

**Position Statement  
on  
Patient Access to Affordable Treatments  
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Dermatologists are committed to providing the most effective and cost-efficient care and therapies to their patients. Patients suffering from chronic, disabling conditions face significant interference with activities of daily life and a substantial impact on their mental health and personal well-being. Access to affordable medication and other treatments for these conditions is not only medically necessary, it is life-changing.

Unfortunately, a variety of environmental factors have affected patients' access to treatment including the following: market forces that have led to drug manufacturer consolidation or elimination; skyrocketing pricing of medications; insurer tiering practices that place higher cost medications out-of-reach for many patients; and often arbitrary formulary policies that force drug switching or cessation of effective therapies based on economics but which do not take into account clinician judgement, or prior clinical improvement.

While the American Academy of Dermatology Association (AADA) understands the need to manage the unpredictable and growing costs of health care, including therapy, it believes that this goal should not be achieved at the cost of patient outcomes or by placing the economic burden on patients.

## **Transparency**

First and foremost, the AADA supports complete transparency in insurance coverage policies for specialty, brand name and generic pharmaceuticals including copayment and coinsurance levels, and how these levels are determined. The processes utilized in setting drug prices, both specialty and generic, should be readily available and easy for patients to access. Formularies should be publicly available and easily accessible online. In addition, the AADA believes that patients and physicians should have access to real-time cost information available at the point of prescribing to ensure cost considerations are a meaningful part of the decision-making process. The estimated cost-sharing and co-insurance amounts should be provided in plain language for consumers in a format that is readily accessible.

## **Price Spikes**

Ongoing significant price fluctuations of drugs make it increasingly difficult for dermatologists to prescribe the most affordable and effective treatment for patients. To protect patients against large price spikes, the AADA supports requiring pharmaceutical manufacturers to provide public notice before implementing price increases that substantially exceed the rate of inflation and provide a rationale for these price increases.

## **Drug Tiering**

The AADA believes it is important that strategies used to priority tier drugs take into account the clinical efficacy as established through scientific evidence, the equivalence of alternatives, and the cost implications to patients. Moving vital medications (such as biologics) into higher level "specialty tiers" that require patients to pay a **percentage** of the actual cost of these drugs rather than a reasonable **fixed** co-payment can impact significantly the ability of patients to access the treatment they need, costing patients hundreds, and in some cases, even thousands, of dollars per month for a single medication. This can place medically necessary treatments out of reach for average Americans. Any designation of a drug as secondary or to be used after a trial with another drug should rely on evidence accumulated for that practice and labeled in product labeling.

Instead of having to pay a percentage-based co-insurance amount, the AADA supports limiting cost-sharing requirements in a specialty tier to the co-pay dollar amount applicable to drugs in a non-preferred brand tier. The AADA believes that limiting cost-sharing requirements in this manner would improve patient access to treatments and reduce financial disability will still help constrain health-care costs.

### **Restrictive Formularies**

The AADA believes that physicians should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient's unique circumstances. The AADA opposes the imposition by insurance companies of restrictive formularies that exclude medications considered necessary in the provision of high quality medical care. Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc. In the interests of high-quality dermatologic care, there are specialized issues in the prescription of dermatologic products that include compounding, the delivery vehicle of the medication, the preservatives used in the medication, and the effectiveness of generic and biosimilar substitutes.<sup>1-5</sup> In the event a restrictive formulary is put in place, there should be a clear and timely appeals process through which physicians may prescribe and procure medications not in the formulary without penalty to their patients.<sup>6-9</sup> When a formulary changes mid-year, this information should be promptly communicated with both physicians and patients.

### **Step Therapy**

The AADA is concerned that step therapy or "fail first" strategies to medication and other treatment options have the potential to negatively impact patient outcomes and quality of life. Any step therapy policy must be supported by appropriate clinical practice guidelines developed by independent experts (or FDA) with knowledge of the condition or conditions under consideration, high quality studies, and research and medical practice; and not solely on the basis of economic reasons. Step therapy incorrectly assumes that all patients start care at the same point in their disease process, and that the trajectory of their condition will be the same. It must also therefore make exceptions for stage and extent of disease, patient characteristics and current treatment, including if the physician believes the recommended course of action by the carrier could cause harm to the patient. In general, patients must be able to have access to alternative treatments if the first line option is not optimal or contraindicated. Patients who are stable on current therapy must be able to remain on their current treatment without penalty and without being required to undergo step therapy. Forcing stable patients to go through step therapy poses a significant risk to the patient of flaring of disease, immunogenicity (negative immune response), adverse effects and secondary nonresponse.<sup>10</sup> Switching therapy can also promote a loss of effectiveness of the prescribed medication should one resume the original medication later. To avoid these adverse effects of switching therapies and to ensure adherence to a prescribed treatment plan, in the event that a patient switches insurance plans, he or she should not be forced to repeat the step therapy process if he or she went through that process with the last insurance plan.

