Access to Care Position Statement

On behalf of individuals struggling to manage complicated, devastating, unpredictable, and potentially fatal diseases of unmet need like Lupus and those who love, advocate for, and treat them, the Lupus and Allied Diseases Association (LADA) supports initiatives that address barriers to healthcare access in order to ensure individuals receive the most appropriate therapies as directed by their treating healthcare professionals and consistent disease management is preserved. Therefore, we are opposed to payer utilization management practices that base treatment decisions predominantly on cost rather than clinical considerations resulting in limited access to medical care, delays in treatment, disease instability and disruptions in patient continuity of care. We strongly support establishing essential patient protections that improve access to vital therapies; in turn reducing the physical and economic impact of disease, improving outcomes, and allowing individuals to lead more productive lives.

- We support the regulation of step therapy or fail first health insurance policies requiring a patient to try and fail on other, generally less expensive treatment options before access is granted for the medication prescribed by the patient's health care provider. Such protocols involve drug sequences determined by the insurer based on cost and expectations about potential treatment responses within a generalized patient population. These protocols are not based on a patient's specific medical profile or the physician's assessment of the best treatment option for the patient's condition.

  Under current step therapy protocols, patients can be required to fail on a drug for an indefinite period of time or fail multiple drugs before the provider can implement a more preferable course of treatment. These practices can result in a lesser standard of care for patients, limit a provider's treatment options and extend the amount of time before effective treatment is underway. Delaying access to medications that offer the greatest potential medical benefit often leads to disease progression. In actuality, this practice overrides the expertise of the prescriber and undermines the provider-patient relationship.

- We oppose non-medical or formulary-driven switching policies designed by commercial insurance companies and pharmacy benefit managers to limit prescription drug coverage to less expensive medications, requiring patients to use a different medication than the one initially prescribed or forcing stable patients off their current effective treatments. These coverage modifications are cost-cutting measures determined by the plan formulary that have no medical justification, therefore the practice has become known as "non-medical switching."

  We believe that public officials should establish policies to ensure that insurers honor their contracts and not alter the terms mid-plan year so that patients have consistent coverage, fair out-of-pocket costs, and stable formularies. Individuals with difficult chronic or rare medical conditions using a previously approved medication to stabilize their condition should have access to that drug throughout the plan year. Furthermore, their out-of-pocket costs set by the health plan or PBM during open enrollment should not increase and patients who are stable on certain medications should not have those medications moved to a more costly or restrictive insurance tier during the respective health plan year.

Cost containment measures such as non-medical switching and step therapy pose a potential ethical dilemma for healthcare professionals by requiring the provider to follow a set course of care, regardless of their best personal judgment. These policies are put in place with the sole focus on cost, not on care personalized to the patient. Forcing patients to switch to or fail less effective treatments, exclusively based on cost, will discourage and stifle drug research and development especially for diseases of unmet need with limited therapies.

- We support efforts to control and limit the maximum co-insurance and out-of-pocket expenses for individuals living with complex, chronic, and/or rare diseases to enable access to affordable treatments. As the cost of prescription drugs continue to rise, commercial health insurance plans have created new "specialty tiers" to dramatically increase the co-payments that consumers pay. Instead of a three-tiered drug formulary structure used by most plans (where Tier 1 is for generics, Tier 2 is for brand name preferred drugs, and Tier 3 is for brand-name non-preferred drugs), some plans have added fourth and fifth tiers for the most expensive medications. These additional tiers assign a percentage cost of the medication as co-insurance, as opposed to a set dollar amount used in the other three tiers, resulting in a 20-35% or even higher co-insurance for medications placed in these specialty tiers.

- We oppose tiering of biologics and novel therapies. Over the past decade, there has been a significant increase in the number of innovative drugs and medical devices being approved by the US Food and Drug Administration. These life-saving and life-sustaining products have had a profound impact on the lives of millions of Americans affected by diseases of unmet need and in some instances even provided cures. For individuals managing chronic, life-diminishing and potentially life-threatening conditions, these innovative treatments have delivered substantial therapeutic benefits, allowing them to remain productive members of society. The practice of tiering is both discriminatory and contrary to the original purpose of insurance as it creates a structure where unhealthy individuals pay more than healthier individuals. Establishing essential cost-sharing safeguards by regulating tiering created by commercial health insurance plans within their prescription drug formularies will improve access to vital therapies; in turn reducing the physical and economic impact of disease and improving quality of life.

