



Lupus Foundation of Northern California

2635 No. First St. #211 ♦ San Jose, CA 95134
408.954.8600 ♦ FAX 408.954.8129 ♦ www.lfnc.org

STATEMENT OF POLICY

ON PATIENT ACCESS TO FDA-APPROVED TREATMENT

The Lupus Foundation of Northern California (LFNC) is a nonprofit organization that looks after the needs and concerns of lupus patients and their families throughout the Northern and Central California region. Its mission is to be a premier source of information on lupus by providing programs and services designed to educate and increase the knowledge of those affected by lupus, promote lupus awareness, and support external research efforts.

The focus of LFNC's advocacy is to help ensure that lupus patients have access to drugs that are determined by their health providers to be the best treatment for their specific conditions and symptoms.

The lupus community has not had the benefit of new and more effective treatment until 2011, when the Food and Drug Administration approved the first lupus drug in almost 50 years!

Since then, the research community has increased its efforts to find more effective treatment protocols. The focus has not only been to develop new drugs but also to revisit existing FDA-approved medication that could, by themselves or in combination with other drugs, benefit lupus patients in addressing their symptoms.

In California, many health plans adhere to Step Therapy (or First Fail), a protocol under which patients must try and fail on more than two cheaper medications before they are allowed access to other generically equivalent drugs, or more effective treatment prescribed by their physicians.

In most cases, the alternative treatments prescribed by the physicians have already been approved by the Food and Drug Administration.

Physicians and patients are gravely concerned about the ongoing interference by insurance companies into the doctor-patient relationship. Often, insurance companies operate outside their scope of responsibility and restrict patient access to proper therapeutic options. They are also trying to influence the patient's choice of medication without knowledge of



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individual patient history, without licensing appropriate to the scope of practice, and without the knowledge of a medical examination.

Providers agree that such policies implemented by local health insurers restrict and obstruct patient medication prescriptions. Specifically, there are insurers that refuse to authorize the use of FDA-approved treatments for diseases including lupus, mixed connective tissue disease, rheumatic disorders and ophthalmic diseases. Insurers routinely require that patients first fail on other non-approved but cheaper medications. In many cases, these alternate medications are off-label or not indicated as treatment for that particular disease.

The requirement that one must fail first before using the FDA-approved medication seems to be a clear violation of pharmacy practice and good medical practice. The evidence-based data used to support the use of any of these classes of medications certainly does not meet the standard applied by the FDA.

As an organization deeply concerned about the well-being of lupus patients, LFNC supports legislation or policy promulgations that would prioritize physician-recommended, workable treatment of lupus patients over health plan protocols such as Step Therapy.

We also urge all health plans in California and elsewhere to revisit, with the aim of relaxing, their policy of rejecting coverage of drugs and treatment that do not follow the Step Therapy protocol.

Like many others diagnosed with serious and chronic diseases, lupus patients respond to medication and treatment in different ways. No two patients are alike, and their health providers know what is best for their treatment.

We believe that health providers -- not health plan administrators -- are in the best position to determine when to prescribe the right medication to lupus patients, especially when the recommended treatment is based on medical science, as evidenced by the stamp of approval resulting from a long and tedious FDA approval process.



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The Board of Directors of the Lupus Foundation of Northern California maintains the position that Step Therapy, in its current form, is not in the best interest of patients. It is urging both health plan companies and state legislators to institute measures that would ensure timely, effective and potentially life-saving, physician-prescribed treatment and medication for lupus and other patients in need.

(Unanimously approved by the Board of Directors at its regular meeting held in San Jose, California, on April 21, 2015)

A handwritten signature in black ink, appearing to read "Jay Remley".

Jay Remley, Board Chair

A handwritten signature in black ink, appearing to read "Rene Astudillo".

Rene Astudillo, Executive Director