** ***currently on formulary, formulary status to be reviewed and agreed***
  - Lantus® (insulin glargine) is a long-acting insulin, which is available as 100 units/ml as a vial, a cartridge, or SoloStar pen® (prefilled pen).

Biosimilar Insulins:

- **Semglee® -** ***currently on formulary in Dartford, Gravesham and Swanley only, formulary status to be reviewed and agreed***
  - Semglee® is a biosimilar glargine insulin. Semglee® has been shown to be equivalent to Lantus® in its pharmacokinetic and pharmacodynamic properties.
  - It is available as 100 units/ml **only** as a prefilled pen (**not** cartridges).
  - The Semglee® pen is based on the comparable insulin delivery system, the Lantus® SoloStar® pen, in size and function.
  - N.B. dispensing errors have occurred due to the similarity in the names of Semglee® and semaglutide (Rybelsus®/Ozempic®), a GLP-1RA.

- **Abasaglar® -** ***currently on formulary, formulary status to be reviewed and agreed***
  - Abasaglar® is a biosimilar glargine insulin. Abasaglar® has been shown to be equivalent to Lantus® in its pharmacokinetic and pharmacodynamic properties.
  - It is available as 100 units/ml, in a cartridge or KwikPen® (prefilled pen).

Originator insulin (insulin glargine 100 units/ml) and device(s)	**Cost (NHSBSA dm+d April 2023)**	**Biosimilar insulin (insulin glargine 100 units/ml) and device(s)**	**Cost (NHSBSA dm+d April 2023)**	**Potential cost saving**
Lantus® 5 x 3ml SoloStar pens or 5 x 3ml cartridges	£34.75	Semglee® 5 x 3ml prefilled pens	£29.99	£4.76
		Abasaglar® 5 x 3ml KwikPens or 5 x 3ml cartridges	£35.28	None

Further clinical guidance on switching from originator insulins to their biosimilar insulins will be released in due course.