Biosimilar insulin glargine utilization in Medicaid: How interchangeability and other policy factors affect variation across states

Kaitlyn Hanson, BA[1]; Joshua Devine, PharmD, PhD[2]; Dooyoung Lim, PhD[2];

[1]Des Moines University College of Osteopathic Medicine; [2] Des Moines University College of Health Sciences

INTRODUCTION

- The Biologics Price Competition and Innovation Act of 2009 established a pathway for drugs highly similar to existing biologics, termed “biosimilars”, to be approved by the Food and Drug Administration and reach the market more quickly than their originator biologic counterparts.
- This legislation included a provision where manufacturers could request an “interchangeable” designation, which, when allowed by state regulations, would enable pharmacists to substitute the biosimilar product for the reference product, without seeking authorization from the prescriber
- In July 2021, Semglee, an insulin glargine product biosimilar to Lantus, became the first biosimilar to receive this “interchangeable” designation.
- In the context of increasing insulin prices, the market entry of this product may present an opportunity to improve access to this medication.

STUDY OBJECTIVE

- This study examined the usage of Semglee and all other non-interchangeable insulin glargine biosimilars among the Medicaid population in all fifty U.S. states and D.C.
- This project explored the relationship between policy and structural factors and usage of insulin glargine biosimilars.0.

METHODS

- Medicaid State Drug Utilization Data were extracted for all insulin glargine products between 2020-2022.
- Market shares were defined as the proportion of units for insulin glargine biosimilar products reimbursed in each state and quarter.
- State laws regarding pharmacist substitution were classified into two categories: states that allow automatic substitution for interchangeable biosimilars and states that do not allow automatic substitution or have not enacted legislation on this issue.
- State Medicaid program structure was organized into four groups: fee-for-service only (FFS); states with managed care organizations (MCOs) subject to statewide PDLs; states with MCOs not subject to statewide PDLs; and states with MCOs where the drug benefit was carved-out to FFS.
- Kruskal-Wallis tests were used to compare the market shares of biosimilar insulin glargine across different groups of states based on their laws, program structures, and PDLs.

Figure 1. Mean Quarterly Market Share by State for Biosimilar and Interchangeable Insulin Glargine in 2022

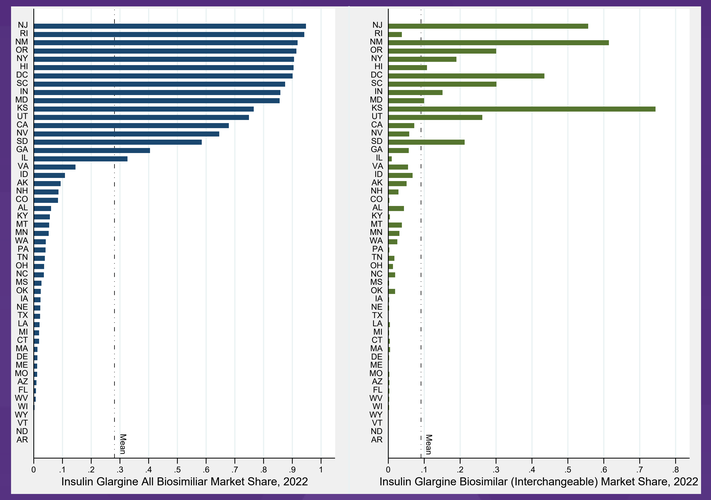
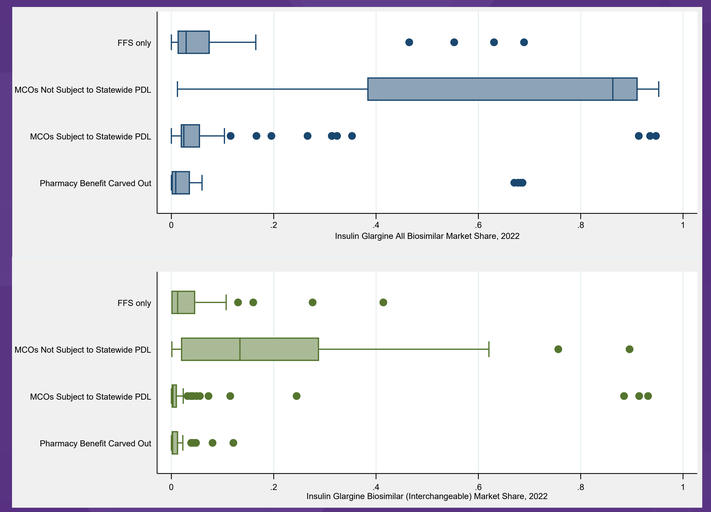


Figure 2. Stratified analysis comparing mean quarterly biosimilar market shares for insulin glargine (IG) by state Medicaid program characteristics in 2022



RESULTS

- Across state Medicaid programs, mean quarterly market shares for biosimilar insulin glargine was 28.7% (SD = 36.2%, range = 0% - 95%) in 2020, 25.9% (SD = 35.8%, range = 0% - 95%) in 2021, and 28.1% (SD = 36.9%, range = 0% - 95%) in 2022.
- Interchangeable biosimilars for insulin glargine (first available in Q4 2021) averaged 9.1% (SD = 17.9%, range = 0% - 93%) during 2022.
- Use of interchangeable insulin glargine was higher among states that lacked regulatory authority to automatically substitute for interchangeable biosimilars vs. states with that authority; 13% vs. 8.8%; $p < 0.01$).
- Market shares of interchangeable insulin glargine were also higher among state Medicaid programs with MCOs that were not subject to statewide PDLs for insulin glargine (18.9%) as compared to those with MCOs subject to statewide PDLs (5.1%), fee-for-service only (4.3%), or states with the pharmacy benefit carved out (1.6%; $p < 0.01$).

CONCLUSIONS

- Use of all biosimilar insulin glargine products among state Medicaid programs increased following the entrance of an interchangeable product, however, the interchangeable product did not dominate in the majority of states.
- The greater adoption of interchangeable biosimilar products in states where pharmacists lack automatic substitution authority may indicate that a lack of interchangeability is not the greatest barrier in increasing biosimilar use.
- Coupled with the dramatically greater uptake of all biosimilars, including interchangeable products, among programs dominated by MCOs not subject to a statewide PDL suggests that state agencies have a different incentive structure than private entities, possibly related to the supplemental rebates they receive from the original biologic manufacturers.
- As more biosimilars enter the market there exists great potential for decreased spending and improved access to medications for patients. Continued examination of the factors impeding biosimilar adoption may allow for continued improvements in these realms.

LIMITATIONS

- National Drug Codes with fewer than 11 prescriptions in a state are excluded from publicly available Medicaid State Drug Utilization Data, in keeping with patient privacy regulations.
- Data regarding manufacturer rebates to state Medicaid agencies is not publicly available, preventing the analysis of what may be an important variable influencing the patterns our project revealed.