

# Formulary Management of Biosimilars

## description

formulary, biosimilar, biosimilars

## Policy Number

CPM.0310

## Purpose

To establish a pathway for biological products to be managed by the Pharmacy Department and Pharmacy and Therapeutics (P&T) Committee.

## Definitions

**Biological Product** - Large, complex molecules produced through biotechnology in a living system used to diagnose, prevent, treat or cure a disease.

**Biosimilar Product** - Biological product which is highly similar to a reference product in terms of safety, purity and potency, and has no clinically meaningful differences.

**Formulary Product Line Item** - Products with the same active pharmaceutical ingredient as a medication already on formulary but either a different dosage form, formulation, or a separate Epic record. Line item requests may be made by any health care professional and are managed by the Department of Pharmacy.

**Interchangeable Biosimilar Product** – An FDA-assigned designation where a biosimilar is expected to produce the same clinical results as the reference product where risk in terms of safety or diminished efficacy when switching between the biosimilar and reference product is not greater than the risk of using the reference product alone. Interchangeable products can be found in the [Purple Book](#) and may be substituted for the reference product without notifying the provider as outlined in the Biologics Price Competition and Innovation Act.

**Reference Product** - Biological product already FDA-approved and which proposed biosimilars are compared with.

**Therapeutic Interchange** - A therapeutic interchange is a substitution of a nonformulary medication with a formulary medication intended to provide similar therapeutic efficacy and safety. For the purposes of this policy, a therapeutic interchange may also specify substitution of a formulary, nonpreferred biological product to a formulary, preferred biological product.



of an adequate supply of the medication. The medication shall be obtained following the pharmacy Drug Procurement Procedure.

4. Therapeutic interchange inclusion criteria:

- a. Therapeutic interchange of biological products applies to all orders for medications that will be administered in a Froedtert Health location or provided through Froedtert Health Home Infusion.
- b. Use of a therapeutic interchange of biological products requires the patient to have an established relationship and active care management with a Froedtert & Medical College of Wisconsin Provider.

5. Therapeutic interchange exclusion criteria:

a. Therapy initiations:

- i. The therapeutic interchange does not apply if a specific biological product is necessary based on prior 2014

## Reference Details

<https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products>

## Issuing Authority

FMLH Policy Committee

## Distribution

Froedtert Memorial Lutheran Hospital

## category

Clinical (formerly Multidisciplinary),