

Semglee Product Availability

In 2021 the FDA approved two biosimilar and interchangeable medications for replacement of the existing Semglee product. The manufacturers of Semglee (primarily Mylan/Viatris) then began phasing out Semglee and replacing it with the biosimilar products. One replacement product is branded, Semglee (insulin glargine-yfgn), and one is a generic, Insulin Glargine (insulin glargine-yfgn).

The changes were specific to Semglee, the Toujeo products and rapid-acting insulin products are unrelated and did not experience formulary or production changes in 2021. It is also useful to note that the Semglee changes occurred without much advance notice. The changes were publicized beginning around September and Mylan announced in November that it would phase out the existing products by calendar year-end. With that rapid transition there were some shortages associated with distribution, production, and market demand—unfortunately none of which were unique to or under the control or influence of the University’s health plan. Participants in other health plans experienced these same disruptions.

When EBRx and this office began to receive notice of the shortages, we first took steps to ensure coverage of alternative insulin products was available in the formulary and approved exceptions for other available insulin products as needed. Then as the supplies began to stabilize the Pharmacy Advisory Committee took action to prefer the equivalent and less expensive generic medication on the formulary.

And prior to the move to biosimilar products, some participants will have experienced a UAS formulary change from Lantus to Semglee. Users were notified and grandfathered for continued Lantus use until July 2021.

In summary, for 2021 and into January 2022 members may have experienced changes in insulin products and costs associated with:

- The University’s formulary change from Lantus to Semglee
- The manufacturer changes in Semglee products
- Limited availability of the existing and new products due to distribution and supply issues
- The University’s formulary change to generic Semglee
- The use of coupons by members and pharmacies offsetting the standard plan member copayment responsibilities
- And members reaching the Rx OOP maximum in 2021 (typically not occurring until the last half or quarter of the calendar year) and returning to the standard copayment for January 2022.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes>

<https://www.healthline.com/diabetesmine/new-low-cost-interchangeable-semglee-insulin>

<https://newsroom.viatris.com/2021-11-16-Viatris-and-Biocon-Biologics-Announce-Launch-of-Interchangeable-SEMGLEE-R-insulin-glargine-yfgn-Injection-and-Insulin-Glargine-insulin-glargine-yfgn-Injection>