Biosimilar Substitutions

Posted on Wednesday December, 11th 2013 at 11:12 am

Biosimilar substitution is an evolving issue that will affect dermatology. Why is this an issue? Biosimilars are medications that can be compared to the "generics" of standard medications. The Biologics Price Competition and Innovation Act of 2009, part of the Affordable Care Act, was conceived by the US Senate with the purpose of creating a balanced pathway for the introduction of biosimilars. Innovation and consumer interests were the foremost concerns. The full Act can be read here; http://www.hhs.gov/healthcare/rights/law/title/vii-improving-access-to-innovative.pdf

The White House explains the purpose of the Act:

"The Act promotes innovation and saves consumers money. It ends anti-competitive behavior by drug companies that keep effective and affordable generic drugs off the market. It extends drug discounts to hospitals and communities that serve low-income patients. And it creates a pathway for the creation of generic versions of biological drugs so that doctors and patients have access to effective and lower cost alternatives." The National Psoriasis Foundation (NPF) welcomed the creation of a regulatory pathway for new, safe and effective biosimilars, adding choice and additional treatment options for the psoriasis and psoriatic arthritis community (www.psoriasis.org). The key phrase in that statement is "safe and effective". The concern is that these drugs may be similar, but may not be chemically the same. This difference, without diligent science, could make a world of difference for our patients. These medications are not available in the United States yet, but the dermatology community needs to keep an eye on this issue and be prepared to act in the best interests of our patients.

One major concern is that the patient and provider will be taken out of the decision-making process and may not be notified that they are getting a medication that is different from what was prescribed. The NPF has 7 criteria they are hoping will be met. These criteria are listed on the NPF website in the article found here: https://www.psoriasis.org/research/foundation-medical-board-issues-statement-on-biosimilar-substitution . The NPF has a position statement that can be found at https://www.psoriasis.org/about-psoriasis/treatments/statement-on-biosimilars.

The American Academy of Dermatology has taken a position as well. It can be found at: http://www.aad.org/Forms/Policies/Uploads/PS/PS-Therapeutic%20Substitution.pdf.

Biosimilars are not exact replicas of biologics and should be treated as unique medications with totally different names and safety data. As a provider one must look at the safety data and side effects of each biosimilar medication carefully. It is extremely important that the provider is able to give permission to the pharmacy to change this class of medications to the biosimilar at the pharmacy level and that it is recorded in the patient's medical record as the biosimilar. It is imperative that the patient and provider are informed of the change (biosimilar instead of biologic medication) that is dispensed to the patient at the pharmacy/point of sale and that there is a permanent record of the change in the patient's medical record.

Biosimilars are coming to the United States. Dermatology nurses and nurse practitioners must be aware of the potential issues and be ready to advocate on behalf of our patients. A biosimilar for infliximab has been approved in Europe. You can read more here;
http://www.pharmatimes.com/article/13-09-12/Hospira_all_set_to_launch_Remicade_biosimilar_in_Europe.aspx

This issue may come up soon in your state. We encourage you to learn more about it and be ready because our patients will have questions and they will turn to nurses for answers they can understand.