Formulary decision guide: Semglee®
(insulin glargine biosimilar)

Key points
- Comparative pharmacokinetic and pharmacodynamic studies have demonstrated the bioequivalence of MYL-1501D (Semglee®) to both US and European reference insulin glargine® in patients with type 1 diabetes mellitus (T1DM)
- Semglee® has demonstrated equivalent efficacy to Lantus® in the treatment of hyperglycaemia in patients with T1DM already treated with reference glargine and in type 2 (T2DM) patients who are insulin naive or already treated with insulin
- The Semglee pen is based on the comparable insulin delivery pen, the Lantus® SoloStar® *, in size and function
- Semglee NHS list price is >20% lower than the reference product.

Drug name
Semglee® ▼ (insulin glargine biosimilar)
100 units/ml solution for injection in pre-filled pen

Indications
- Treatment of diabetes mellitus in adults, adolescents, and children aged 2 years and above.

Dosage
- Semglee should be administered once daily at any time, but at the same time each day
- The pre-filled pen delivers insulin in increments of 1 unit up to a maximum single dose of 80 units
- The dose regimen (dose and timing) should be individually adjusted

Biosimilars
- In a 2016 report, the EU Commission stated: The availability of biosimilars ... offers potential economic benefit to healthcare systems, while supporting patients' access to new treatment options brought about by advances in medical science
- NICE Key therapeutic topic (KTT15) recommends ensuring that all biological medicines, including biosimilar medicines, are prescribed by brand name so that products cannot be automatically substituted at the point of dispensing.

Bioequivalence
- A study comparing the pharmacokinetics (PK) and pharmacodynamics (PD) of MYL-1501D (Semglee®) with Lantus® in patients with T1DM demonstrated bioequivalence with both US and European reference insulin glargine; Semglee has a similar PK profile to the reference product and the PD data support the PK results
- INSTRIDE 2 (a non-inferiority study comparing the efficacy and safety of Mylan's insulin glargine with Lantus in T2DM patients) demonstrated non-inferiority between MYL-1501D and the reference product for reduction of glycated haemoglobin (HbA1c) during 24 weeks of treatment.

Study evidence—efficacy
- An open-label randomised study in T1DM found similar changes in HbA1c and self-monitored blood glucose from baseline to week 24 for Semglee® and reference insulin glargine
- An open-label randomised study comparing the efficacy of Semglee® with Lantus® in 560 patients with T2DM, found that Semglee® had equivalent efficacy to Lantus® in the reduction of Hba1c.

Study evidence—safety
- In the INSTRIDE 2 study, hypoglycaemia was the most common treatment-emergent adverse event (TEAE) in both treatment groups (62 patients [22.5%] in the Semglee® group and 56 patients [19.9%] in the reference product group)
- The overall and nocturnal rates of hypoglycaemia (episodes/30 days) were similar between treatment groups throughout the 24-week study
- No statistically significant differences in hypoglycaemia rate or incidence profile were observed between the Semglee and reference product groups at any visit.

Device
- The Semglee® pen is based on the comparable insulin delivery pen: the Lantus® SoloStar®, in size and function: - It is designed to be used for multiple subcutaneous injections with disposable needles - the pre-filled pen gives patients dosing flexibility, allowing up to 80 insulin units with a single injection
- Patients who are already using the reference insulin glargine and the reference pen should notice no major differences when transitioning to Semglee® and its pre-filled pen.

Cost
- NHS England’s targets for the adoption of best-value biologics are:
  - 90% of new patients starting on the best-value biologic

This formulary decision guide was developed from content provided by Mylan Ltd in a format developed by Guidelines in Practice.
Prescribing information can be found on the back page.
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Insulin glargine biosimilar

Semglee®

Insulin glargine

Dosage and administration

Switch from insulin glargine 300 units/ml

References

4. MIMS online. (accessed 19 October 2018)

Insulin glargine

Semglee® (insulin glargine biosimilar)

(assuming biosimilars) within 3 months of product launch

80% of applicable existing patients switched to the best-value biologic (including biosimilars) within 12 months or sooner if possible (except if standard treatment course is less than 6 months)

Semglee NHS list price is >20% lower than the reference product.

