Bringing Biosimilars to Market: Why Naming and Coding Matter

At Pfenex, we are committed to growing the biosimilar market in the U.S. so more patients can gain access to these life-changing drugs.

Back to Basics: What is a Biosimilar?

Biosimilars are comparable to generic drugs, except that they are based on biologics—drugs produced from a living organism—rather than pharmaceuticals, which are made from synthetic chemicals. Both biosimilars and the biologics upon which they are based treat some of the most common but complex and life-threatening diseases – such as diabetes, arthritis, and cancer— with incredible results. At Pfenex, we are committed to growing the biosimilar market in the U.S. so more patients can gain access to these life-changing drugs.

Breaking it Down: Naming and Coding a Biosimilar

As biosimilars gain a stronger foothold in the U.S. healthcare market, there are two key issues awaiting necessary legislative or regulatory clarity. First, there is the question of whether biosimilars should use the same International Nonproprietary Name (INN) as their respective reference products. Second, the U.S. has yet to define a decisive system for biosimilars coding within the Healthcare Common Procedure Coding System (HCPCS) with respect to medical reimbursement and insurance.

Below, we dive into how regulatory agencies should move forward on these issues to best support biosimilar development in the U.S.

NAMING

To support the use of biosimilars in the United States, it is our position biosimilars should be given the same INN as the reference product. Using different names for biosimilars would only make it more difficult for patients and consumers to have access to these life-changing medicines. And we have compelling examples to demonstrate the case for same names – both the European and Australian markets, where biosimilars have been successfully in use for years, allow the same INN for biosimilars and the reference product, at no detriment to patient safety.

Bottom Line: We support same names for biosimilars and the reference product, as it will encourage market uptake, ensure patient safety and avoid confusion among providers and dispensers.

CODING

Additionally, it is our position that biosimilars should have the same HCPCS code as the reference product. Having the same code for the reference and biosimilar products creates a simpler, less error-prone system, one which many physicians are already accustomed. The other key aspect of having the same coding for the reference product and the biosimilar revolves around cost effectiveness and increased access for patients to these potentially lifesaving drugs. Using the same code will foster competition in the marketplace, and provide an even playing field between the reference product and the biosimilar.

Bottom Line: We support same codes for biosimilars and reference products as it will decrease costs and ensure more patients access to these important products by giving healthcare providers a choice to administer the biosimilar within the same reimbursement model.