[GUIDANCE IS OUTDATED AND HAS BEEN WITHDRAWN ON 31 AUGUST 2022.]

Insulin glargine biosimilar (Basaglar)

for the treatment of type 1 and type 2 diabetes mellitus

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendation

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Insulin glargine biosimilar (Basaglar) injection 100 units/ml cartridge for the treatment of type 1 and type 2 diabetes mellitus in adults, adolescents and children aged 6 years or above, where treatment with insulin is required.

Subsidy status

Insulin glargine biosimilar (Basaglar) injection 100 units/ml cartridge is recommended for inclusion on the Standard Drug List (SDL) for the abovementioned indication.

The manufacturer has offered to provide pens for use with the Basaglar cartridge free of charge to all new patients.

SDL subsidy **does not** apply to insulin glargine biosimilar (Basaglar) Kwikpen injection 100 units/ml.

Published on 16 October 2017

Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of Basaglar for the treatment of type 1 and type 2 diabetes mellitus. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from the public healthcare institutions. Published clinical and economic evidence for Basaglar was considered in line with its registered indication.

1.2 The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition
- Clinical effectiveness and safety of the technology
- Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives
- Estimated annual technology cost and the number of patients likely to benefit from the technology

1.3 Additional factors, including social and value judgments, may also inform the Committee's subsidy considerations.

Clinical need

2.1 A biosimilar is a biological therapeutic product with proven similar physicochemical characteristics, biological activity, safety and efficacy to the reference biological product. Basaglar is a biosimilar of insulin glargine (a long-acting insulin analogue) and its reference biologic is Lantus, which is currently listed on SDL for the same indication under evaluation for Basaglar.

2.2 Local clinical experts had limited experience with the use of Basaglar at the time of evaluation, but indicated that it would be a suitable treatment option, especially for new patients, if it was significantly cheaper than Lantus and was associated with substantial cost savings for patients.

Clinical effectiveness and safety

3.1 The Committee discussed the clinical effectiveness of Basaglar. Two phase III randomised, multicentre, parallel-group, non-inferiority trials demonstrated clinical comparability of Basaglar with Lantus in patients with type 1 (ELEMENT 1 trial) and type 2 (ELEMENT 2 trial) diabetes. The primary endpoint in both studies was HbA1c change from baseline to 24 weeks, with a pre-specified non-inferiority margin of 0.4% change in HbA1c. The Committee acknowledged that this margin was in line with the minimal clinically important difference (MCID) of 0.3%-0.4% for anti-hyperglycaemic agents previously accepted by international regulators.

3.2 In both trials, the Committee noted that:

- Basaglar showed comparable efficacy to Lantus in achieving HbA1c reduction at week 24. There were no statistically significant treatment differences in other efficacy measures.
- Safety outcomes were also comparable, including frequency of serious adverse events, hypoglycaemia, weight change and development of insulin antibodies.

3.3 Secondary, post-hoc analyses in a subgroup of patients previously treated with Lantus before enrolment in both ELEMENT trials showed no significant differences in clinical outcomes for patients who switched from Lantus to Basaglar.

Cost effectiveness

4.1 No local or overseas cost-effectiveness studies comparing Basaglar with Lantus were identified. The Committee agreed that a cost-minimisation analysis was appropriate to assess the cost effectiveness of Basaglar, in view of its comparable efficacy with Lantus.

4.2 Following ACE's value-based pricing (VBP) discussions with the manufacturers of Basaglar and Lantus, the Committee acknowledged that the proposed price of Basaglar Kwikpen was higher than the price of Lantus pen. However, the price of Basaglar cartridge was considerably lower than the proposed price of Lantus pen.

Estimated annual technology cost

5.1 The Committee acknowledged that Basaglar cartridge is likely to be prescribed for new patients in the short-term, and most existing patients would remain on Lantus pen given its improved affordability and retained SDL status following VBP discussions.

5.2 No additional annual cost impact to the government was estimated in the first year of listing on SDL due to potential cost savings from patients initiating treatment with Basaglar instead of Lantus. Further savings from existing patients switching from Lantus to Basaglar were also acknowledged by the Committee.

Additional considerations

6.1 As part of their pricing proposal, the manufacturer of Basaglar has offered to provide pens for use with the cartridge free of charge to all new patients.

Recommendation

7.1 On the basis of the evidence available, the Committee recommended insulin glargine biosimilar (Basaglar) injection 100 units/ml cartridge for listing on SDL for the treatment of type 1 and type 2 diabetes mellitus, due to its comparable clinical outcomes to Lantus and acceptable cost-effectiveness at the price proposed by the manufacturer.

7.2 The Committee did not recommend Basaglar Kwikpen injection (pre-filled pen) for listing on SDL, as Lantus pen is already subsidised for patients at a lower price.

About the Agency

The Agency for Care Effectiveness (ACE) is the national health technology assessment agency in Singapore residing within the Ministry of Health. It conducts evaluations to inform the subsidy of treatments, and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore. When using the guidance, the responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at www.ace-hta.gov.sg/about

Head (Evaluation)
Agency for Care Effectiveness
Email: ACE_HTA@moh.gov.sg