

American Heart Association/American Stroke Association Statement on Drug Formularies

Underlined terms are defined on page 3 of the document.

1. The AHA supports a formulary system that:
 - Assures access to the range of medications that patients with cardiovascular disease may need;
 - Is under the supervision of qualified physicians, pharmacists, and other appropriate health professionals;
 - Provides protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;
 - Has policies for the development, maintenance, approval and dissemination of the drug formulary, and for periodic - at least yearly - comprehensive review of formulary drugs; and
 - Provides active surveillance mechanisms to regularly monitor both compliance with these standards and outcomes where substitution has occurred, and to intercede where indicated.
2. When developing the formulary, the AHA supports the use of methods and criteria that are open and transparent and objectively evaluate all available medications, taking the following factors into account:
 - Level and strength of evidence;
 - Potential differences in patients' medical conditions;
 - Patient-specific information (e.g., pediatric patients, pregnant women, elderly patients, transplant patients, immuno-compromised patients);
 - FDA's Orange book¹ guidance; and
 - Economic factors, although their consideration should not be a primary factor.
3. Formulary information, encompassing the pharmaceutical products included, their tier and level of cost sharing, processes for changes or adjustments, as well as restriction strategies must be made transparent to the consumer.
4. The AHA opposes therapeutic substitution in any patient care setting.
5. When necessary, the AHA supports therapeutic interchange, including the practice of generic substitution, in designated circumstances.
6. When therapeutic interchange does occur, the patient should be notified verbally, in writing, or electronically, before or at the point of distribution. Individualized communications should be based on a patient's specific level of health/reading literacy. In the absence of a collaborative drug therapy management (CDTM) protocol, the provider

should be notified verbally, in writing, or electronically, before or at the point of distribution.

7. AHA recognizes the role of economic considerations in developing a formulary. Any changes to a formulary (e.g., mid-year tier switches) should balance access and cost considerations. These changes, as well as the alternative coverage options available to the consumer and reason for the switch, must be made known to prescriber *and* patient with adequate time (minimum of 90 days) for appropriate therapeutic interchange to occur. If the formulary-approved agent has not been shown to be effective and/or is not FDA-approved for a specific condition, cost should not be the only consideration when evaluating the substitution of an alternative agent that has scientific evidence and/or FDA approval for said condition.
8. The AHA supports the prescriber's ability to override, without undue administrative burden, the substitution of a restricted, non-formulary, or more expensive drug when necessary for an individual patient. This process is referred to as prior authorization.
 - Prior authorization processes should be as efficient, streamlined, and as responsive as possible and include the following components:
 - Development of streamlined prior authorization forms
 - Adherence to a 72 hour deadline to approve, deny, or request supplementation of a prior authorization request and a 24 hour deadline to approve or deny the request upon receipt of supplementation or for an emergency review.
 - Automatic prior authorization approval of a three day supply of prescription drugs in emergency situations.
 - Discretion of insurers to implement routine/annual medication review without causing undue burden on patients who are medically stable on a chronic disease medication.
 - Decisions about particular medications for use by a patient should be made by the patient and provider. Methods such as "fail first," should include a process for prescribers to bypass when medically appropriate.
 - Methods, such as "prescriber prevails," require further evidence of their effectiveness in helping patients obtain the most appropriate and effective drug therapies. The AHA supports formularies' preference for special dosage/delivery products which, while a generic or less expensive version might exist for substitution, can be shown to significantly improve adherence or lower medical care costs because of improved outcomes.
9. In the case of narrow therapeutic index drugs, the AHA does not support generic-to-generic interchange.
10. Biosimilars do not require demonstration of efficacy and safety compared to the brand-name product in clinical outcomes trials and whether meaningful differences may exist regarding impact on clinical outcomes is uncertain. With these safety issues in mind, as new biosimilars appear on the market, close pharmacovigilance should be conducted to

completely characterize the drug risk and efficacy profile. The process for determining the appropriate interchange of a biosimilar for a biologic should be consistent with the interchange process defined below.

Definitions

Biosimilars: “Generic” biologics that are copies of a therapeutic protein, not manufactured by an innovator company, and approved through an abbreviated process. Biosimilars are also known as biogenerics, post-patent biologics, and follow-on biologics.

Formulary: A compilation of drugs or drug products in a drug inventory list. Formularies may be created by a healthcare facility, healthcare system, payer, or a third party.

Formulary system: A method whereby members of the healthcare system, working through the pharmacy and therapeutics committee, evaluate, appraise, and select from among the numerous available drug entities and drug products those that are considered most cost-effective in patient care.

Generic substitution: The act of switching between a branded drug and its therapeutically equivalent generic version.

Narrow therapeutic index drugs: Drugs identified as having less than a 2-fold difference between the median lethal and the median effective dose or having less than a 2-fold difference between the minimum toxic and minimum effective concentrations in the blood and where safe and effective use of the drug requires careful titration and patient monitoring (e.g., warfarin, cyclosporine, digoxin).

Therapeutic equivalent, therapeutic alternate: Drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses.

Therapeutic interchange: The act of dispensing, with the authorization of the initial prescriber, an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, with different pharmacokinetic properties. This interchange is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcomes, and safety profile.

Therapeutic substitution: Therapeutic interchange that occurs without the prior authorization of the prescriber.

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ⁱ Available at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>