

Insulin Glargine

Product:
INSULIN GLARGINE (Lantus®)
10mL vial, 3mL cartridge

Class of drugs:
Insulin

Indication:
Treatment of diabetes mellitus

Manufacturer:
Sanofi-Aventis Canada Inc.

CED Recommendation

The CED recommended that insulin glargine (Lantus) not be listed on the Formulary unless there is a significant price reduction. The CED found that when blood glucose control and major hypoglycemic events are considered together, there is no convincing evidence that insulin glargine (Lantus) is superior to NPH insulin, a lower cost alternative.

Executive Officer Decision

Following the CED's recommendation and a subsequent listing agreement with the manufacturer based on price and utilization, the Executive Officer approved funding for insulin glargine (Lantus) on the Ontario Drug Benefit Formulary.

Status

Funding available through the Ontario Public Drug Programs as a General Benefit on the Ontario Drug Benefit Formulary. (Note: Funding was previously considered through the Exceptional Access Program according to specific criteria.)

Highlights of Recommendation:

- ◆ Insulin glargine (Lantus) is a long-acting insulin analogue indicated for the treatment of Type 1 and Type 2 diabetes mellitus.
- ◆ The Committee noted that the main comparator for insulin glargine (Lantus) is NPH insulin, an alternative intermediate/long-acting insulin listed on the Ontario Drug Benefit Formulary.
- ◆ Available evidence indicates that insulin glargine (Lantus) provides similar efficacy in blood glucose control as NPH insulin in patients with Type 1 or Type 2 diabetes.
- ◆ In terms of safety profile, the overall evidence indicates insulin glargine (Lantus) is comparable to NPH insulin with respect to the risk of severe hypoglycemia (low blood sugar).
- ◆ On measures of overall and nocturnal hypoglycemia, trial results are variable. Some studies reported that insulin glargine (Lantus) reduced the incidence of overall and nocturnal hypoglycemia compared with NPH insulin, while other studies found no significant differences between the two products. Since all of these trials were not blinded and often symptoms were not confirmed with blood glucose measurement, these data are unreliable.
- ◆ Insulin glargine (Lantus) is approximately three times more expensive than NPH insulin.
- ◆ **Overall, the Committee found no convincing evidence that insulin glargine (Lantus) consistently led to an improved blood glucose control with an accompanying equal or lower incidence of major hypoglycemia compared with NPH insulin. As such, the Committee noted that the significant price premium for insulin glargine (Lantus) over NPH insulin is not justified.**

Background:

Diabetes mellitus is a disease that occurs because the pancreas does not produce enough insulin (a hormone) and/or the cells in the body do not respond to insulin properly to help control the level of glucose (sugar) in the blood. With Type 1 diabetes, the body does not make insulin. With Type 2 diabetes, the body does not make or use insulin well. Normally, when the body digests food, glucose enters the bloodstream as a fuel source, and insulin moves glucose from the bloodstream into cells. In diabetes, high levels of glucose remain in the bloodstream resulting in long-term health complications if left untreated. The long-term consequences of poorly treated diabetes include heart attacks, strokes, blood vessel disease, nerve damage (neuropathy), kidney disease, blindness and foot infections/limb loss.

Treatment for diabetes always begins with and includes diet and lifestyle modifications (e.g. weight loss, exercise). Patients with Type 1 diabetes are managed with insulin. Patients with Type 2 diabetes often require oral medications and/or insulin.

Insulin glargine (Lantus) is a long-acting (basal) insulin analogue indicated for the management of Type 1 and Type 2 diabetes mellitus. Patients use it once daily, usually in combination with short or rapid-acting insulin.

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Detailed Discussion:

- ◆ The Committee considered the funding of insulin glargine (Lantus) on several occasions, most recently in May 2007.
- ◆ The Committee reviewed all high quality evidence available, including unpublished trials. Twenty randomized controlled studies that compared insulin glargine (Lantus) to NPH insulin in patients with Type 1 or Type 2 diabetes were considered.
- ◆ The studies did not find significant differences between insulin glargine (Lantus) and NPH insulin on hemoglobin A1c levels (a measure of blood glucose control).
- ◆ Furthermore, no significant differences between insulin glargine (Lantus) and NPH insulin were observed with respect to the incidence of severe hypoglycemia.
- ◆ Inconsistent results were found for incidence of overall and nocturnal hypoglycemic events. For nocturnal hypoglycemia, 4 of 6 trials in Type 1 diabetes showed a lower incidence with insulin glargine (Lantus) compared with NPH insulin, but two large trials failed to observe this difference after 1 to 7 months of follow-up. In Type 2 diabetes, 6 of 8 studies found that fewer patients on insulin glargine (Lantus) had nocturnal hypoglycemic events compared to patients on NPH insulin, and 2 studies did not detect a significant difference between the two products. The overall incidence of hypoglycemia was reduced in 3 of 7 trials for patients with Type 1 diabetes and in 4 of 8 trials in patients with Type 2 diabetes. Since all of these trials were not blinded and often symptoms were not confirmed with blood glucose measurement, firm conclusions could not be drawn from these study results.
- ◆ Insulin glargine (Lantus) is approximately three times the cost of NPH insulin.
- ◆ Overall, the Committee noted that when hemoglobin A1c levels and major hypoglycemic episodes are considered together, there is no convincing evidence that insulin glargine (Lantus) is superior to NPH insulin. The Committee did acknowledge that there is some evidence that insulin glargine (Lantus) may reduced the incidence of nocturnal and overall hypoglycemia. However, the significant price premium for insulin glargine (Lantus) could not be justified. The Committee recommended that insulin glargine (Lantus) not be listed on the Formulary unless there is a significant price reduction.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended in October 2006 that insulin glargine (Lantus) not be listed.



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