# LAC+USC MEDICAL CENTER POLICY



| Subject: **BIOSIMILARS** | Original Issue Date: 5/18/18 | Policy # **955** |
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| | Supersedes: 5/18/18 | Effective Date: 8/16/21 |

| Departments Consulted: | Reviewed & Approved by: | Approved by: |
|---|---|---|
| Pharmacy & Therapeutics Committee | Attending Staff Association<br>Executive Committee<br>Senior Executive Council | (Signature on File)<br>Chief Medical Officer |
| | | (Signature on File)<br>Chief Executive Officer |

## PURPOSE

A. The complexity of characterizing and manufacturing biologic medications creates an inherent difficulty in establishing absolute equivalence between two or more products.

B. A proposed biologic medication may be approved as a “biosimilar” or an “interchangeable biosimilar” by the FDA. These designations are published by the FDA in the Purple Book.

C. Use of biosimilars and interchangeable biosimilars has the potential to reduce medical expense and improve access to care.

## POLICY

A. Upon receipt of a medication order or prescription for a biologic medication, the pharmacist may automatically substitute one of the following, if available:
   a. An interchangeable biosimilar
   b. A biosimilar for which automatic substitution has been deemed appropriate by the medical center

B. The Purple Book will be used to identify interchangeable biosimilars. The pharmacy will establish and maintain a list of other biosimilars for which automatic substitution has been deemed appropriate by the medical center.

C. The prescriber may write “Do not substitute” on the medication order or prescription.

## DEFINITIONS

- Biologic medications: medications often derived from living systems and consisting of complex molecules or a mixture of molecules
- Biosimilar: a biologic medication that is highly similar to and has no clinically meaningful differences from an existing reference product

- Interchangeable biosimilar: a biosimilar medication that is approved by the FDA as a substitute for an existing reference product without involvement of the prescriber

## RESPONSIBILITY

Pharmacy Department

## REFERENCES

- California Code Business and Professions Code 4073.5. Accessed February 2018.
- Considerations in demonstrating interchangeability with a reference product: guidance for industry (draft). U.S. Food and Drug Administration. January 2017.
- Scientific considerations in demonstrating biosimilarity to a reference product: guidance for industry. U.S. Food and Drug Administration. April 2015.

## REVISION DATES

August 16, 2021