Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	**24th November 2015**
Appraisal & Details	**Abasaglar®▼ Insulin Glargine Biosimilar 100 units/ml for the treatment of type 1 or type 2 diabetes mellitus.** The Northern (NHS) Treatment Advisory Group considered an appraisal of Abasaglar© insulin glargine biosimilar 100 units per ml for the treatment of diabetes mellitus in adults, adolescents and children aged two years and above.
Recommendation	**The Northern (NHS) Treatment Advisory Group recommends the use of Abasaglar© insulin glargine biosimilar as a first line option for use in adults who are eligible for treatment with insulin glargine as per NICE guidance (NG17, 2015)** The group noted that Abasaglar© is the first biosimilar insulin approved in the EU. It has an identical amino acid sequence to that of the active ingredient in the reference product Lantus®(insulin glargine 100 units/ml). The licensed indication, dosing regimen, pharmaceutical form, and strength of Abasaglar® are identical to those of Lantus®. Abasaglar® differs from Lantus® with respect to excipients used, but the final quantitative formulation is the same. However, it will still be important to monitor patients for any dose adjustments should they be switched from the reference product. All insulin glargine products must be prescribed by brand name to prevent any confusion around product prescribed.
Clinical evidence summary	The EU regulatory process demands an extensive comparability exercise is performed through a stepwise process that begins with structural, physicochemical and biological analysis, non-clinical, then pharmacokinetic (PK) and pharmacodynamic studies (PD), followed by clinical safety and efficacy trials. In the extensive comparability exercise it was shown that the PK and PD profiles, the relative bioavailability and the duration of action of Abasaglar® are comparable to those of Lantus®. The clinical efficacy of Abasaglar® given once-daily was compared to that of once-daily Lantus® in two similarly designed randomised, active-control, parallel group studies. Both studies were designed to show non-inferiority of Abasaglar versus Lantus based on the primary endpoint of change in HbA1c from baseline to 24 weeks, with a non-inferiority margin of 0.4% HbA1c, and if met 0.3%. Both treatment groups achieved similar decreases in mean HbA1c values from baseline to 24 weeks and 52 weeks. Abasaglar® was found to be non-inferior to Lantus® at the predefined inferiority margins of 0.4%, and the more stringent criteria of 0.3%. There were no clinically significant treatment differences in any secondary efficacy measures, including FBG, insulin dose, and body weight at 24 weeks.

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Safety	The overall safety profile of Abasaglar® was comparable to Lantus® and was in line with the documented safety profile of the reference product. The proportion of patients with detectable anti-insulin antibodies was comparable throughout both studies. There was no evidence that the antibody response had any impact on efficacy and safety outcomes in either treatment group. No new or unexpected safety signals were detected. Several new insulin products have come to market recently, and healthcare professionals and patients need to understand the insulin strength of these products and how to use them correctly to minimise the risk of medication errors such as the wrong insulin dose being administered. An organisational risk minimisation strategy around use of high strength and biosimilar insulins would be advisable to reduce the risk of errors, particularly around the interface i.e on hospital admission or discharge.
Patient Perspective	Patients may be concerned about using a biosimilar product however they can be reassured that a comprehensive comparability exercise has been performed that shows that Abasaglar® is non-inferior (the 'same as) the reference product Lantus®. Patients may need to be taught how to use the pen device as these may look and work slightly differently to the reference product.
Cost analysis summary	Abasaglar® costs £35.28 per pack of 5 x 3ml prefilled KwikPens. (1,500 units) and £35.28 per pack of 5 x 3ml cartridges for use in reusable Savvio pen (1,500 units). The per unit acquisition cost of Abasaglar represents a discount of approximately 15% on the corresponding list price of Lantus®.
Financial impact PbR: In-tariff	In the NTAG area more is spent on drugs for diabetes than any other BNF section. A total of 425,392 insulin items were prescribed at a cost of around £19.1 million. Of these, insulin glargine accounted for 20% at a cost of around £4.4 million. Use of Abasaglar® as the first line option will be cost saving; other insulin biosimilars are due to be licensed and launched in 2016.