What are Biosimilar Insulins?

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"Wow! Look! They gave me six vials of insulin! FOR FREE! I paid nothing!" I vividly remember the first time in my adult life that I didn't have to worry about the amount of insulin I had through my insurance. I came home and told my husband that. His reply was so poignant and true, "that's like me being excited for oxygen." I remember being afraid to leave the pharmacy in case they were going to mail me a multi-thousand-dollar bill later and asked the pharmacist twice before leaving, "Are you sure?" And I remember her understanding my fear.

Everybody has been talking about insulin prices in the U.S. throughout the last few years. The cost of insulin has caused families and people living with diabetes to ration their insulin supplies and cost some their lives due to this rationing.[1,2] Only after massive public outcry and pressure from lawmakers, the three manufacturers of insulin announced that they will have a $35 monthly cap for people with private health insurance in the U.S.[3] There still is not a "generic" insulin, but what we do have are biosimilars.

Why are there no generic insulins?

The way that insulins are patented allow insulin companies to maintain the patents on insulin molecules to prevent generics from being produced.[4] Since the insulin molecules are slightly changed, the patents are then extended with the slight change. This has been supported by the complex and for-profit U.S. Healthcare System throughout the last few decades.[5] This is a multi-layered issue that, of all places, is summarized well by comedian Hasan Minhaj.[6]

What is a Biosimilar?

For a medication to be considered "biosimilar," it has to have the same effect as the original product with an almost identical structure.[7] Generic medications have more simple chemical structures, while biosimilars are less defined and more complicated. Insulin is complex because it is a synthetic biological hormone, making it more difficult and expensive to make, and adding to the challenge in generics.

The first biosimilar insulin was approved very recently – 2021 – and more continue to be brought to market. For long-acting insulin, there are Semglee and Basaglar, which are biosimilars for insulin glargine. For Rapid acting, there is Admelog (insulin lispro). The goal of having these options was to have lower cost insulins for people living with diabetes and to help reduce the ever-growing problem of insulin rationing.

Interchangeable versus Biosimilar

Of course, it's more complicated than just biosimilars…for something to be considered interchangeable, it has to meet even more strict requirements than biosimilars.[7] This means that if you take an interchangeable insulin, it should work exactly how the other insulin works. Semglee was the first insulin to achieve interchangeable status. When an insulin is considered interchangeable, pharmacists can switch the prescriptions to the biosimilar and help save people with diabetes money.

What does this mean for PWD?

The FDA's goal in creating pathways for insulins to have biosimilar options was focused on cost-savings for people with diabetes. However, according to a study from the American Journal of Managed Care in November, 2022, despite a large increase in use of

Basaglar compared to Lantus, there were not significant cost savings for the people with diabetes.[8] The data that the study reviewed showed that the issue was insurance companies were reimbursing less to patients for the Basaglar than they would for other insulins, leading to higher out-of-pocket costs for many people.

For the brand-name insulins, there are many opportunities to lower the out-of-pocket costs such as manufacturer's coupons and services such as GoodRx. These do not exist for biosimilars, which means they may not be the most cost effective, depending on the insurance plan coverage. The reimbursement was not evaluated for public health insurance – Medicaid and Medicare programs.

Additionally, the concept of interchangeability and switching is something that is a bit of a grey area. (Just what we need in diabetes, more grey area…) Even with the brand-name biologic insulins, there are variabilities in people with diabetes and in preparations, batches, and vials of insulins.[9] Then you add the layers of difference between what is considered "biosimilar" versus "interchangeable," consider what the PBM's and insurance companies will even let you have as a person with diabetes, and you realize it's like licking your finger and holding it into the air to see which way the wind is blowing that determines your access to specific insulins.

Overall, the addition of biosimilars into the market for people with diabetes should prove beneficial over time. It makes me optimistic that people are working towards a common goal of increasing access and lowering the cost of insulin for us "consumers." Since I literally depend on insulin to survive, it's something near and dear to my heart, my pancreas, my body…all of it. I'm looking forward to the continued development of both new and "old" insulins for everyone with diabetes.

For more information on patient assistance programs, check out CWD's Page on Affordable Access to Insulin.

References:

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