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American Heart Association Policy Statement on Drug Formularies

Underlined terms are defined on page 4 of the document.

1. The AHA supports a formulary system that:

    - Assures access to the range of pharmaceuticals 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 pharmaceuticals, taking the following factors into account, which are consistent with Medicaid program requirements:

    - 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 book[i] guidance; and
    - Economic factors, although their consideration should not be a primary factor.

3. Medicaid programs operate what are known as a preferred drug lists (PDLs), which must include any FDA-approved medication is available so long as the manufacturer offers a discount to the federal government. In this way, they may be referred to as "open formularies." The AHA supports open formularies and opposes state proposals to close them.

4. The AHA opposes therapeutic substitution in any patient care setting.

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5. When necessary, the AHA supports therapeutic interchange, including the practice of generic substitution, in designated circumstances. In the case of narrow therapeutic index drugs, the AHA does not support generic-to-generic interchange.

6. When therapeutic interchange does occur, the patient should be notified verbally, in writing, or electronically, before or at the point of distribution. 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. The AHA supports transparency of pharmacy benefit information for consumers so that they may make informed decisions regarding medical products. In this way, 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 consumers in an understandable format before they purchase their plan. Similarly, AHA opposes clauses in contracts between pharmacies and benefit managers (PBMs) that prohibit pharmacists from discussing different payment options with patients. These clauses are often referred to as "gag clauses."

8. While AHA recognizes the role of economic considerations in developing a formulary, we oppose mid-year tier switches (also referred to as "non-medical switching"). Consumers rely on accurate plan and formulary information at the beginning of a benefit year. They must have confidence that the plan components will remain the same throughout the year. In the case of first in class medications, the AHA supports quick evaluation for potential inclusion on the formulary regardless of timing in the plan year.

9. 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 48-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
    - Automatic prior authorization approval of a three-day supply of prescription drugs in emergency situations.
    - A maximum of a "one step edit," or one medical product to be tried before the prescribed drug is covered.
    - Exemption process for patients who, at the beginning of a plan year, are medically stable on a non-formulary medication. We support evidence-based clinical care guidelines that indicate annual medication reconciliation and review by a provider, but as it applies to prior authorization processes, patients whose providers have determined them to be stable on their current regimen should be exempted.

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10. Decisions about particular medications for use by a patient should be made by the patient and provider. 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. Methods such as "fail first," or "step therapy" should include such a process for prescribers to bypass when medically appropriate.

11. The AHA supports formularies' use of strategies to improve medication adherence. These include:

    - 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.
    - Medication synchronization that allows all of a patient's refills to come due on the same day once a month, thereby enabling patients to reduce the number of visits to the pharmacy. Patients should be allowed to opt-out of the process, particularly if they rely on non-synchronized refills for financial purposes.

12. 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 on page 4 and be fully and clearly communicated to the prescriber.

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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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Acknowledgements

The preceding policy statement concerning drug formularies was updated and approved by an expert panel convened by the American Heart Association/American Stroke Association.

The preceding policy statement was approved by the American Heart Association's Advocacy Coordinating Committee on October 23, 2018.

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