Adverse events

In the open-label randomised study INSTRIDE 2, the incidence of TEAEs was generally similar for patients on Semglee and patients on Lantus: 64.1% and 58.2%, respectively, experienced at least one TEAE over 24 weeks

See the Summary of Product Characteristics for full details of undesirable effects.

Semglee® ▼ (Insulin glargine) 100 units/ml solution for injection in pre filled pen

Prescribing information

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indication: Semglee® is indicated in the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. Presentation: Each ml contains 100 units insulin glargine* (equivalent to 3.64 mg). Each pen contains 3 ml of solution for injection, equivalent to 300 units. Dosage and administration: Semglee® (insulin glargine) has a prolonged duration of action. It should be administered once daily at any time but at the same time each day. The pre filled pen delivers insulin in increments of 1 unit up to a maximum single dose of 80 units. The dose regimen (dose and timing) should be individually adjusted. In patients with type 2 diabetes mellitus, Semglee® can also be given together with orally active antidiabetic medicinal products. The potency of Semglee® is stated in units and these units are exclusive to Semglee®. Special population: Elderly population (≥ 65 years old): progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Renal impairment: insulin requirements may be diminished due to reduced insulin metabolism. Hepatic impairment: insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism. Paediatric population: For adolescents and children aged 2 years and older patients, the dose regimen (dose and timing) should be individually adjusted. For children below 2 years of age the safety and efficacy of Semglee® have not been established. No data are available. Switch from other insulins to Semglee®:

When switching from a treatment regimen with an intermediate or long acting insulin to a regimen with Semglee®, a change of the dose of the basal insulin may be required and the concomitant antidiabetic treatment may need to be adjusted (dose and timing of additional regular insulins or fast acting insulin analogues or the dose of oral antidiabetic medicinal products). Switch from twice daily NPH insulin to Semglee®:

To reduce the risk of nocturnal and early morning hypoglycaemia, daily dose of once daily basal insulin should be reduced by 20–30% during the first weeks of treatment. Switch from insulin glargine 300 units/ml to Semglee®:

Semglee® and insulin glargine 300 units/ml are bioequivalent and are not directly interchangeable. To reduce the risk of hypoglycaemia in this group, Semglee® dose should be reduced by approximately 20%. During the first weeks increase mealtime insulin, after this period the regimen should be adjusted individually. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. A further adjustment in dose regimen may become necessary with improved metabolic control, change of timing of insulin, patient weight or lifestyle changes. Patients with high insulin doses because of antibodies to human insulin may experience an improved insulin response with Semglee®.

Method of administration: Semglee® is administered subcutaneously only. Injection sites must be rotated within a given injection area from one injection to the next. Semglee® must not be mixed with any other insulin or diluted. Before using the pre filled pen, the instructions for use included in the package leaflet must be read carefully. Contraindications: Known hypersensitivity to the active substances or to any of the excipients. Warnings and precautions: Warnings: Semglee® is not the insulin of choice for the treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hyper or hypoglycaemic episodes, the patient’s adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered. Changes in insulin strength, manufacturer, type, origin, method of manufacture and/or method of administration may result in the need for a change in dose and time of administration. Injection sites and no specific malformative nor feto/neonatal toxicity of insulin glargine. Animal data do not indicate reproductive toxicitiy. The use of Semglee® may be considered during pregnancy, if clinically needed. Careful monitoring of glucose control is essential. Breast feeding It is unknown whether insulin glargine is excreted in human milk. Women may require adjustments in insulin dose and diet. Effects on ability to drive and use machines: The patient’s ability to concentrate and react may be impaired as a result of hypoglycaemia or hyperglycaemia and, for example, as a result of visual impairment. Undesirable effects: Very common: Hypoglycaemia. Common: Lipo hypertrophy, injection site reactions. Uncommon: Lipaesthesia. For rare and very rare undesirable effects, please refer to SmPC.