### **Payer Mandated Drug Substitution (Non-medical switching)**

Payer mandated drug substitution describes the altering of benefits coverage to force changing the patient's medication regimen for reasons other than lack of clinical efficacy, adverse side-effects or poor medication adherence. When patient's access to efficacious medication is lost through payer mandated drug substitution, the ability to manage the disease is impacted, and may incur recurring symptoms and side-effects. Furthermore, there is evidence that the more a patient switches from one biologic to another, the less effective later treatments can be and overall costs may actually increase.<sup>11,12</sup> Increased utilization of the healthcare system may result through emergency department visits and hospitalizations, additional office visits, and lab tests and additional medications to deal with flares as a result of non-medical switching.<sup>13,14,15</sup> The AADA recognizes the business need that drives payers to make formulary changes but believes it is paramount for patients to have the ability to remain on their current and efficacious treatment without significant additional patient cost and burden. Patients who are stable on their medication should be allowed to keep using the same medication. The Academy does not support financial incentive programs that prioritize payer business interests over the quality and safety of patient care such as financial incentives to

patients who are stable on their medication to switch to another medication solely on the basis of cost savings to the payer.

### **Prior Authorization**

Prior authorization policies for medications that are specialized, highly nuanced and patient dependent are inappropriate and place a third party, with no knowledge of the complexity or full history of a patient's condition, in a decision-making position that is inappropriate. The choice of therapy should be between a physician and his/her patient where consideration of all factors—efficacy and safety of all treatment options, co-morbidities, and support system—are taken into account and fully discussed and vetted. Prior authorization and appeals policies should not unduly burden physicians or patients in accessing optimal drug therapy.<sup>16</sup> The process in which prior authorization determinations are made should be standardized and the speed of determination should be quantified and minimized. Undue delays can cause irreparable harm to patients in need of specific treatments.

### **Caps on Out-of-Pocket Costs**

The AADA believes cost sharing for patients should not be excessive in that it prohibits patients from accessing prescriptions and thus jeopardizing the recommended course of treatment. Predetermined cost sharing requirements should be based on the costs of the medication, known available alternatives, severity of illness or disease and expected health outcomes. If a cap on out-of-pocket costs is in place, it must be enforced prior to the deductible being reached by the patient.

### **Drug Importation**

For patients for whom the economic burden or other issues have left little recourse for accessing needed treatments, the AADA supports the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products meet all FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported. To support patient safety efforts, the AADA will educate its members regarding the risks and benefits associated with drug importation and reimportation efforts.<sup>17</sup>

### **FDA Approval Processes**

The AADA believes that a primary driver of pharmaceutical costs is the reduced level of competition for a variety of drugs and biologics. To that end, the AADA supports legislative efforts to provide the FDA with added authority and resources needed to expedite the review process and get additional drugs and biologics to market.

### **Generic Drugs**

The AADA supports removing barriers to the development and entry of generic drugs in the marketplace, which will increase competition and lower prices of pharmaceuticals. Research has shown that dramatic increases in generic drug costs are associated with a lack of market competition.<sup>18,19</sup> Reducing barriers to entry for generic drugs can ensure a health and functioning generic drug market.<sup>20</sup>

### **Pharmacy Benefit Managers**

The AADA supports transparency in the structure in which Pharmacy Benefit Managers (PBMs) operate. The consolidation of the industry and current financial arrangements must be monitored to avoid a conflict of interest when developing formularies and/or tiers. The AADA also calls for more transparency in the negotiation process of PBMs. Pharmaceutical manufacturers shall disclose discounts and rebates provided to PBMs, and PBMs shall disclose how much of the rebates and discounts are passed on to the patient. Further investigation is necessary to determine the extent to which PBM negotiations and arranged rebates affect formularies, tiers, and drug prices.

### **Brown Bagging of Pharmaceuticals**

Brown bagging, in which physician-administered drugs are shipped directly from a pharmaceutical wholesaler to a patient or pharmacy rather than to the physician, after which the patient must transport the medication to the physician's office, poses significant safety issues for chemotherapy drugs and biologics. Some medications are highly susceptible to changes in light, temperature and humidity. Exposure to adverse environmental conditions can alter the drugs' activity and thus its effectiveness. The AAD opposes insurance plan designs that require patients to utilize this brown-bagging mechanism in order to have physician-administered medications covered and supports maintaining physician and patient decision-making in terms of what type of arrangement is most appropriate for an individual patient.

