

Recommendations and Reasons

Committee to Evaluate Drugs (CED)

Insulin glargine

Product:

Insulin glargine (Lantus SoloStar®)
100 IU/mL, 3mL pre-filled pens for
injection

Class of drugs: Insulin analogue

Indication:

Treatment of diabetes mellitus

Manufacturer:

Sanofi Aventis Canada Inc.

CED Recommendation-

The CED recommended that insulin glargine (Lantus SoloSTAR®) 100 U/mL prefilled disposable pen be listed as a General Benefit on the ODB Formulary, provided the format was added to the current listing agreement for insulin glargine vial and cartridge to manage costs.

Executive Officer Decision

Based on the CED's recommendation and a subsequent listing agreement with the manufacturer based on cost and utilization, the Executive Officer decided to list insulin glargine (Lantus SoloStar®) pre-filled disposable pen on the ODB Formulary.

Status

Funding through the Ontario Public Drug Programs as a General Benefit on the ODB Formulary.

Highlights of Recommendation:

- ◆ Insulin glargine is a long-acting type of insulin analogue for the treatment of Type 1 and Type 2 diabetes mellitus.
- ◆ Insulin glargine is available as 100U/mL in the 10mL vial and 3mL cartridge formats, which are both listed on the ODB Formulary as a General Benefit. The pre-filled disposable pen contains 3mL of insulin glargine 100U/mL.
- ◆ Patients have a preference for the pre-filled disposable pen format based on non-comparative observational studies and a manufacturer based survey.
- ◆ Insulin glargine costs more per unit in the pre-filled pen format compared to the vial format but is the same price as the cartridge format. The CED noted that there is a price premium of the pre-filled pen format compared to the vial format for other listed insulin products.
- ◆ **Overall, the CED acknowledged that patients have a preference due to the ease of administration for the pre-filled pen format over other formats. As such, the CED recommended that insulin glargine pre-filled disposable pen be listed on the ODB Formulary similar to the insulin glargine vial and cartridge.**

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 at all. With Type 2 diabetes, the body does not make enough insulin 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 outcomes of poorly treated diabetes include heart attacks, strokes, blood vessel disease, nerve damage (neuropathy), kidney disease, blindness and foot infections/limb loss.

Patients with Type 1 diabetes are managed with insulin. Patients with Type 2 diabetes often require oral medications and/or insulin if weight loss and dietary changes on their own do not lead to improved blood glucose control.

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

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Detailed Discussion:

- ◆ Insulin glargine is now available in a 3mL pre-filled, ready-to-use, disposable pen in addition to the 10mL vial and 3mL cartridge for use in the reusable pen injector.
- ◆ According to the manufacturer, the pre-filled pen offers a 25-percent greater maximum dosing capacity than other similar insulin pens, requires less time for health professionals to train patients how to use it, requires less physical strength and dexterity to use, and provides an accurate and reliable dose, minimizing the risk of hypoglycemia or hyperglycemia. However, there are no clinical data demonstrating that the pre-filled pen requires less training time or reduces dosing errors.
- ◆ Observational surveys of technical aspects and patient perception suggest acceptable or more favourable performance and preference for the pre-filled disposable pen when compared to alternate formats.
- ◆ The safety and efficacy of insulin glargine in the pre-filled disposable pen format would be similar to insulin glargine in the vial and cartridge formats since all formats contain the same concentration (100U/mL) of insulin glargine and the 3mL cartridge in the pre-filled disposable pen is identical in all aspects to the existing 3mL cartridge for the reusable pen injector.
- ◆ Insulin glargine in the pre-filled disposable pen format costs more on per unit basis than in the vial format, but costs the same per unit as the 3mL cartridge. The CED noted that a price premium also exists on other insulin products available in the pre-filled pen format over the vial format.
- ◆ **Overall, the CED noted that based on observational studies, patients have a higher preference and the perception of ease of administration for the pre-filled pen format over the vial and cartridge formats.**

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee (CEDAC) did not review this product.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Hepburn Block, 9th Floor

80 Grosvenor Street, Queen's Park

Toronto, Ontario M7A 1R3

or click: <http://www.health.gov.on.ca/>

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