

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

October 4, 2021

ISSUE No.
1634

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IN BRIEF

Semglee – Insulin Glargine Interchangeable with Lantus

Insulin glargine-yfgn (*Semglee* – Viatrix), a follow-on insulin glargine product, has now received interchangeability status with the reference product *Lantus* from the FDA. It is the first biosimilar insulin product to receive this designation in the US. Now a pharmacist can substitute *Semglee* for *Lantus* as a lower-cost alternative without permission from the prescriber.

A biosimilar is a biologic product that is highly similar to and has no clinically meaningful differences from the FDA-approved reference product. For a biosimilar to be approved as an interchangeable product, the manufacturer must conduct clinical trials to prove that the results will be the same if the patient switches between the reference product and the biosimilar.¹ In an open-label trial (INSTRIDE 3) in patients with type 1 diabetes, switching between *Lantus* and *Semglee* resulted in similar efficacy, safety, and immunogenicity.²

Basaglar, another follow-on insulin glargine product similar to *Lantus* in composition, strength, and biological properties, has produced similar clinical results, but does not have biosimilar or interchangeability status.^{3,4}

Table 1. Insulin Glargine Products

Drug	Concentration	Formulations	Cost ¹
<i>Lantus</i> (Sanofi)	100 units/mL	10 mL vials	\$283.60
		3 mL <i>SoloStar</i> ²	85.10
<i>Toujeo</i> (Sanofi)	300 units/mL	1.5 mL <i>SoloStar</i> ²	129.60
		3 mL <i>Max SoloStar</i> ²	259.20
<i>Basaglar</i> (Lilly) ³	100 units/mL	3 mL <i>KwikPen</i> ²	65.30
<i>Semglee</i> (Viatrix) ⁴	100 units/mL	10 mL vials	98.70
		3 mL prefilled pen	29.60

1. Approximate WAC for one 10-mL vial or one pen. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly, September 5, 2021. Reprinted with permission by First Databank, Inc. All rights reserved. ©2021. www.fdbhealth.com/drug-pricing-policy.
2. Prefilled disposable pen.
3. Follow-on product similar to *Lantus*, but does not have biosimilar or interchangeability status with *Lantus*.
4. Biosimilar product interchangeable with *Lantus*.

The manufacturer of *Semglee* will have exclusivity for 12 months before the FDA can designate another biosimilar as interchangeable with *Lantus*. ■

1. FDA Guidance Document. Clinical immunogenicity considerations for biosimilar and interchangeable insulin products. November 2019. Available at: <https://bit.ly/2VYOJ9I>. Accessed September 13, 2021.
2. TC Blevins et al. Efficacy and safety of MYL-1501D versus insulin glargine in people with type 1 diabetes mellitus: results of the INSTRIDE 3 phase 3 switch study. *Diabetes Obes Metab* 2020; 22:365.
3. In brief: *Semglee* – a new insulin glargine for diabetes. *Med Lett Drugs Ther* 2021; 63:14.
4. Another insulin glargine (*Basaglar*) for diabetes. *Med Lett Drugs Ther* 2017; 59:3.

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