

Comment on “Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics”



To the Editor: We read with interest the recently published “Joint [American Academy of Dermatology-National Psoriasis Foundation] AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics,”¹ and we recognize the importance of this update to the 2008 AAD psoriasis guidelines.

We write to clarify 1 point in the guidelines about tumor necrosis factor α (TNF- α) biosimilars. In the section entitled TNF- α biosimilars, the guidelines state the following:

“TNF- α biosimilars approved by the [Food and Drug Administration] (FDA) should be considered similar to the reference branded version of the drug and therefore interchangeable. An interchangeable product means that the FDA has concluded that it may be substituted for the reference product without consulting the prescriber. The aforementioned guidelines/recommendation should apply similarly to biosimilar versions of TNF- α inhibitors.”

The first sentence is an incorrect presentation of the 2 distinct regulatory pathways for biosimilars and interchangeable products. A biosimilar cannot be considered an interchangeable product unless an appropriately designed interchangeability study has been conducted and has proven that the interchangeable product will produce the same

clinical result as the original product in any given patient, and that switching or alternating back-and-forth between the interchangeable biologic and the original product would not cause any changes in safety or efficacy.

To date, no FDA-approved TNF- α biosimilar has demonstrated interchangeability; therefore, substitution cannot be automatic and should require a discussion between the provider and patient.

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REFERENCE

1. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4): 1029-1072.

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