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 (also known as reference products) 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 mature in the U.S. market, guidelines for naming and coding of biosimilars will play an integral role in their uptake by third-party payers, physicians, and patients.

Below, we look at how regulatory agencies should approach International Nonproprietary Names (INNs) and reimbursement within the Healthcare Common Procedure Coding System (HCPCS) to best support biosimilar development in the U.S.

NAMING

To support the use of biosimilars in the U.S., it is our position biosimilars should be given the same INN as the reference product. The current proposal from the FDA to add a suffix to traditional INNs stands to slow growth of the biosimilar market, stifle cost-reduction opportunities, and reduce patient access. We have compelling examples to demonstrate the case for same names – both the Europe biosimilar markets have successfully used the same INN for years and continue to maintain high standards of drug tracking and patient safety.

Just recently, 21 leading industry and patient care groups – including CVS Health, Express Scripts, Kaiser Permanente, Pharmaceutical Care Management Association, and Rite Aid – as well as the Federal Trade Commission (FTC) also expressed their support for a system that supports the same INNs for biosimilars and the reference product.

CODING

It is our position that the decision to group all biosimilars to a single reference product under the same Healthcare Common Procedure Coding System (HCPCS) code, with the reference product maintaining a separate code does not support the development of a robust biosimilars market. We remain concerned that the current proposal will hinder biosimilar uptake and discourage innovation by not establishing a reimbursement model for biosimilars based on a product's unique average sales price (ASP).

As defined by the U.S. Food and Drug Administration (FDA), biosimilars are proven to have no clinically meaningful difference in safety, purity, and potency from a reference product. Because biosimilars are comparatively developed to a given reference product, rather than other biosimilars, it is illogical to tie reimbursement to other molecular entities to which the biosimilar was not initially compared. As such, we believe each product should have an individual HCPCS code, which is in accordance with the Biologics Price Competition and Innovation Act (BPCIA). It is our believe that such a policy will better ensure innovation and drive market entry, ultimately allowing the U.S. to realize the full promise of biosimilars.

We Aren't Alone: What Others Are Saying

"As health care stakeholders, we are concerned that adding distinguishable suffixes to every biologic, biosimilar, and interchangeable biologic will confuse both providers and patients, and have the unintended effect of slowing the uptake of these cost saving products."

- Statement from Blue Cross and Blue Shield Association, CVS Health, Express Scripts, Kaiser Permanente, Pharmaceutical Care Management Association, Rite Aid, and 15 other leading industry and patient care groups.

"An example from Europe suggests that biosimilars with distinct nonproprietary names are less commercially successful than biosimilars with the same nonproprietary name as the reference biologic."

- Statement from the Federal Trade Commission (FTC)