- We support efforts to establish proper guidance for biological therapies and are committed to ensuring the biosimilars regulatory pathway recognizes the complexities of autoimmune patients and products are approved as being highly similar to the original product and sufficient proof of clinical efficacy, safety, and tolerability is provided. Furthermore, we support the establishment of a biosimilars policy that includes unique nonproprietary names in order to assure patient safety, provide vital transparency, and aid in accurate product identification during the prescribing, dispensing and pharmacovigilance processes, promote compliance, and ensure timeliness in addressing adverse events.

  We strongly believe that each biosimilar should be considered individually for each disease state, since biosimilars are not precise replicas of the originator biologic, their performance may not be equivalent in every patient population, resulting in unexpected divergent effects. Autoimmune patients are so hypersensitive that even the slightest change in manufacturing, dose or method of delivery, (subcutaneous, injectable vs. infusible), can provoke immunogenicity or heightened immune response and disease complications. There must be sufficient proof of clinical efficacy, safety, purity, potency and tolerability provided for each distinct patient population to grant indication extrapolation; not just projected clinical safety and efficacy data.

At this initial juncture of biosimilar development, we believe that it is critical for both patients and physicians to be confident that these drugs are safe and as effective as the original innovator biological medication. In order to be designated as "interchangeable" biosimilars must unequivocally produce the same clinical result in any given patient as the biologic reference product, therefore, we support a policy requiring rigorous criteria that includes non-clinical and clinical data. We believe that pharmacovigilance is essential for all biological medicines because these treatments may produce idiosyncratic reactions in autoimmune patients who may also be hypersensitive to changes in production methods or impurities. We also support evaluation of biosimilars through post-marketing surveillance in order to not diminish product efficacy and be detrimental to patient safety.

- We support the development and utilization of standardized prior authorization forms that will facilitate efficient, quality patient care and ensure timely delivery of medical care by easily interfacing with Electronic Health Records and reducing the administrative burden for healthcare practices and insurance companies. As more pharmacies and providers adopt new standards that allow for an electronic transmission of this information, standardization will streamline the prior approval process resulting in individuals receiving appropriate treatment while improving healthcare outcomes.

Because multi-system, heterogeneous, autoimmune diseases like lupus are extremely unpredictable and highly individualized, maintaining disease stability by having access to the full array of treatments is critical to patient well-being. We recognize that any disruption in continuity of care as a result of payer utilization management policies, formulary changes, increased copays, or other cost containment measures has detrimental consequences for individuals dealing with complex care needs such as heightened immune responses (immunogenicity), adverse effects, increased symptomology, disease exacerbation, additional medical visits, and an increase in healthcare utilization and augmented costs.

For individuals struggling to manage complex, chronic and rare conditions, access to appropriate medication can dramatically improve disease outcome and quality of life. Effective treatment can reduce the severity and frequency of disease activity and decelerate its progression, enabling individuals to remain productive. The determination of the most optimum and appropriate medical treatment is best accomplished by open and transparent communication between the patient and the healthcare provider who is educated and ethically bound to treat to the uniqueness of the individual; not to an insurance cost-cutting mandate.

The Lupus and Allied Diseases Association is a passion driven, patient advocacy organization dedicated to improving quality of life for those impacted by lupus and allied diseases and conditions of unmet need by promoting innovative advocacy, awareness and biomedical research program initiatives. We are also committed to fostering collaboration among stakeholders in order to encourage patient-centered care and ensure public policy keeps pace with biomedical research innovation.

Now more than ever, as we usher in an era of personalized health care and initiatives like 21st Century Cures, Healthier Americans and Precision Medicine move forward, it is evident that reformation of unethical and egregious payer practices is long overdue. These protocols must be revolutionized to keep pace with biomedical innovation and to ensure ethical responsibilities are being met. It is imperative that we protect consumers and preserve healthcare provider's rights to make medical decisions in the best interest of their patients and ensure ethical accountability. **Please contact Kathleen Arntsen at lupuskaa@aol.com or 315-264-9101 if you have any questions.**