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Consensus Guidance switching from Parent Insulin to Biosimilar Insulin in Patient with type 2 diabetes in Primary Care

Biosimilar medicines should be considered to be therapeutically equivalent to the originator biological medical medicines within their authorised indications.

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 Health Economy Formulary, prescribers are encouraged to follow a phased approach to its introduction:
    - **Phase 1 - Stabilise** the supply for existing patients on the original brand. Ensure that all insulins are prescribed by brands.
    - **Phase 2 - Introduce** the biosimilar insulin for **new type 2 patients**
    - **Phase 3 - Switch** existing **type 2 patients** from the originator brand to the biosimilar brand, with appropriate counselling where this is clinically appropriate.
    - **Phase 4 – Introduce** the biosimilar insulin for **new type 1 patients**
- Prescribers are reminded that whenever a patient's insulin is changed, their insulin passport should be updated.

The NEEDS specialist diabetes team support the above plan for biosimilar phasing in, it is in line with Diabetes UK position statement. Please refer to the 'Prescribing Commissioning Policy for Biosimilar Insulin'

Key points to consider & discuss with patients:

Most common symptoms of hypoglycaemia*

- Sweating
- Trembling
- Confusion
- Lack of co-ordination
- Hunger
- Palpitations
- Drowsiness
- Difficulty Speaking

*N.B. Elderly, frail, people with longstanding diabetes or frequent hypoglycaemia may not experience or recognise these symptoms

Reasons for suboptimal control on insulin

- Poor adherence to prescribed dose quantity, frequency, or timing
- Dose requires titration/review
- Poor injection technique (e.g. site rotation, process, storage) and/or lipohypertrophy
- Psychological causes e.g. needle phobia
- Diet and lifestyle
- Intercurrent or concurrent illness
- Interacting drugs e.g. recent course of steroids or antipsychotic drugs

Optimal control is defined as:

- No blood glucose levels <4mmol/l **and**
- No hypoglycaemia (hypo's) in past 2 weeks **and**
- Individualised HbA1c target obtained **and**
- Individualised blood glucose within target ranges achieved

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Switches should only happen after an individual assessment and discussion with the patient. This could entail a routine face to face review or phone/ virtual review. If there are clear reasons to remain on existing insulin do not proceed with switch to biosimilar. All discussions and changes should be clearly documented in the patient records.

Reasons for suboptimal control should be identified and addressed as part of the switch and if required referred to practice diabetes clinicians or specialist team if criteria met for advice and guidance on alternative insulin and next steps. Patients can also be signposted to diabetes education at this stage.

Steps to switching individuals with Type 2 diabetes to a biosimilar insulin

- Identify existing users of non-biosimilar insulin who have steady/ acceptable or good control. E.g., Close to their target, within +/- 5mmol/mol HbA1c target and no other indication to change current format of insulin regime, but may benefit from future dose titrations to achieve target.

**For anyone with HbA1c >5mmol/mol over target &/or concerns around regular hypoglycaemia or other diabetes related issues, a full diabetes review is likely required where whole insulin and medication regime will be reconsidered **

- Discuss rationale for switch with patient and obtain consent
- Offer information on biosimilar as appropriate
- The dose, time of dose and pen needles should remain **the same** for patients with optimal control.
- Explain switch will allow cost savings with no anticipated difference in day-to-day control, without compromising efficacy or safety

HbA1c/glucose slightly ABOVE target

- initiate at same dose, review patient after 7 days
- monitor and then titrate insulin to target (+ 10-20% every 7 days)
- if patient does not reach target, consider alternative insulin regimen

HbA1c/glucose slightly BELOW target

- initiate at 20% lower dose for 7 days
- monitor and titrate
- reduce dose further by 10-20% if experiencing hypoglycaemic episodes, or too much time below target

If patient complex to optimise outside of usual guidance, arrange input with practice diabetes team or seek specialist advice in the usual way

- Issue a new insulin passport and advise the patient to destroy the old one.
- Continue to monitor as per recommended monitoring guidelines.
- Inform patient to contact usual diabetes healthcare professional if they have any issues with the new insulin brand.
- **Adverse effects that may be attributable to a biosimilar insulin should be reported to the MHRA using the Yellow Card system.**

Further reading: https://diabetesonthenet.com/journal-diabetes-nursing/biosimilar-insulins-an-in-depth-guide/

Diabetes UK position statement: https://rb.gy/juflw

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