Consensus Guidance for Switching from Lantus® to Abasaglar® insulin glargine

**PLEASE NOTE**: NPH INSULIN SUCH AS INSULATARD IS THE PREFERRED BASAL INSULIN (see NG28 NICE guideline for details). Analogue insulins such as Insulin detemir or insulin glargine can be considered as an alternative for some people in certain situations when the person:
- needs assistance from a carer or healthcare professional to inject insulin, and use of analogue insulin would reduce the frequency of injections from twice to once daily
- OR has a lifestyle which is restricted by recurrent symptomatic hypoglycaemic episodes
- OR would otherwise need twice daily NPH insulin injections in combination with oral glucose lowering drugs

1. **Is patient having >60 units of insulin glargine a day?**
   - NO
   - YES

2. **Is patient stable?**
   - YES
   - NO

3. **Is the HbA1c >58mmol/mol?**
   - YES
   - NO

4. **Does the patient have hypoglycaemic episodes?**
   - YES
   - NO

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**Consider change from Lantus to Abasaglar, dose for dose.**

- Safetynet and review patient as necessary

**Consider switch to Abasaglar but reduce dose by 10%:**
- Verify current Lantus dose and reduce this by 10%.
- This will be the starting dose of Abasaglar.
- Patient should monitor their blood glucose as needed.
- Review the patient in a week and titrate the dose of Abasaglar as necessary to achieve the target blood glucose levels.

**Patient may be suitable for change to a more concentrated insulin which is >100units/ml e.g. Toujeo® which has 300units/ml.**

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If patient is running at higher than their target blood glucose levels then consider switch from Lantus to Abasaglar dose for dose, safetynet and review as necessary.
Effectiveness
- Insulin glargine biosimilar 100 units/ml (Abasaglar) once daily was non-inferior to insulin glargine 100 units/ml (Lantus) in people with type 1 diabetes (treatment difference 0.11% points [1.18 mmol/mol] p>0.05) for change in HbA1c from baseline (1 open-label RCT, n=535, 24 weeks). (1)
- Insulin glargine biosimilar 100 units/ml (Abasaglar) once daily was non-inferior to insulin glargine 100 units/ml (Lantus) in people with type 2 diabetes (treatment difference 0.05% points [0.57 mmol/mol] p>0.05) for change in HbA1c from baseline (1 double-blind RCT, n=756, 24 weeks). (1)

Safety
- The safety profile of Abasaglar is comparable to that of Lantus and as expected for an insulin product. No additional safety signals were detected with regard to hypoglycaemia, allergic reactions or injection site reactions and the immunogenicity profiles are comparable (European public assessment report [EPAR]).
- The Abasaglar summary of product characteristics lists the same contraindications, cautions and undesirable effects as for Lantus and lists hypoglycaemia as a very common adverse reaction.

Patient factors
- Abasaglar is given once daily by subcutaneous injection, and is available as 100 units/ml in cartridges or as a KwikPen pre-filled pen.
- Across the 2 RCTs similar numbers of people withdrew because of adverse events with Abasaglar compared with Lantus (1% compared with 2% in people with type 1 diabetes and 2% compared with 3% in people with type 2 diabetes). (1)
- Abasaglar is a new insulin product and people with diabetes need to understand the differences between Abasaglar and other new insulin products that have recently become available to minimise medication error risk.
- All biological medicines, including biosimilar medicines, should be prescribed by brand name so that products cannot be automatically substituted at the point of dispensing.
- The choice of whether a patient receives a biosimilar or originator biological medicine rests with the responsible clinician in consultation with the patient.

Resource implications
- The cost of Abasaglar cartridges 100 units/ml, 5×3 ml for the pen or Abasaglar pre-filled pen 100 units/ml, 5×3 ml is £35.28 (excluding VAT; prices taken from MIMS, November 2015). This is 15% less than the cost of Lantus.
- Comparable costs for other standard-strength basal insulins range from £17.50 to £72.00 for 5x3 ml cartridges or pre-filled pens (excluding VAT; prices taken from MIMS, November 2015).
- The cost of Abasaglar and other basal insulins will depend on the preparation chosen and the insulin dosage used.

What is a biological medicine?
Biological medicines are derived from living cells or organisms and consist of large, highly complex molecular entities which may be difficult to characterise. Due to the variability of the biological system and the manufacturing process, biological medicines, such as insulin, may show a certain degree of variation, even between batches of the same product.

What is a biosimilar medicine?
A biosimilar medicine is a biological medicine that is developed to be highly similar and clinically equivalent to an existing biological medicine. A biosimilar contains a version of an active substance of an already approved biological medicine, which is referred to as the ‘reference medicine’ or ‘originator medicine’. Similarity to the reference medicine in terms of quality, structural characteristics, biological activity, safety and efficacy must be established based on a comprehensive scientific comparability exercise such that they do not have any clinically meaningful differences from the reference medicine in terms of quality, safety and efficacy. Comparability is a well-established concept. Biosimilar medicines are not the same as generic medicines, which contain simpler chemical structures and are identical, in terms of molecular structure, to their reference drugs.

How is the safety of biosimilar medicines monitored?
As for all medicines, the safety of biosimilar medicines is continuously monitored after authorisation. Each company is required to set up a system to monitor side effects reported with its medicines. Patients can also report suspected side effects themselves. The regulatory authorities evaluate the safety data that is captured as well as the company’s safety monitoring system. When signals of a safety concern arise, regulatory authorities investigate and take action as appropriate. (2)

References:

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