

Did You Know...

The Food and Drug Administration's (FDA) first approved interchangeable biosimilar insulin product, Semglee, will be covered on the Express Scripts National Preferred Formulary beginning January 1, 2022, and *Lantus will no longer be a covered insulin glargine product*. The Duke Health Plans including Duke Basic, Duke Select, and Duke BCBS plans (Duke Care and Duke Options) utilize the Express Scripts National Preferred Formulary.

What is Semglee?

Semglee is a biosimilar insulin glargine (YFGN) product that can be auto substituted at pharmacies for its reference product, Lantus (insulin glargine) **without a new prescription**– similar to how a pharmacy can substitute atorvastatin for Lipitor. A biosimilar is a biological product that is similar to a reference product based on key characteristics including purity, structure, bioactivity and immunogenicity.^{1,2}

	Semglee (yfgn)	Lantus	Basaglar
Is this product allowed for auto-substitution at pharmacies?	Yes, this product is interchangeable.	Yes, this product is interchangeable.	No , this product is not interchangeable.
Product formulations and delivery devices	Vial and Pen-injector	Vial and Pen-injector	Pen-injector only
Will this product be preferred on the Express Scripts National Preferred Formulary?	Yes	No – Will be EXCLUDED	Yes

What action do prescribers need to take?

This is FYI only. For members covered under Duke Basic, Duke Select and Duke Blue Cross Blue Shield plans, **you do NOT need to rewrite prescriptions for insulin glargine. Semglee is an interchangeable insulin glargine product and can be substituted at pharmacies as above.** You may be asked to educate your patients on the differences between products should they have questions.

How will this impact my patients?

Patients may have questions regarding the name/product change but the clinical efficacy of Semglee is similar to that of Lantus, hence patients should not experience differences with the product switch. The Semglee delivery device is similar to the innovator product's delivery device. Encourage patients to ask their pharmacist any questions they may have regarding Semglee administration.

In a rare situation where a patient is unable to use Semglee due to a clinical reason, a clinical exception process is in place. A provider or their staff may call 1-800-753-2851, provide the clinical rationale, and request coverage. The rationale will be reviewed by Express Scripts and a coverage determination will be made accordingly.

¹Commissioner, Office of the. "FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes." FDA. FDA, July 30, 2021. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes>.

²Research, Center for Drug Evaluation and. "Biosimilars." FDA. FDA, July 27, 2021. <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>.