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.

Policy

1. Prior to addition of a biosimilar to *Froedtert Health Formulary*, the reference biological product will be subject to a full review for formulary addition and P&T Committee vote per the *Formulary Management and P&T Committee Functions Policy (CPM.0217).*

a. Formulary review will include evaluation of the reference product and all approved and available biosimilar products.

i. If outpatient use of the requested drug is expected, consideration will be given to add all reference and biosimilar products to formulary with the selection of a single preferred product (may be reference or biosimilar).

ii. If no outpatient use is expected, a single biological product will be chosen for formulary addition (may be reference or a biosimilar).

2. When a reference biological has biosimilars available and more than 1 of these products is part of *Froedtert Health Formulary*, a preferred formulary agent will be selected by the System P&T Committee.

a. The preferred formulary agent may be either a reference or biosimilar product and will be selected based on an evaluation of safety, efficacy, approved indications, biosimilarity/switch studies (when applicable), and a financial assessment that may include acquisition cost, expected reimbursement, ease of product procurement, and availability of patient support services.

b. If a biosimilar is selected as the preferred formulary agent, the biosimilar will be used for FDA-approved indications of the reference product and any compendia reference supported indications of the reference product.

c. Any change to the preferred formulary agent must be approved by the System P&T Committee.

d. Outside of extenuating circumstances (eg, supply problems), biosimilar products that are not interchangeable will not routinely be evaluated for a change in the preferred formulary agent more frequently than every 2 years.

3. Once a biological product with biosimilar products is added to formulary a therapeutic interchange will be created directing use to the preferred biological agent.

a. If a single biological agent is on formulary the therapeutic interchange will substitute nonformulary products to the formulary product.

b. If more than 1 product of a reference drug and its biosimilars is added to formulary a therapeutic interchange will substitute nonformulary and nonpreferred formulary products to the preferred formulary product.

c. Pharmacy staff will use the therapeutic interchange to automatically select the preferred formulary biological product or biological product mandated by insurance when the prescriber has indicated use of the therapeutic interchange is appropriate. Prescribers will only be contacted regarding a product substitution if he or she has specified an allowed exemption from the therapeutic interchange (section 5b) when placing the medication order.

i. Nonformulary and nonpreferred biological agents will not be routinely stocked or dispensed. If the prescriber requests a nonformulary or nonpreferred biological agent be ordered for immediate use for a specific patient, the dose to be used and the duration of therapy should be obtained to facilitate procurement

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 authorization outcome or other financial evaluation (e.g., patient assistance program).

b. therapy continuations or restarts:

i. The therapeutic interchange does not apply if a specific biological product is necessary based on prior authorization outcome or other financial evaluation (e.g., patient assistance program).

ii. When documented in the electronic health record (EHR) medication order by the prescriber, other exemptions from use of the therapeutic interchange are:

1) The patient has previously had an adequate trial of the formulary preferred product with minimal clinical response.

Note: Loss of clinical response to a biological product after established maintenance therapy is NOT an indication to switch biosimilar products.

2) The patient has a history of intolerance, contraindication, or adverse event to the formulary preferred product.

3) The patient is already receiving a nonpreferred biological product AND has previously had at least 1 switch between the reference or biosimilar products that are not deemed interchangeable by the FDA in the previous 2 years.

4) The patient is already receiving a nonpreferred biological product AND additional duration of therapy is not expected to exceed 3 months.

6. When a reference product or 1 of its biosimilar products is part of Froedtert Health Formulary, newly approved or nonformulary biosimilar products may be added as a line-item extension as a nonpreferred product to be used when deemed necessary by a prior authorization outcome or other financial evaluation.

Procedure

n/a

Reference Details

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

Issuing Authority

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Distribution

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category

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