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- <sup>1</sup> Steger JW, Wolverton SE, Greenberg RD, Ling MR, Resnick SD, James WD. Dermatologic drug formulary: An American Academy of Dermatology white paper. *J Amer Acad Dermatol* 1996; 34:99-109
- <sup>2</sup> Helm MF, Farah JB, Carvalho M, et al. Compounded Topical Medications for Diseases of the Skin: A Long Tradition Still Relevant Today. *North American Journal of Medicine and Science*. 2017 Jul 31;10(3).
- <sup>3</sup> Danby SG, Draelos ZD, Gold LFS, et al. Vehicles for atopic dermatitis therapies: more than just a placebo [published online ahead of print, 2020 Jul 16]. *J Dermatolog Treat*. 2020;1-14. doi:10.1080/09546634.2020.1789050
- <sup>4</sup> Deza G, Giménez-Arnau AM. Allergic contact dermatitis in preservatives: current standing and future options. *Curr Opin Allergy Clin Immunol*. 2017;17(4):263-268. doi:10.1097/ACI.0000000000000373
- <sup>5</sup> Moots R, Azevedo V, Coindreau JL, et al. Switching Between Reference Biologics and Biosimilars for the Treatment of Rheumatology, Gastroenterology, and Dermatology Inflammatory Conditions: Considerations for the Clinician. *Curr Rheumatol Rep*. 2017;19(6):37. doi:10.1007/s11926-017-0658-4
- <sup>6</sup> James WD. Dermatologic formularies in the managed care setting. *Arch Dermatol* 1996; 132:1120-1
- <sup>7</sup> Virtual Mentor. 2014;16(4):261-264. doi: 10.1001/virtualmentor.2014.16.4.coet2-1404.
- <sup>8</sup> American Academy of Family Physicians. Patient-Centered Formularies. 2020.
- <sup>9</sup> Daniel H; Health and Public Policy Committee of the American College of Physicians. Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians. *Ann Intern Med*. 2016;165(1):50-52. doi:10.7326/M15-2768
- <sup>10</sup> National Psoriasis Foundation. Position Statement on Access to Care. September 2020
- <sup>11</sup> Dolinar R, Kohn CG, Lavernia F, Nguyen E. The non-medical switching of prescription medications. *Postgrad Med*. 2019 Jun;131(5):335-341. doi: 10.1080/00325481.2019.1618195. Epub 2019 May 29. PMID: 31081414. Which summarized "there is considerable evidence that non-medical switching, particularly when applied to medication used to treat chronic conditions such as diabetes, may impact patient outcomes, medication-taking behavior, and use of health care services. Ultimately, overall costs may be increased, as savings by insurers are cancelled out by higher costs to the health care system as a whole, such as extra administration, treatment failure from new medicines, and increased adverse events.
- <sup>12</sup> Nguyen E, Weeda ER, Sobieraj DM, Bookhart BK, Piech CT, Coleman CI. Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review. *Curr Med Res Opin*. 2016 Jul;32(7):1281-90. doi: 10.1185/03007995.2016.1170673. Epub 2016 Apr 1. PMID: 27033747. Which concluded "Non-medical switching was more often associated with negative or neutral effects than positive effects on an array of important outcomes. Among patients with stable/well controlled disease, non-medical switching was associated with mostly negative effects.
- <sup>13</sup> Costa OS, Salam T, Duhig A, Patel AA, Cameron A, Voelker J, Bookhart B, Coleman CI. Specialist physician perspectives on non-medical switching of prescription medications. *J Mark Access Health Policy*. 2020 Mar 9;8(1):1738637. doi: 10.1080/20016689.2020.1738637. PMID: 32284826; PMCID: PMC7144249. [Specialist physician perspectives on non-medical switching of prescription medications - PubMed \(nih.gov\)](#)
- <sup>14</sup> Nguyen E, Weeda ER, Sobieraj DM, et al. Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review. *Curr Med Res Opin*. 2016;32:1281–1290. - [PubMed](#)
- <sup>15</sup> Weeda ER, Nguyen E, Martin S, et al. The impact of non-medical switching among ambulatory patients: an updated systematic literature review. *J Mark Access Health Policy*. 2019;7:1–16. - [PMC](#) - [PubMed](#)
- <sup>16</sup> H-285.965 Managed Care Cost Containment Involving Prescription Drugs; AMA Policy Compendium 2020
- <sup>17</sup> D-100.983 Prescription Drug Importation and Patient Safety; AMA Policy Compendium Sept 2015
- <sup>18</sup> Barbieri JS, Margolis DJ, Brod BA. Influence of Market Competition on Tetracycline Pricing and Impact of Price Increases on Clinician Prescribing Behavior. *J Invest Dermatol*. 2017;137(12):2491-2496. doi:10.1016/j.jid.2017.07.835

<sup>19</sup> Li DG, Joyce C, Mostaghimi A. Association Between Market Competition and Prices of Generic Topical Dermatology Drugs. JAMA Dermatol. 2018;154(12):1441-1446. doi:10.1001/jamadermatol.2018.3798

<sup>20</sup> Raney SG, Luke MC. A new paradigm for topical generic drug products: Impact on therapeutic access. J Am Acad Dermatol. 2020;82(6):1570-1571. doi:10.1016/j.jaad.2020.01.062

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